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DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

6 CFR Part 5

[Docket No. DHS–2021–0020]

RIN 1601–AB21

Privacy Act of 1974

AGENCY: Office of the Secretary, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: The Department of Homeland Security (DHS or Department) is updating its regulations related to the procedures for submitting Freedom of Information Act (FOIA) and Privacy Act of 1974 requests to clarify that requesters must generally submit their Freedom of Information Act (FOIA) requests and Privacy Act requests electronically.

DATES: This final rule is effective January 22, 2026.

FOR FURTHER INFORMATION CONTACT: Roman Jankowski, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528, (202) 343–1717, Privacy@hq.dhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary of Homeland Security has authority under 5 U.S.C. 301, 552, and 552a, and 6 U.S.C. 112(e) to issue Freedom of Information Act and Privacy Act regulations. That authority has been delegated to the Chief Privacy Officer of the Department pursuant to 6 U.S.C. 142 and DHS Del. No. 13001, Rev. 01 (June 2, 2020). Most recently, DHS updated its procedures implementing the Freedom of Information Act and Privacy Act, 5 U.S.C. 552a., at 6 CFR part 5, subparts A and B on November 16, 2022 (87 FR 68599) and February 27, 2024 (89 FR 14369).

II. Discussion of Changes

This rule updates Title 6, part 5, paragraphs 5.3(a)(2) and 5.21(a)(6), which provide instructions to requesters on how and where to make FOIA and Privacy Act (and Judicial Redress Act (JRA) if applicable) requests for DHS records. The rule generally requires requesters to submit their Freedom of Information Act (FOIA) requests and Privacy Act requests electronically through the web portal at <https://www.dhs.gov/foia> or other acceptable Federal Government or DHS Component websites. DHS and its components will generally no longer accept FOIA or Privacy Act/JRA requests mailed to the DHS Privacy Office, or other DHS components, or via fax or email. By accepting requests only through DHS's or its components' websites, DHS will ensure requests are sent to the correct DHS Headquarters office or DHS component. In addition, this will reduce the time to interact with requesters and also expedite the time requesters will receive responsive records to their requests. In addition, this change will allow the Department to respond to requesters quickly and efficiently to correct any mistakes made in submitting their requests or clarifying their requests. Upon request, DHS FOIA public liaisons may facilitate, in limited circumstances (e.g., incarceration), an alternative method to submit requests for requesters who are unable to submit electronic requests. Requesters who are unable to submit electronic requests should contact the Office or DHS Component they wish to seek records from.

III. Regulatory History

DHS did not publish a notice of proposed rulemaking for this rule. Under 5 U.S.C. 553(b)(A), this final rule is exempt from notice and public comment rulemaking requirements because the change involves rules of agency organization, procedure, or practice. In addition, under 5 U.S.C. 553(b)(B), an agency may bypass notice and comment requirements if it finds, for good cause, that notice and comment is impracticable, unnecessary, or contrary to the public interest. DHS finds that notice and comment is unnecessary here because the change to the manner of submitting FOIA and Privacy Act requests is an agency procedural update that will have

minimal substantive effect on the public. Specifically, DHS believes that submitting a request through a publicly accessible web portal is a routine and accepted method of seeking information in today's society, and the vast majority of requesters already submit their requests this way. Furthermore, DHS will continue to consider requests for exceptions in limited circumstances for requesters who lack internet access. In addition, the rule is procedural because it changes only the manner in which the public presents FOIA and Privacy requests to DHS, and not the substance of those requests. Notice and comment is unnecessary because the public has come to accept using web pages to submit information and generally does so routinely. Electronic submission via web portal is also more efficient than using the U.S. Postal Service, and allows for better tracking of the submission and quicker response by the Government.

III. Regulatory Analyses

A. Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 14192 (Unleashing Prosperity Through Deregulation)

Executive Orders 13563 and 12866 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. Executive Order 14192 establishes a policy that the executive branch be “prudent and financially responsible in the expenditure of funds, from both public and private sources, and [] alleviate unnecessary regulatory burdens placed on the American people.”

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 this rule. This rule is also not subject to Executive Order 14192 because the rule is not significant under Executive Order 12866 and because it is related to agency organization, management, or personnel. See OMB Memorandum M–25–20, “Guidance Implementing

Section 3 of Executive Order 14192, titled ‘Unleashing Prosperity Through Deregulation’ (Mar. 26, 2025).

DHS has considered the costs and benefits of this rule. This rule will not impose any new costs on the government or the public. The rule’s benefits include increased efficiency in processing and responding to FOIA and Privacy Act/JRA requests and decreased lag times for handling requests that would otherwise come from non-portal sources. Specifically, the rule allows DHS FOIA personnel to spend less time on data entry and administrative tasks if the requester submits through the electronic portal rather than through email, fax or physical mail. Spending less time on initial data entry and administrative tasks will allow DHS FOIA personnel to spend more time searching and reviewing records to respond to the requests.

Unfunded Mandates Reform Act of 1995

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

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, and section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601 note, agencies must consider the impact of their rulemakings on “small entities” (small businesses, small organizations, and local governments). 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. DHS has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. DHS does not believe this rule imposes any additional direct costs on small entities.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996 (as amended), 5 U.S.C. 804(2). The Office of Management and Budget’s Office of Information and Regulatory Affairs has

not found that this rule is likely to result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

National Environmental Policy Act

DHS reviews regulatory actions to determine whether the National Environmental Policy Act (NEPA) applies to them and, if so, what degree of analysis is required. DHS Directive 023–01 Rev. 01 (Directive) and Instruction Manual 023–01–001–01 Rev. 01 (Instruction Manual) establish the procedures that DHS and its components use to comply with NEPA.

NEPA allows Federal agencies to establish, in their NEPA implementing procedures, categories of actions (“categorical exclusions”) that experience has shown do not, individually or cumulatively, have a significant effect on the human environment and, therefore, do not require an environmental assessment or environmental impact statement. The Instruction Manual, Appendix A, lists the DHS categorical exclusions.

Under DHS NEPA implementing procedures, for an action to be categorically excluded, it must satisfy each of the following three conditions: (1) the entire action clearly fits within one or more of the categorical exclusions; (2) the action is not a piece of a larger action; and (3) no extraordinary circumstances exist that create the potential for a significant environmental effect.

This rule is strictly procedural and is limited to updating the method by which requesters may submit requests for information under FOIA and the Privacy Act/JRA. DHS has reviewed this rule and finds that it clearly fits within categorical exclusion A3(a) as an administrative or procedural rule that will have no significant effect on the environment, is not part of a larger Federal action, and does not present extraordinary circumstances that create the potential for significant environmental impacts. Therefore, the rule is categorically excluded from further NEPA review.

List of Subjects in 6 CFR Part 5

Classified Information, Courts, Freedom of information, Government employees, Privacy.

For the reasons stated in the preamble, DHS amends Chapter I part 5

of Title 6, Code of Federal Regulations, as follows:

PART 5—DISCLOSURE OF RECORDS AND INFORMATION

- 1. The authority citation for Part 5 continues to read as follows:

Authority: 6 U.S.C. 101 *et seq.*; Pub. L. 107–296, 116 Stat. 2135; 5 U.S.C. 301; 6 U.S.C. 142; DHS Del. No. 13001, Rev. 01 (June 2, 2020).

Subpart A also issued under 5 U.S.C. 552. Subpart B also issued under 5 U.S.C. 552a and 552 note.

- 2. Amend § 5.3 by revising paragraphs (a)(2) and (c) to read as follows:

§ 5.3 Requirements for making requests.

(a) * * *

(2) A requester may send their request to the Privacy Office, U.S. Department of Homeland Security, via the internet at <https://www.dhs.gov/foia> or for any of the Headquarters Offices of the Department of Homeland Security listed in Appendix A to Subpart 5, or <https://www.foia.gov/>. Upon request, DHS FOIA public liaisons may facilitate, in limited circumstances (*e.g.*, incarceration), an alternative method to submit requests for requesters who are unable to submit electronic requests. Please direct such requests to the liaison of the Office or DHS Component you wish to seek records from, which can be found listed in Appendix A to Subpart 5 or found here: <https://www.dhs.gov/foia-contact-information>. In addition, if a requester does not know which DHS component may maintain responsive records to a request, the requester may explicitly ask for assistance from the DHS Privacy Office with identifying the proper component that most likely maintains any potential responsive records. Upon a request for assistance and based on information provided in the FOIA request and by the requester, the Privacy Office will forward the request to the DHS component(s) that it determines to be most likely, as of the date of the request for information, to maintain the records that are sought. The Privacy Office will notify the requester that it is forwarding the request, including identifying the component(s) where the request has been sent, provide the FOIA Public Liaison contact information for the respective component(s), and provide administrative appeal rights in the response. If the requester does not agree with the Privacy Office’s determination regarding which components would likely have records responsive to the request, the requester must submit a timely appeal of the Privacy Office’s determination. Although these are not to

be considered misdirected requests, the recipient DHS component shall be granted the same number of days to respond as permitted by 6 CFR 5.4(c) and 5.5(a).

* * * * *

(c) If a request does not adequately describe the records sought, DHS may at its discretion either seek additional information from the requester, or administratively close the request. Requests for clarification or more information will be made in writing electronically whenever possible (either via electronic mail or portal message) except when DHS requests to speak on the phone to discuss the request. If DHS communicates via a phone call, DHS will summarize the call in a follow up electronic mail or portal message. If DHS corresponds only electronically via electronic mail or portal message, requesters must respond to requests for additional information also by electronic mail or portal message in the same medium as the DHS correspondence. In order to be considered timely, responses to requests for additional information must be received by electronic mail or portal message within 30 working days of the electronic mail or portal message request for additional information. If the requester does not respond to a request for additional information within 30 working days, the request may be administratively closed at DHS's discretion. This administrative closure does not prejudice the requester's ability to submit a new request for further consideration with additional information. Upon request, DHS FOIA public liaisons may facilitate, in limited circumstances (e.g., incarceration), an alternative method to submit requests for requesters who are unable to submit electronic requests. Please direct such requests to the liaison of the Office or DHS Component you wish to seek records from, which can be found listed in Appendix A to Subpart 5 or found here: <https://www.dhs.gov/foia-contact-information>.

■ 3. Amend § 5.21 by revising paragraphs (a)(6) and (c) to read as follows:

§ 5.21 Requests for access to records.

(a) * * *

(6) An individual may send a request to the Privacy Office via the internet at <https://www.dhs.gov/foia> for any of the Headquarters Offices of the Department of Homeland Security listed Appendix A to Subpart 5, or <https://www.foia.gov/>. Upon request, DHS FOIA public liaisons may facilitate, in limited circumstances (e.g., incarceration), an

alternative method to submit requests for requesters who are unable to submit electronic requests. Please direct such requests to the liaison of the Office or DHS Component you wish to seek records from, which can be found listed in Appendix A to Subpart 5 or here: <https://www.dhs.gov/foia-contact-information>. In addition, if a requester does not know which DHS component may maintain responsive records to a request, the requester may explicitly ask for assistance from the DHS Privacy Office with identifying the proper component that most likely maintains any potential responsive records citing this section of the regulations. Upon a request for assistance and based on information provided in the FOIA request and by the requester, the Privacy Office will forward the request to the DHS component(s) that it determines to be most likely, as of the date of the request for information, to maintain the records that are sought. The Privacy Office will notify the requester that it is forwarding the request, including identifying the component(s) where the request has been sent, provide the FOIA Public Liaison contact information for the respective component(s), and provide administrative appeal rights in the response. If the requester does not agree with the Privacy Office's determination regarding which components would likely have records responsive to the request, the requester must submit a timely appeal of the Privacy Office's determination. For the quickest possible handling, the requester should mark the request letter "Privacy Act Request" or "Judicial Redress Act Request."

* * * * *

(c) *Description of records sought.* A requester must describe the records sought in sufficient detail to enable Department personnel to locate the system of records covering them with a reasonable amount of effort. Whenever possible, the request should describe the records sought, the time periods in which the requester believes they were compiled, the office or location in which the requester believes the records are kept, and the name or identifying number of each system of records in which the requester believes they are kept. The Department publishes notices in the **Federal Register** that describe its components' systems of records. These notices can be found on the Department's website here: <https://www.dhs.gov/system-records-notices-sorns>. If a request does not adequately describe the records sought, DHS may at its discretion either seek additional information from the requester or

administratively close the request. Requests for clarification or more information must be made in writing via electronic mail. To be considered timely, responses to requests for additional information must be received by electronic mail within 30 working days of the electronic mail request for additional information. If the requester does not respond timely, the request may be administratively closed at DHS's discretion. This administrative closure does not prejudice the requester's ability to submit a new request for further consideration with additional information.

■ 4. Revise Appendix A to Part 5 to read as follows:

Appendix A to Part 5—FOIA/Privacy Act Offices of the Department of Homeland Security

I. For Headquarters Offices of the Department of Homeland Security, FOIA and Privacy Act (or JRA if applicable) requests should be submitted electronically via <https://foiarequest.dhs.gov/>. For a listing of Headquarters Offices and contact information, please see <https://www.dhs.gov/foia-contact-information>. Additional contact information for questions: Phone: 202–343–1743 or 866–431–0486, Fax: 202–343–4011, or Email: foia@hq.dhs.gov. The Public Liaison may also be contacted using this information.

II. For the following components and offices of the Department of Homeland Security, FOIA and Privacy Act (or JRA if applicable) requests should also be submitted electronically by way of instructions at <https://www.dhs.gov/foia-contact-information> or through an alternative dedicated DHS component website. For each component, the Public Liaison may also be contacted using the information below for questions about submission of requests. The components are:

Cybersecurity and Infrastructure Security Agency (CISA)

Additional contact information for questions: Phone: 202–343–1743 or 866–431–0486, Fax: 202–343–4011, or Email: CISAFOIA@hq.dhs.gov.

U.S. Customs and Border Protection (CBP)

Additional contact information for questions: Phone: 202–325–0150 or Email: cbpfoiapublicliaison@cbp.dhs.gov.

Federal Emergency Management Agency (FEMA)

Additional contact information for questions: Phone: 202–646–3323, Fax: 202–646–3347, or Email: fema-foia@fema.dhs.gov.

Federal Law Enforcement Training Center (FLETC)

Additional contact information for questions: Phone: 912–267–3103, Fax: 912–267–3113, or Email: fletc-foia@dhs.gov.

Immigration and Customs Enforcement (ICE)

Additional contact information for questions: Phone: 866-633-1182, Fax: 202-732-4265, or Email: ice-foia@ice.dhs.gov.

Office of Inspector General

Additional contact information for questions: Phone: 202-981-6100, or Email: foia.oig@dhs.gov.

Transportation Security Administration (TSA)

Additional contact information for questions: Phone: 1-866-FOIA-TSA or 571-227-2300, or Email: foia@tsa.dhs.gov.

U.S. Citizenship and Immigration Services (USCIS)

Additional contact information for questions: Phone: 1-800-375-5283, USCIS Contact Center, or Email: FOIAPAQuestions@uscis.dhs.gov.

U.S. Coast Guard (USCG)

Additional contact information for questions: Phone: 202-475-3522, Fax: 202-372-8413, or Email: efoia@uscg.mil.

U.S. Secret Service (USSS)

Additional contact information for questions: Phone: 202-406-6370, Fax: 202-406-5586, or Email: FOIA@uss.s.dhs.gov.

Roman Jankowski,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2025-23783 Filed 12-22-25; 8:45 am]

BILLING CODE 9110-9L-P

FEDERAL HOUSING FINANCE AGENCY**12 CFR Parts 1209, 1281, and 1282**

RIN 2590-AB59

2026–2028 Enterprise Housing Goals

AGENCY: Federal Housing Finance Agency.

ACTION: Final rule.

SUMMARY: The Federal Housing Finance Agency (FHFA) is issuing a final rule on the housing goals for Fannie Mae and Freddie Mac (the Enterprises) for 2026 through 2028 as required by the Federal Housing Enterprises Financial Safety and Soundness Act of 1992. The rule establishes benchmark levels for the housing goals for 2026 through 2028. The rule replaces the two area-based subgoals with one low-income areas subgoal, simplifies the goal determination process, clarifies inflation adjustments to maximum civil money penalties related to housing goals, and makes other technical changes.

DATES: This final rule is effective February 23, 2026.

FOR FURTHER INFORMATION CONTACT: For general questions, please contact

MediaInquiries@FHFA.gov. For technical questions, please contact Leda Bloomfield, Senior Associate Director, Office of Affordable Housing and Community Investment, Division of Housing Mission and Goals, 202-649-3415, Leda.Bloomfield@fhfa.gov; Siobhan Kelly, Senior Associate Director, Office of Single and Multifamily Policy, Division of Housing Mission and Goals, 202-649-3142, Siobhan.Kelly@fhfa.gov; or Kevin Sheehan, Associate General Counsel, Office of General Counsel, 202-649-3086, Kevin.Sheehan@fhfa.gov. These are not toll-free numbers. The mailing address is: Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. For TTY/TRS users with hearing and speech disabilities, dial 711 and ask to be connected to any of the contact numbers above.

SUPPLEMENTARY INFORMATION:**I. Background****A. Statutory and Regulatory Background for Enterprise Housing Goals**

The Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (Safety and Soundness Act) requires FHFA to establish several annual housing goals for both single-family and multifamily mortgages purchased by the Enterprises.¹ The annual housing goals are one measure of the extent to which the Enterprises are meeting their public purposes as defined by statute, which include “an affirmative obligation to facilitate the financing of affordable housing for low- and moderate-income families in a manner consistent with their overall public purposes, while maintaining a strong financial condition and a reasonable economic return.”²

FHFA establishes annual housing goals for Enterprise purchases of single-family and multifamily mortgages consistent with the requirements of the Safety and Soundness Act. The structure of the housing goals and the parameters for determining how mortgage purchases are counted or not counted towards the goals are defined in FHFA’s Enterprise housing goals regulation.³ This final rule establishes benchmark levels for the single-family and multifamily housing goals for 2026–2028.

Single-family housing goals. The single-family housing goals defined under the Safety and Soundness Act include separate categories for home

purchase mortgages for low-income families, very low-income families, and families that reside in low-income areas.⁴ For purposes of the single-family housing goals, families that reside in low-income areas⁵ include: (1) families in low-income census tracts, defined as census tracts with median income less than or equal to 80 percent of area median income (AMI);⁶ (2) families with incomes less than or equal to 100 percent of AMI who reside in minority census tracts (defined as census tracts with a minority population of at least 30 percent and a tract median income of less than 100 percent of AMI);⁷ and (3) families with incomes less than or equal to 100 percent of AMI who reside in designated disaster areas.⁸ The current Enterprise housing goals regulation also includes subgoals⁹ within the low-income areas home purchase goal.¹⁰ Performance on the single-family home purchase goals and subgoals is measured as the percentage of the total home purchase mortgages purchased by an Enterprise each year that qualify for each goal or subgoal. There is also a separate goal for single-family refinance mortgages for low-income families, and performance on the refinance goal is determined in a similar way.

Under the Safety and Soundness Act, the single-family housing goals are limited to mortgages on owner-occupied housing with one to four units. The single-family goals cover first lien, conventional, conforming mortgages, meaning mortgages that are not subordinate to other mortgage liens, that are not insured or guaranteed by the Federal Housing Administration or another government agency, and that have principal balances that do not exceed the conforming loan limits for Enterprise mortgages.

Multifamily housing goals. The multifamily housing goals defined under the Safety and Soundness Act

⁴ 12 U.S.C. 4562(a)(1). To distinguish the goals and subgoals related to home purchase mortgages from the goal related to refinance mortgages, this preamble refers to the “low-income home purchase goal” and the “very low-income home purchase goal” to refer to the low-income families housing goal and the very low-income families housing goal, respectively, described in 12 CFR 1282.12(c) and (d).

⁵ See 12 U.S.C. 4502(28); 12 CFR 1282.1 (definition of “families in low-income areas”).

⁶ 12 CFR 1282.1 (par. (i) of definition of “families in low-income areas”).

⁷ 12 U.S.C. 4502(29); 12 CFR 1282.1 (par. (ii) of definition of “families in low-income areas” and definition of “minority census tract”).

⁸ 12 U.S.C. 4502(28); 12 CFR 1282.1 (definition of “designated disaster area” and par. (iii) of definition of “families in low-income areas”).

⁹ For brevity, sometimes this preamble uses the term “goals” to refer to goals and subgoals.

¹⁰ 12 CFR 1282.12(f).

¹ 12 U.S.C. 4561(a).

² 12 U.S.C. 4501(7).

³ 12 CFR part 1282.

include separate categories for mortgages on multifamily properties (properties with five or more units) with rental units affordable to low-income and very low-income families. The Safety and Soundness Act also requires reporting on smaller properties.¹¹ The multifamily housing goals generally include all Enterprise multifamily mortgage purchases, regardless of the purpose of the loan. The multifamily housing goals evaluate the performance of the Enterprises based on the share of affordable units in properties that serve as collateral for mortgages purchased by an Enterprise (loans that are excluded as ineligible under 12 CFR 1282.16(b) are not counted for purposes of measuring Enterprise performance). The Enterprise housing goals regulation does not include a retrospective market level measure for the multifamily housing goals, due in part to a lack of comprehensive data about the multifamily market. As a result, FHFA measures Enterprise multifamily housing goals performance against the benchmark levels only and the final rule retains this approach.

The Safety and Soundness Act requires that affordability for rental units under the multifamily housing goals be determined based on rents that “[do] not exceed 30 percent of the maximum income level of such income

category, with appropriate adjustments for unit size as measured by the number of bedrooms.”¹² The Enterprise housing goals regulation considers the net rent paid by the renter, *i.e.*, the rent is decreased by any subsidy payments that the renter may receive, including housing assistance payments.¹³

B. Considerations After Publication of the Final Rule

If, after publication of this final rule, new information indicates that any of the single-family or multifamily housing goals or subgoals should be adjusted in light of market conditions or the safety and soundness of the Enterprises, or for any other reason, FHFA may take any steps that are necessary and appropriate to respond, consistent with the Safety and Soundness Act and the Enterprise housing goals regulation.

For example, under the Safety and Soundness Act and the Enterprise housing goals regulation, FHFA is permitted to reduce a benchmark level in response to an Enterprise petition for reduction for any of the single-family or multifamily housing goals or subgoals in a particular year. Any adjustment in response to such a petition must be based on a determination by FHFA that: (1) market and economic conditions or the financial condition of the Enterprise require a reduction; or (2) efforts to meet the goal or subgoal would result in the

constraint of liquidity, over-investment in certain market segments, or other consequences contrary to the intent of the Safety and Soundness Act or the purposes of the Enterprises’ charter acts.¹⁴ The Safety and Soundness Act and the Enterprise housing goals regulation also consider the possibility that achievement of a particular housing goal or subgoal may or may not have been feasible for an Enterprise. If FHFA determines that a housing goal or subgoal was not feasible for an Enterprise to achieve, then the statute and regulation do not require any further action related to that housing goal or subgoal for that year.¹⁵ If FHFA determines that an Enterprise did not meet a housing goal or subgoal and that achievement of the housing goal or subgoal was feasible, then the statute and regulation provide FHFA with discretionary authority to require the Enterprise to submit a housing plan describing the specific actions the Enterprise will take to improve its housing goals performance.¹⁶

II. Summary of Final Rule

A. Benchmark Levels for the Single-Family Housing Goals and Subgoal

This final rule establishes the benchmark levels for the single-family housing goals for 2026–2028 as follows:

Goal or subgoal	Criteria	Current benchmark level for 2025–2027 (percent)	Final benchmark level for 2026–2028 (percent)
Low-Income Home Purchase Goal (LIP).	Home purchase mortgages on single-family, owner-occupied properties, to borrowers with incomes no greater than 80 percent of area median income (AMI).	25.0	21.0
Very Low-Income Home Purchase Goal (VLIP).	Home purchase mortgages on single-family, owner-occupied properties, to borrowers with incomes no greater than 50 percent of AMI.	6.0	3.5
Low-Income Refinance Goal (LIR) ..	Refinance mortgages on single-family, owner-occupied properties, to borrowers with incomes no greater than 80 percent of AMI.	26.0	21.0
Low-Income Areas Home Purchase Subgoal (LIA).	Home purchase mortgages on single-family, owner-occupied properties with: • Borrowers in census tracts with tract median income of no greater than 80 percent of area median income; or • Borrowers with income no greater than 100 percent of area median income in census tracts where (i) tract income is less than 100 percent of area median income, and (ii) minorities comprise at least 30 percent of the tract population.	N/A	16.0

The final rule combines the current low-income census tracts home purchase subgoal and the minority census tracts home purchase subgoal into a single low-income areas home

purchase subgoal. The benchmark level for the low-income areas home purchase goal is the sum of the benchmark levels for the low-income areas home purchase subgoal, plus an additional amount that

will be determined separately by FHFA that takes into account families in disaster areas with incomes no greater than 100 percent of AMI.¹⁷ The low-income areas home purchase goal is

¹¹ 12 U.S.C. 4563(a)(3).

¹² See 12 U.S.C. 4563(c).

¹³ See 12 CFR 1282.1 (par. (i)(B) of definition of “rent”).

¹⁴ See 12 U.S.C. 4564(b); 12 CFR 1282.14(d).

¹⁵ See 12 U.S.C. 4566(b); 12 CFR 1282.21(a) (current regulation); 12 CFR 1282.22(a) (final rule).

¹⁶ See 12 U.S.C. 4566(c); 12 CFR 1282.21(a) (current regulation); 12 CFR 1282.22(a) (final rule).

¹⁷ See 12 CFR 1282.12(e). The low-income areas home purchase goal benchmark level for 2025 is 21 percent.

published annually on FHFA's website.¹⁸

To simplify the structure of the Enterprise housing goals regulation, FHFA is removing the temporary measurement buffers for the housing goals that the Agency previously established for 2025–2027. The measurement buffers were established to encourage the Enterprises to focus on achieving certain single-family housing goals by meeting the market level, if the benchmark level turns out to be higher

than the market level. These measurement buffers partly addressed the uncertainty in forecasting the market several years in advance as well as the time lag in determining the actual market level retrospectively. Since the 2026–2028 benchmarks are set below the forecasted marketed level, FHFA expects that the Enterprises will be able to calibrate their mortgage purchase strategies to anticipate small fluctuations in market uncertainty, making it unnecessary to maintain an

additional regulatory buffer. This accomplishes the original intent of the measurement buffers, rendering the buffers duplicative and unnecessary.

B. Benchmark Levels for the Multifamily Housing Goals and Subgoal

The final rule establishes the benchmark levels for the multifamily housing goals and subgoal for 2026–2028 as follows:

Goal and subgoal	Criteria	Current benchmark level for 2025–2027 (percent)	Final benchmark level for 2026–2028 (percent)
Low-Income Goal	Percentage share of all goal-eligible units in multifamily properties financed by mortgages purchased by the Enterprises in the year that are affordable to low-income families, defined as families with incomes less than or equal to 80 percent of AMI.	61.0	61.0
Very Low-Income Goal	Percentage share of all goal-eligible units in multifamily properties financed by mortgages purchased by the Enterprises in the year that are affordable to very low-income families, defined as families with incomes less than or equal to 50 percent of AMI.	14.0	14.0
Small Multifamily Low-Income Subgoal.	Percentage share of all goal-eligible units in all multifamily properties financed by mortgages purchased by the Enterprises in the year that are units in small multifamily properties affordable to low-income families, defined as families with incomes less than or equal to 80 percent of AMI.	2.0	2.0

C. Required Adjustments to Maximum Civil Money Penalty Amounts

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015¹⁹ (Adjustment Improvements Act) requires FHFA to adjust the level of civil monetary penalties for inflation (including an initial catch-up adjustment and annual adjustments thereafter). The final rule makes explicit that the required inflation adjustments apply to civil money penalties described in section 1345 of the Safety and Soundness Act (12 U.S.C. 4585), including penalties applicable to the Enterprise and Federal Home Loan Bank housing goals.

D. Notice of Preliminary Determination of Compliance With Housing Goals

To streamline the housing goal compliance determination processes, this final rule requires the Director to provide written notice to an Enterprise of a preliminary determination only if an Enterprise has failed to meet a housing goal or subgoal.

E. Technical Changes

The final rule also makes technical changes to the names of the single-family housing goals to distinguish between goals related to home purchase mortgages and the goal related to refinance mortgages.

III. Overview of Comments

On October 2, 2025, FHFA published a notice of proposed rulemaking (proposed rule) in the **Federal Register** (90 FR 47632) proposing single-family and multifamily housing goals for 2026–2028. Public comments were accepted between October 2nd and November 3rd, 2025.

FHFA received 19 comments in response to the proposed rule, which are published on FHFA's website.²⁰ Of these, 18 include substantial comments about the topics in the proposed rule. The comments submitted include letters from four individuals, six nonprofit policy advocacy groups, and nine trade associations. Six comment letters were signed by coalitions of organizations.

Five comments were in favor of the proposed rule, nine were not in favor, and four comments expressed mixed support. Three trade associations and two individuals generally supported the rule due to its anticipated benefits for middle-income borrowers and low-income renters, as well as its potential to reduce market distortions and regulatory burdens. Policy advocacy groups and one trade group generally opposed the rule because they believe it would reduce support for low- to moderate-income borrowers. Four trade groups supported parts of the proposed rule, such as the multifamily benchmarks, but opposed different parts of the single-family benchmarks. Several comments related to topics outside of the scope of rulemaking including recommendations for manufactured housing policy activity and legislative proposals to address housing affordability. Comments received and FHFA's responses are summarized by topic below.

¹⁸ See Housing Goal Annual Housing Activity Reports and Determinations for each Enterprise at <https://www.fhfa.gov/programs/affordable-housing/enterprise-housing-goals>.

¹⁹ Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Public Law 114–74, title VII, sec. 701, 129 Stat. 599 (28 U.S.C. 2461 note) (2015), available at <https://www.govinfo.gov/>

[content/pkg/PLAW-114publ74/pdf/PLAW-114publ74.pdf](https://www.fhfa.gov/regulation/federal-register/proposed-rulemaking/2026-2028-enterprise-housing-goals-proposed-rule).

²⁰ Available at <https://www.fhfa.gov/regulation/federal-register/proposed-rulemaking/2026-2028-enterprise-housing-goals-proposed-rule>.

IV. Single-Family Housing Goals and Subgoal

A. Factors Considered in Setting the Single-Family Housing Goal Benchmark Levels

The Safety and Soundness Act requires FHFA to consider the following seven factors in setting the single-family housing goals:

1. National housing needs;
2. Economic, housing, and demographic conditions, including expected market developments;
3. The performance and effort of the Enterprises toward achieving the housing goals in previous years;
4. The ability of the Enterprises to lead the industry in making mortgage credit available;
5. Such other reliable mortgage data as may be available;
6. The size of the purchase money conventional mortgage market, or refinance conventional mortgage market, as applicable, serving each of the types of families described, relative to the size of the overall purchase money mortgage market or the overall refinance mortgage market, respectively; and
7. The need to maintain the sound financial condition of the Enterprises.²¹

FHFA has considered each of these seven statutory factors in setting the benchmark levels for each of the single-family housing goals in this final rule. FHFA also has considered each of the comments received in response to the proposed rule, as discussed in more detail below.

FHFA's analysis of the single-family housing goals depends in part on a market forecast model developed by FHFA. The most recently developed models, published in December 2024, relied on 20 years of HMDA data, from 2004 to 2023, the latest year for which public HMDA data was available when the proposed rule was issued. FHFA also uses Moody's Analytics forecasts data as the primary data source for the model's independent or driver variables. Additional discussion of the most recent market forecast models can be found in a technical report on FHFA's website.²²

B. National Housing Needs and Economic, Housing, and Demographic Conditions

FHFA received several comments from national advocacy groups and

individuals on the current state of housing affordability, racial disparities in lending, and threats to economic sustainability in the United States. Two commenters argued that the lower benchmarks would improve affordable housing, strengthen communities, and reduce inequality. However, most commenters contended that the lower benchmarks would widen gaps in affordable housing availability and increase financial hardship for low- to moderate-income borrowers. Some commenters claimed that FHFA asserted that mission focused lending undermines safety and soundness. These commenters argued FHFA should not prioritize recapitalization over equitable access to capital and the public interest. Furthermore, advocacy groups stated that the nation faces a housing affordability crisis compounded by a fair housing crisis, both of which exacerbate challenges for borrowers. Commenters provided evidence that racial homeownership gaps remain as wide today as in 1968 and cited ongoing redlining, exclusionary zoning laws, and labor market discrimination.

Other commenters, including trade associations, praised FHFA's efforts to enhance the supply of affordable housing and promote efficiency and innovation in the housing market. Specifically, trade associations supported FHFA's focus on housing supply in the proposed rule. They argued that the Enterprises should reconsider deployment of housing goal subsidies to address drivers of housing affordability issues. Some policy advocacy groups, however, rejected the notion that current affordable housing supply conditions justify a reduction in goals, emphasizing that the Enterprises have a mandate to support borrowers regardless of housing supply levels.

The Agency also received comments on the proposed rule's impact on first-time homebuyers. Advocacy groups noted that homeownership remains out of reach for borrowers across all income levels, emphasizing that single-family home prices have risen faster than median incomes in nearly all metropolitan areas. They urged FHFA not to reduce the single-family benchmarks, emphasizing that Enterprise-backed mortgages represent important opportunities for first-time homebuyers. Advocacy groups further expressed concern that persistent drivers of wealth inequality, such as exposure to natural disasters and worsening macroeconomic conditions, continue to disproportionately affect low- to moderate-income communities, and cautioned that the single-family benchmarks should not be set at levels

that could exacerbate disparities among borrowers.

FHFA also received comments in favor of its broad efforts to better serve middle- and working-class Americans. Trade organizations praised FHFA for acknowledging the past evidence of "denominator management" and other market distortions that negatively impact middle class borrowers and supported FHFA's proposed efforts to negate these effects. Other commenters argued that the regulation does not expand access to housing credit for all borrowers, but, instead, primarily benefits wealthier households. Some policy advocacy groups also challenged FHFA's belief that the rule, if finalized as proposed, will better support middle-income borrowers, noting that the current housing goals already target this group and that reducing the benchmarks undermines the regulation's intended objective. Commenters emphasized that middle-income borrowers should be supported by the Enterprises in all economic cycles and across all regions, and argued that the proposed benchmarks do not achieve this goal. Additionally, advocacy groups criticized FHFA for not providing sufficient quantitative evidence to support the assertion that moderate-income households will face increasing obstacles to homeownership due to competition among millennials pursuing first-time homeownership.

FHFA acknowledges the nation's affordable housing crisis, and believes that finalizing the proposed rule will be a meaningful step toward addressing these challenges for Americans. The rule accounts for the limited supply of affordable housing and establishes benchmark levels designed to prevent unfair market distortions, such as discouraging or denying access to mortgages for credit-eligible applicants in order to meet housing goals targets. The lower single-family benchmarks are also intended to help mitigate potential price escalation that could disproportionately harm affordability for goal-eligible populations. Furthermore, the proposed benchmarks will enable the Enterprises to focus their efforts on developing products and resources that better support first-time homeownership and enhance affordability, rather than competing in a bidding war over a limited supply of goal-qualifying loans. FHFA finds that the proposed rule, once finalized, will likely expand access to mortgage credit for approximately 201,000 additional goal-eligible borrowers who otherwise might not obtain mortgage financing. Therefore, FHFA concurs with commenters who argue that the lower

²¹ See 12 U.S.C. 4562(e)(2)(B).

²² Details on FHFA's single-family market models are available in the technical report "The Size of the Affordable Mortgage Market: 2025–2027 Enterprise Single-Family Housing Goals," (December 2024), available at <https://www.fhfa.gov/research/papers/2025-2027-enterprise-single-family-housing-goals-12-2024>.

single-family benchmarks will improve housing affordability and reduce inequalities for Americans.

The Agency is committed to ensuring non-discriminatory access to mortgage credit across the nation and works to ensure that fair lending laws and requirements are followed by all of its regulated entities. However, FHFA disagrees that the setting of housing goal benchmarks has direct impact on redlining, exclusionary zoning laws, or labor market discrimination. Rather, the Agency's policy is to ensure that all households have equal access regardless of race and ethnicity. Over the past year, the Agency has overseen and supported efforts by the Enterprises to make housing more affordable, including, for example, through down payment and closing cost assistance to very low-income borrowers, enhanced free borrower education, and modern underwriting that considers a borrower's rental payment history and cash flow.

While the rule is designed to support low- to moderate-income borrowers in light of ongoing affordability and fair lending challenges, FHFA emphasizes that other market participants also play a vital role in advancing affordable housing. State Housing Finance Agencies (HFAs), the Rural Housing Service (RHS), the Federal Housing Administration (FHA), and the Department of Veterans Affairs (VA) are among the government entities that help provide liquidity and access to credit for low- to moderate-income borrowers. These organizations are often able to offer more favorable products tailored to the unique needs of these borrowers. As noted above and in the preamble to the proposed rule, the final rule ensures that benchmark levels are calibrated to avoid crowding out government entities and other sources of mortgage liquidity, thereby fostering a balanced and coordinated effort to expand affordable housing opportunities.

Lastly, FHFA finds that, given current affordability challenges and heightened market uncertainty, it would be imprudent to set benchmarks at overly aggressive levels. To maintain compliance with statutory safety and soundness requirements and to promote long-term housing market stability, FHFA believes it is essential to establish benchmark levels that strengthen the Enterprises' financial positions while continuing to ensure that low- and moderate-income families are effectively served.

C. Performance and Effort of the Enterprises in Achieving Housing Goals in Previous Years

Commenters representing industry trade organizations supported the Agency's position regarding the potential for past goals to have been too aggressive and beyond the capacity of available supply in the market. In their view, the primary issue is the limited supply of affordable homes, and an over-emphasis on the demand side of the equation (high goal benchmarks) has historically led to market distortions and "gamesmanship," including an extreme bidding war for goal-qualifying loans.

Commenters specifically referenced past market data and FHFA's own 2024 determination that the 2023 low-income and very low-income home purchase goals were not feasible to achieve. They posit that FHFA's failure to reset these benchmarks resulted in the Enterprises engaging in the kind of competition that the proposed rule noted produces market distortions, such as pricing increases or managing down the "denominator" of total loans purchased.

These commenters largely supported the proposed benchmarks, believing they were appropriately set at the low end of model confidence intervals or just below model estimates. They viewed this level as providing necessary flexibility for the Enterprises to respond to the market while maintaining their statutory obligations. The ultimate measure of success, they argued, should be the real-world impact on affordability and household sustainability, not just meeting a numerical loan production target. A commenter further noted that aggressive goal setting can inadvertently increase housing costs.

Conversely, many commenters disagreed that the Enterprises are crowding out other market participants and that their actions may lead to market distortion, stating that no evidence was presented. A commenter asserted that any perceived inefficiencies may lie in the Enterprises' underwriting and pricing frameworks, not in the goals themselves, and that updating those frameworks could strengthen liquidity for lenders while maintaining robust goals.

FHFA appreciates the thoughtful comments regarding the historical impact of setting housing goal benchmarks and the suggestions for improving the measurement of goal success. The Agency concurs with commenters who observed that aggressive goal setting in the past, where targets exceeded the available supply in the market, resulted in market

distortions and bidding wars that ultimately do not benefit the homebuyer. This aligns with FHFA's rationale that benchmarks set inappropriately high penalizes middle-class borrowers and creates an inefficient subsidy mechanism. The Agency's determination that the 2023 low-income and very low-income goals were infeasible further reinforces the need for realistic, achievable targets.

FHFA also agrees that the housing goals should increase affordability and promote sustainable homeownership, not simply meet a numerical target. The proposed recalibration of the Enterprise housing goals is warranted to address the concern, as detailed in the proposed rule and reiterated in this final rule, that past benchmarks were too high, which hindered the efficient deployment of funds. The new benchmarks are designed to provide the necessary flexibility for the Enterprises to respond to market conditions, meet their statutory obligations, and facilitate a thorough examination of lending patterns without causing undue market distortion.

The Agency finds merit in the suggestion to focus on loan performance as an integral measure of housing goal success. Ensuring loan sustainability is directly tied to FHFA's core responsibility to maintain the safety and soundness of the housing finance system. FHFA will examine incorporating household sustainability factors into future goal credit calculations or performance assessments.

Regarding the comment that questioned the evidence of "denominator management," FHFA relies on its analysis of how the Enterprises' pricing mechanisms and operational efforts, when driven by high benchmarks, can lead to the displacement of private capital and distort competition with other federal entities and harm middle-income borrowers. As noted in the proposed rule and the Regulatory Impact Analysis, FHFA notes that the non-Enterprise market segment²³ has experienced a growth in their share of goal-eligible loans since 2022, while the Enterprises acquisitions declined, potentially indicating "denominator management."

FHFA aims to encourage the Enterprises to reassess the deployment

²³ Graph 2 in the Regulatory Impact Analysis includes all non-Enterprise originations. However, Graph 4 to the proposed rule provides the shares of the conforming mortgage market for all new originations; the Graph shows that since 2022, the share of non-Agency originations (retained portfolio, PLS market, etc.) has grown.

of housing goal subsidies to more effectively address the underlying drivers of housing affordability. As described in the proposed rule and the Regulatory Impact Analysis, current benchmarks have contributed to bidding wars and market distortions over a limited housing supply. Housing supply conditions therefore directly affect the statutory factors FHFA must consider when setting benchmarks, including, but not limited to: the Enterprises' ability to fulfill public needs; their leadership role in the mortgage industry; and their support of safe and sound mortgage practices. Accordingly, FHFA finds that current and forecasted housing supply conditions may justify a reduction in goals, as affordable housing supply is part of the statutory considerations for benchmark-setting.

As noted previously in the preamble to the proposed rule and the Regulatory Impact Analysis, FHFA continues to believe that finalizing the proposed rule will expand access to housing credit for all borrowers. Critiques suggesting that the rule primarily benefits wealthier borrowers are unfounded. Goal-eligible loans exclude borrowers in the highest income brackets, such as investors and mortgages exceeding the conforming loan limit. Moreover, the Enterprises remain incentivized to meet statutory requirements for low- and moderate-income borrowers, as failure to comply could result in penalties. Lenders are also likely to continue originating loans to low- and moderate-income borrowers due to pay-ups (premiums) in secondary market trading and because these loans represent a significant and profitable segment of the homebuying market.

FHFA finds that finalizing the proposed rule will better support middle-income borrowers compared to the current rule. While the same number of goal-qualifying borrowers will be served, the proposed rule reduces the likelihood of turning away middle-income borrowers who do not fit a goal-qualifying definition solely to meet a ratio of goal-qualifying to goal-eligible borrowers. According to FHFA's regulatory impact analysis, finalizing the proposed rule is expected to result in an increase of 201,000 loans to goal-eligible borrowers, with the largest gains likely for middle-income households.

As described in the proposed rule, FHFA considers demographic factors as part of its post-model adjustment process to identify appropriate benchmarks based on model forecasts. One of the factors discussed was a potential significant increase in demand compared to the baseline forecasts due to indications that millennials are driving increased competition for

moderate-income homeownership opportunities. According to NAR's *Home Buyers and Sellers Generational Trends 2025* report and a Michigan Journal of Economics survey, millennials represent the largest share (29%) of recent homebuyers,²⁴ signaling current demand, and 55% are expected to inherit wealth over the next five years, indicating future demand.²⁵ Furthermore, the Joint Center for Housing Studies' 2025 report projects that the number of households aged 35–44 will grow by 3.0 million between 2025 and 2035. FHFA therefore finds it likely that an increasing number of moderate-income borrowers will seek homeownership and will likely benefit from the proposed rule. FHFA is committed to monitoring the impact of the final benchmarks to ensure borrowers across all economic cycles and regions are supported.

D. Ability To Lead the Industry in Making Mortgage Credit Available

Many commenters asserted that the Enterprises have a statutory mandate to serve low- to moderate-income borrowers and communities and to lead the industry in making mortgage credit available. Commenters cited the Enterprises' public missions and the requirements under the Safety and Soundness Act, which includes a specific factor for FHFA to consider in setting goals: the Enterprises' ability to lead the market in supporting access to mortgage credit.²⁶ These commenters contend that Congress mandates the Enterprises to lead the industry in making mortgage credit available for low- and moderate-income borrowers. Many of the commenters believe that these goals, as proposed, would not fulfill this mandate.

Several commenters also disagreed with the rationale in the proposed rule that suggests it may be inappropriate for the Enterprises to have an outsized market share in mortgage lending to low- to moderate-income or that the Enterprises should cede their market share to allow for other industry participants. Some commenters

expressed concern that the proposed benchmarks over-emphasize middle-income borrowers at the expense of low- to moderate-income borrowers.

Commenters disputed the Agency's suggestion that other federal government programs (FHA, VA, and USDA/RHS), state Housing Finance Agency (HFA) programs, or the private-label securities (PLS) market could serve to make mortgage credit available for low- to moderate-income borrowers. Commenters explained that VA and USDA loans have statutory eligibility restrictions that limit their availability, and one commenter expressed concern that a reduction in the benchmark may "create a credit gap for households on the margin of eligibility for both programs." Furthermore, commenters noted that although FHA serves a wider segment of the market, these loans are generally more expensive for many creditworthy households due to higher upfront and ongoing costs in the form of a higher mortgage insurance premium, and interest rate, as well as the lifetime nature of the mortgage insurance. Commenters note that similar borrowers who qualify for a conventional mortgage are able to use Enterprise loan products often receive lower interest rates and cancelable mortgage insurance, reducing the lifetime costs of the mortgage.

Commenters contended that bank balance sheets cannot be expected to fill the gap, as banks already receive full Community Reinvestment Act (CRA) credit for loans sold to the Enterprises and have no reason to increase the share of low- to moderate-income loans they hold on balance sheet. Commenters pointed out that the PLS market is cyclical and historically has primarily funded mortgages to higher-income borrowers, with the one exception being the subprime lending boom preceding the 2008 financial crisis. Rather, a commenter noted, the PLS market is highly sensitive to global capital flows, and during times of credit pressure (such as the 2008 global financial crisis and the 2020–2021 coronavirus pandemic) the PLS market has either ceased to function, or fully withdrew from participating in the market. At these times, only government lending and the Enterprises remained to stabilize the mortgage market. Concern was also raised that supporting PLS market growth is not a mandate in statute and raises market stability concerns.

A few commenters agreed with the underlying principle that the Enterprises should not be the sole source of mortgage liquidity and that pricing should determine the extent of their reach. These commenters noted

²⁴ See National Association of Realtors, "2025 Home Buyers and Sellers Generational Trends Report," (2025), available at https://cms.nar.realtor/sites/default/files/2025-03/2025-home-buyers-and-sellers-generational-trends-report-04-01-2025.pdf?_gl=1*8shge6*_gcl_au*OTc2MTQxNzk4LjE3NjI4MTAzNTY.

²⁵ See Michigan Journal of Economic, "The Great Wealth Transfer and its Implications for the American Economy," available at <https://sites.lsa.umich.edu/mje/2025/04/03/the-great-wealth-transfer-and-its-implications-for-the-american-economy/>.

²⁶ See 12 U.S.C. 4562(e)(2)(B)(iv) and 4563(a)(4)(D).

that while it is appropriate for the Enterprises to increase market share in periods of market stress or periods of retreat by other market participants to ensure credit availability, when the private markets are operating in a healthy manner, the Enterprises can and should reduce market share. Several commenters, including industry groups, supported the notion that goals should be set at an appropriate level to avoid market distortions and prevent the Enterprises from crowding out private sector participants.

A different set of commenters offered a criticism of past goals, arguing that setting them too low led to a sharp growth in volume for FHA, VA, and RHS programs, and simultaneously reduced private capital participation through instruments like private mortgage insurance and credit risk transfers. In their view, goals set too low concentrate risk with the federal government, which runs counter to the Congressional objective for the Enterprises to share risk with private capital providers. These commentators expressed a preference for an appropriate level of private capital to be deployed in the low- to moderate-income space, arguing this would increase affordability and efficiency while reducing dependence on Federal government support.

FHFA appreciates the commenters' detailed feedback regarding the statutory mission of the Enterprises and their role in the secondary mortgage market. The Agency acknowledges the Enterprises' fundamental statutory mandate to serve all borrowers, including low- to moderate-income borrowers and communities throughout the country. FHFA believes that the rule is designed to ensure that the Enterprises fulfill this statutory purpose while ensuring that all borrowers have equal access to a liquid secondary market, and balancing safety and soundness. FHFA disagrees that the benchmarks are at odds with this important role.

FHFA also notes that the Director is required by statute to establish goal targets by considering both historical performance and a number of statutory factors. One of these factors is "the ability of the enterprise to lead the industry in making mortgage credit available."²⁷ This factor does not mean that the Enterprises must lead the industry; rather, the Enterprises' ability to lead the industry is one of several factors considered in conjunction with historical performance in setting goals. FHFA believes that the goal setting

methodology described in the preamble to the proposed rule follows the statutory framework by considering all the required factors to set benchmarks that reflect the policy priorities of the Director.

FHFA agrees with the commenters who believe that the Enterprises should not be the sole source of mortgage credit liquidity, particularly for low- to moderate-income borrowers. The Agency maintains a policy interest in ensuring the Enterprises do not crowd out other market participants and intends to use the flexibility provided by the new goals to collect and analyze comprehensive data to definitively assess the relationship between goal levels and market behavior, including potential pricing inefficiencies. A diverse secondary mortgage market—one that includes the Enterprises, Federal government loan programs, state and local Housing Finance Agencies, and a robust, sustainable private-label securities market—is essential. This diversity allows for healthy competition that can reduce costs for borrowers, foster innovation, and ensure a more resilient and reliable supply of liquidity across the economic cycle.

The Agency's approach is consistent with the policy objectives of promoting competition, increasing private sector participation, and ensuring the Enterprises' role is defined without duplicating support provided by the Federal Housing Administration or other federal programs. Setting goals appropriately requires balancing the statutory obligation to promote access to affordable credit with the need to ensure safety and soundness while avoiding unnecessary and costly duplication of support. The Agency also acknowledges the critical need to reduce taxpayer exposure to risk and promote private capital participation.

The determination of the final goal targets balances the statutory obligation to promote access to affordable credit, the Enterprises' ability to lead the market, and the need to promote a sustainable, liquid, and competitive secondary market that includes other market participants and private risk-sharing mechanisms. The goal levels ultimately established are determined to provide a sufficient incentive for the Enterprises to fulfill their mission to low- to moderate-income borrowers and serve as leaders in the market while encouraging the sustainable growth and participation of other, non-Enterprise market participants and the appropriate deployment of private capital. Furthermore, as noted above, FHFA's analysis of past goal performance, where Enterprises continued to perform above

benchmarks even when they were set lower, suggests that the Enterprises will maintain strong liquidity and outreach to low- to moderate-income borrowers, as is consistent with their broader statutory mission.

For many low- to moderate-income borrowers, the Enterprises are the appropriate liquidity providers, for others it may be FHA or VA (via Ginnie Mae), while still others could be better served by the PLS market. It is important, however, to clearly distinguish between the setting of the housing goals benchmarks and the selling and underwriting requirements of the Enterprises. In response to a commenter's belief that lower benchmarks could create a "credit gap," FHFA notes that a reduced benchmark is separate and distinct from Enterprise business decisions regarding the appropriate amount of credit risk; further, it is unlikely that an applicant's mortgage that was eligible for purchase by the Enterprises would be ineligible by FHA. As noted above, FHFA does not agree that FHA loans are always a more expensive alternative because pricing depends on a borrower's financial profile, loan terms, and market conditions. FHFA also acknowledges that FHA has a clear statutory mandate to make homeownership more accessible, particularly for low- to moderate-income borrowers with low down payments.

It is FHFA's intent to ensure that the Enterprises do not crowd out other participants²⁸ and believes the updated benchmarks will encourage their involvement. It is also clear that under the current housing goals benchmarks, a distortive effect is present and FHFA believes that the means to correct this is to appropriately size the goals to the needs of the market. It is with this in mind that FHFA seeks to the right-size the goals and ensure that all borrowers are served appropriately and extended credit that fits within a borrower's need and circumstance. As noted earlier, the new benchmarks should not be viewed as a ceiling for the Enterprises, and the Enterprises are still expected to make best efforts at serving all segments of the market, ensuring they meet their affirmative statutory obligations.

E. Low-Income Purchase and Very Low-Income Purchase Goal Determinations

FHFA received a total of 11 comment letters from advocacy groups regarding

²⁸ As noted above, Graph 4 to the proposed rule provides the shares of the conforming mortgage market for all new originations; the Graph shows that since 2022, the share of non-Agency originations (retained portfolio, PLS market, etc.) has grown.

²⁷ 12 U.S.C. 4562(e)(2)(B)(iv).

the single-family purchase benchmarks. All letters focused on the proposed reduction of the low-income purchase (LIP) benchmark from 25.0 percent to 21.0 percent, while all but one also addressed the proposed reduction of the very low-income purchase (VLIP) benchmark from 6.0 percent to 3.5 percent for the years 2026–2028.

The commenters generally expressed concerns that the proposed goals are not ambitious enough and fall below current market levels, undermining the assistance that the Enterprises could provide to families in need. They argued that these reduced goals could jeopardize the statutory mission of the Enterprises and significantly limit lending opportunities for households with incomes up to 80 percent and 50 percent of area median income for LIP and VLIP, respectively.

Additionally, several commenters raised issues with FHFA's reliance on qualitative evidence related to the crowding out of other funding sources, the increasing costs for middle-income borrowers, and the notion that increased lending to low and moderate-income borrowers could undermine safety and soundness. Despite these Agency concerns, the commenters argue that market data supports maintaining the current benchmark levels, which they say have consistently been met in previous years. The commenters advocate for more ambitious goals, especially given the ongoing affordability challenges in the housing market.

Most of the commenters urged FHFA to either maintain the current benchmarks or reassess them based on

additional empirical data, rather than qualitative evidence and industry sentiment. One of these commenters suggested that the Enterprises could exceed the current purchase benchmarks, requesting increases in both LIP and VLIP benchmarks, although no specific targets were provided.

In contrast to the commenters advocating higher benchmarks, there were two letters from industry trade groups expressing their appreciation to FHFA for its recognition of the potential for market distortion and efforts to more appropriately calibrate the goals. One of these commenters pointed out that the LIP and VLIP goals were not feasible to achieve for 2023.

FHFA has thoroughly reviewed the comments and decided to retain the proposed reductions to both single-family purchase goals. This decision is based on FHFA's consideration of each of the statutory factors and the comments received, as discussed above.

The Agency reaffirms that while data is crucial, qualitative insights from stakeholder experience also play an essential role in understanding the complexities of the mortgage finance landscape. These qualitative assessments enrich the understanding of market dynamics and borrower needs. Further, the Agency provided quantitative data using the National Mortgage Database, noting unexpectedly lower acquisitions of goal-eligible loans by the Enterprises beginning in 2022, which may be explained by denominator management strategies identified by market participants through the qualitative data. The

Regulatory Impact Analysis estimates that in 2024, the Enterprises would have acquired an additional 67,000 goal-eligible loans per annum without having to purchase any fewer housing goal qualifying loans. Both qualitative and quantitative data provide unique and valuable insights into the market. In this case, both qualitative and quantitative information reinforce the need for FHFA to make adjustments to the goals to appropriately align incentives with desired outcomes.

FHFA aims to balance market dynamics by reconciling the Enterprises' commitment to affordable lending with the necessity of providing liquidity in the broader market. The Agency believes that maintaining these revised goals will reduce market distortions and mitigate unintended consequences while continuing to provide robust support for low- to moderate-income households. Furthermore, FHFA acknowledges the current economic realities affecting the housing landscape, such as a significant decrease in affordable inventory and rising costs, necessitating a reevaluation of attainable targets.

With a focus on long-term stability in the housing market, FHFA believes that implementing lower benchmarks is a prudent strategy to ensure the Enterprises can operate sustainably while protecting their financial health and the structural integrity of the secondary mortgage market. It is important to note that these goals reflect minimum requirements, and the Agency expects the Enterprises to exceed these benchmarks whenever feasible and prudent.

TABLE 1—SINGLE-FAMILY LOW-INCOME HOME PURCHASE GOAL

Year	Historical performance				2025	2026	2027	2028
	2021	2022	2023	2024				
Actual Market	26.7%	26.8%	26.3%					
Benchmark	24.0%	28.0%	28.0%	28.0%	25.0%	21.0%	21.0%	21.0%
Fannie Mae Performance								
Low-Income Home Purchase Mortgages	375,569	278,799	189,439	189,247				
Total Home Purchase Mortgages	1,306,459	1,016,371	726,139	710,076				
Low-Income % of Home Purchase Mortgages	28.7%	27.4%	26.1%	26.7%				
Freddie Mac Performance								
Low-Income Home Purchase Mortgages	329,426	264,118	209,432	200,757				
Total Home Purchase Mortgages	1,201,540	911,037	735,932	753,338				
Low-Income % of Home Purchase Mortgages	27.4%	29.0%	28.5%	26.6%				

As presented in Table 2, the market level for the low-income home purchase housing goal, derived from HMDA data, declined from 27.6 percent in 2020 to 26.3 percent in 2023. FHFA's most recent forecast for this goal projects a

continued market level decline, averaging 25.9 ± 5.6 percent. FHFA's current model forecasts the market level to remain below 26.0 percent through 2027, with an average forecast midpoint value of 25.9 percent.

Regarding Enterprise performance, Freddie Mac recorded a low-income home purchase performance of 29.0 percent in 2022 and 28.5 percent in 2023, exceeding both the benchmark and market levels in those years. Fannie

Mae's performance in 2022 was 27.4 percent, which was below the benchmark level but above the market level. In 2023, however, Fannie Mae's performance decreased to 26.1 percent,

falling below both the benchmark and the market levels. For 2023, FHFA determined that while Fannie Mae did not meet the goal, the established benchmark was not feasible for the

Enterprise.²⁹ For 2024, both Enterprises exceeded the market level, with Fannie Mae's performance at 26.7 percent and Freddie Mac's performance at 26.6 percent.

TABLE 2—SINGLE-FAMILY VERY LOW-INCOME HOME PURCHASE GOAL

Year	Historical performance				2025	2026	2027	2028
	2021	2022	2023	2024				
Actual Market	6.8%	6.8%	6.5%					
Benchmark	6.0%	7.0%	7.0%	7.0%	6.0%	3.5%	3.5%	3.5%
Fannie Mae Performance								
Very Low-Income Home Purchase Mortgages	97,154	69,919	43,792	41,783				
Total Home Purchase Mortgages	1,306,459	1,016,371	726,139	710,076				
Very Low-Income % of Home Purchase Mortgages	7.4%	6.9%	6.0%	5.9%				
Freddie Mac Performance								
Very Low-Income Home Purchase Mortgages	75,945	64,850	50,244	46,055				
Total Home Purchase Mortgages	1,201,540	911,037	735,932	753,338				
Very Low-Income % of Home Purchase Mortgages	6.3%	7.1%	6.8%	6.1%				

As detailed in Table 3, the market level for the very low-income home purchase housing goal, derived from HMDA data, decreased from 7.0 percent in 2020 to 6.5 percent in 2023. FHFA's most recent forecast projects a continued market level decline, averaging 6.0 ± 2.5 percent. FHFA's current model forecasts the market to continue its downward trajectory reaching below 6 percent through 2027, with an average forecast midpoint value of 5.9 percent.

Regarding the Enterprises, both Enterprises met the very low-income home purchase goal in 2022, with Freddie Mac's performance at 7.1 percent and Fannie Mae's performance at 6.9 percent. In 2023, Freddie Mac met the very low-income home purchase goal, with performance at 6.8 percent, but Fannie Mae's performance was 6.0 percent, which was below both the market and the benchmark. For 2024, Freddie Mac again met the very low-income home purchase goal, while Fannie Mae's performance was 5.9 percent, below both the market and the benchmark.

The Agency remains committed to its statutory mission of promoting affordable housing. However, the latest available market performance data, market forecasts, and Enterprise performance all indicate that the current benchmark levels for the low-income home purchase goal and the very low-income home purchase goal are set too aggressively. FHFA believes that the reductions in the LIP and VLIP goals are

a necessary strategy to maintain the stability of the Enterprises and the broader housing market. FHFA values the constructive dialogue and insights from stakeholders and will continue to monitor market conditions closely to evaluate the ongoing viability of these housing goals.

F. Low-Income Areas, Minority Census Tracts, & Low-Income Census Tracts Subgoal Determinations

The Agency received several comments regarding the restoration of the low-income areas subgoal, which would merge the current minority census tracts subgoal and the low-income census tracts subgoal. One individual supported the restoration of the low-income areas subgoal as it reduces administrative burden.

One individual, one trade association, two nonprofits, and three policy advocacy groups disagreed with the proposal to restore the previous subgoal and urged FHFA to keep the two area-based subgoals separate. They argued that given that the Enterprises can meet the low-income census tracts segment by serving borrowers at any income, combining both segments could result in greater service to higher-income borrowers and reduced focus on lower-income homebuyers in minority census tracts. One policy advocacy group argued that this change could result in the Enterprises' purchasing up to 88,000 fewer loans in minority census tracts from 2026 to 2028. In addition, commenters noted that while this

merger may reduce administrative burden, it may make it more difficult to track the Enterprises' performance in the minority census tracts.

As stated in the proposed rule, FHFA is restoring the low-income areas subgoal to simplify the regulatory framework, improve operational clarity for the Enterprises, and better align the subgoal with existing borrower-based metrics. This merger ensures that both segments of the subgoal remain supported while considering the implementation challenges related to the current structure. This change also advances the Administration's priorities for race neutral policies, and for regulatory reform by reducing compliance costs, increasing efficiency, and reducing regulatory burden.

Under the current structure, all higher-income borrower loans in low-income census tracts that are also minority census tracts qualify for the low-income census tracts subgoal only, while the lower-income loans in those census tracts qualify for the minority census tracts subgoal only. Although this separation enables the Enterprises to focus on lower-income borrowers in census tracts that are both minority and low-income in one subgoal (the minority census tracts subgoal), it also places higher-income loans in those census tracts in the other subgoal, which increases operational complexity.

However, a 2020 study of Enterprise acquisitions between 2010 and 2019, conducted by FHFA, found that under the previous structure, when the loans

²⁹ FHFA's final determination of Fannie Mae's performance for 2023, available at [https://](https://www.fhfa.gov/sites/default/files/2024-11/2023-Final-Determination-Letter-Fannie-Mae.pdf)

www.fhfa.gov/sites/default/files/2024-11/2023-Final-Determination-Letter-Fannie-Mae.pdf.

were not separated as described above, the share of loans made to borrowers with incomes greater than 100 percent of AMI and residing in low-income census tracts declined from 40.7 percent in 2010 to 37.0 percent in 2019.³⁰ The trend was similar among borrowers residing in minority census tracts, with the share of higher-income borrowers declining from 45.4 percent in 2010 to 42.9 percent in 2019.³¹ The share of high-income borrowers peaked between 2014 and 2016, corresponding with an overall increase in loan volume, decline in mortgage rates, and expansion of credit availability. In the following years, FHFA observed an overall decline in the share of higher-income borrowers

that qualified for this housing goal. Based on this evidence, and assuming that the trend observed during the 2010 to 2019 study period is representative of the subgoal as a whole, there does not appear to be any evidence that having a combined goal results in reduced support for low-income borrowers. FHFA believes that the Enterprises will continue to support lower-income borrowers when borrowers in low-income census tracts and minority census tracts are served under one subgoal.

Additionally, FHFA notes that the public will still be able to track the Enterprises' performance in minority census tracts without the minority census tracts subgoal. The Enterprises

provide this information in Tables 7 and 9 of their Annual Mortgage Reports published on their websites.³² Additionally, FHFA publishes information on borrower race and ethnicity by loan product compared to the market in its Annual Housing Report.³³

Given the operational challenges that emerged with the current structure, and the evidence of Enterprise behavior under the previous structure, FHFA believes that it is reasonable and prudent to restore the low-income areas subgoal as it will reduce administrative burden while encouraging the Enterprises to focus on supporting borrowers in low-income areas.

TABLE 3—SINGLE-FAMILY LOW-INCOME AREAS HOME PURCHASE SUBGOAL

Year	Historical performance				2025	2026	2027	2028
	2021	2022	2023	2024				
Actual Market	19.1%	21.8%	22.1%					
Benchmark	14.0%	N/A	N/A	N/A	N/A	16.0%	16.0%	16.0%
Fannie Mae Performance								
Minority Census Tracts Home Purchase Mortgages	143,340	137,474	91,202	92,060				
Low-Income Census Tracts Home Purchase Mortgages	122,177	94,864	67,844	68,370				
Low-Income Areas Subgoal Home Purchase Mortgages	265,517	232,338	159,046	160,430				
Total Home Purchase Mortgages	1,306,459	1,016,371	726,139	710,076				
Low-Income Area Subgoal % of Home Purchase Mortgages	20.3%	22.9%	21.9%	22.6%				
Freddie Mac Performance								
Minority Census Tracts Home Purchase Mortgages	111,691	116,223	97,378	90,754				
Low-Income Census Tracts Home Purchase Mortgages	104,401	82,883	69,459	69,438				
Low-Income Areas Subgoal Home Purchase Mortgages	216,092	199,106	166,837	160,192				
Total Home Purchase Mortgages	1,201,540	911,037	735,932	753,338				
Low-Income Area Subgoal % of Home Purchase Mortgages	18.0%	21.9%	22.7%	21.3%				

The numbers in italics refer to FHFA's tabulations of the market and Enterprise performance had this subgoal been in place from 2022–2024.

Table 3 shows the market levels and Enterprise performance on this subgoal in 2021, along with implied market levels and Enterprise performance for the years 2022 through 2024, during which the low-income areas subgoal was replaced by the low-income census tracts and minority census tracts subgoals. As shown above, both Enterprises exceeded the proposed benchmark level for this subgoal in 2022, 2023, and 2024.

Based on the comments received and FHFA's consideration of the statutory factors, including the recent performance of the Enterprises and the market forecasts shown in Table 3, FHFA has determined that the benchmark level for the low-income areas home purchase subgoal should be established at the level that was proposed by FHFA earlier this year, 16 percent.

G. Low-Income Refinance Goal Determinations

The Agency received comments regarding the proposal to maintain the low-income refinance benchmark level at 26.0 percent. A trade organization supported FHFA's proposal to maintain the benchmark level as was finalized in the 2025–2027 rule, given the segment's sensitivity to interest rates. Another trade organization urged FHFA to consider lowering the low-income

³⁰ Advanced Notice of Proposed Rulemaking, Table 3: Borrower Income Relative to AMI (Enterprise Loans Only), available at <https://www.govinfo.gov/content/pkg/FR-2020-12-21/pdf/2020-28084.pdf>.

³¹ *Ibid.*

³² See Fannie Mae's 2024 Annual Mortgage Report, available at <https://www.fanniemae.com/media/55596/display> and Freddie Mac's 2024 Annual Mortgage Report, available at <https://www.freddie-mac.com/about/pdf/2024-annual-mortgage-report.pdf>.

³³ Under 12 U.S.C. 4544(b)(3), FHFA is required to “aggregate and analyze data on income, race, and

gender by census tract and other relevant classifications, and compare such data with larger demographic, housing, and economic trends.” See FHFA's 2024 Annual Housing Report, available at <https://www.fhfa.gov/document/annual-housing-report-2024>.

refinance benchmark level—which is below the lower bound of the market forecast confidence interval—also due to the segment’s sensitivity to interest rates.³⁴ They noted that there is a potential for a decline in interest rates given the Administration’s stated policy priorities. They also urged FHFA to reinstate the measurement buffer for this goal, due to the potential of interest rates declining to a level that does not support the proposed benchmark level (as explained below).

As noted in the proposed rule, the Enterprises’ annual performance on the low-income refinance goal tends to be inversely proportional to the volume of low-income refinance loans the market produces and the Enterprises purchase during a given year.³⁵ For example, during the low mortgage rate environment in 2020, overall low-income refinance volume in the market increased significantly, exceeding 1.3 million loans.³⁶ However, the total market volume for all refinances also surged, reaching over 6.3 million loans.³⁷ This resulted in a low-income refinance market performance of only 21.0 percent. During that time period, as

well as during 2015 to 2017, neither the Enterprises nor the market was able to perform above the 26.0 percent proposed target.

Conversely, in 2023, amidst higher mortgage rates, the overall low-income refinance volume contracted sharply to approximately 160,000 loans, while total market refinance volume declined to about 397,000 loans.³⁸ This contraction in volume corresponded to a substantially higher low-income refinance market performance of 40.3 percent. The Enterprises’ performance on the low-income refinance goal mirrored this pattern, with their low-income refinance percentages increasing significantly during this later period, even as the absolute volume of their low-income refinance mortgage purchases decreased.

Moreover, since the publication of the proposed rule, FHFA has observed declines in the 30-year mortgage rate in September and October. These rates correspond to expected increases in refinances for primary residences compared to the rest of 2025. With this surge in refinance activity, the Agency has already observed a decline in the

rate of low-income refinance mortgages below the proposed benchmark. This performance is consistent with our expectations based on historical market performance.

Although mortgage rates are expected to decline during the 2026–2028 housing goals period, FHFA’s model cannot forecast the low-income refinance market with a high degree of confidence due to the unpredictability of future interest rates and the strong sensitivity of refinance originations to interest rates. FHFA initially proposed to maintain the benchmark level at 26.0 percent, which is below the lower bound of the confidence interval in the market forecast used in the 2025–2027 final rule, to account for this uncertainty. Additionally, FHFA included the measurement buffer in the 2025–2027 final rule to enable the Enterprises to focus on meeting the market if mortgage rates decline more significantly than expected. Without a measurement buffer, FHFA believes that a 26.0 percent benchmark level may not be achievable if mortgage rates decline and the Enterprises need to focus on the market level to meet the goal.

TABLE 4—SINGLE-FAMILY LOW-INCOME REFINANCE GOAL

Year	Historical performance				2025	2026	2027	2028
	2021	2022	2023	2024				
Actual Market	26.1%	37.3%	40.3%					
Benchmark	21.0%	26.0%	26.0%	26.0%	26.0%	26.0%	26.0%	26.0%
Fannie Mae Performance								
Low-Income Refinance Mortgages	809,452	279,020	60,682	67,584				
Total Refinance Mortgages	3,089,529	803,634	157,984	185,763				
Low-Income % of Refinance Mortgages	26.2%	34.7%	38.4%	36.4%				
Freddie Mac Performance								
Low-Income Refinance Mortgages	658,845	254,332	54,906	61,557				
Total Refinance Mortgages	2,651,858	686,394	127,043	186,266				
Low-Income % of Refinance Mortgages	24.8%	37.1%	43.2%	33.0%				

As shown in Table 4, both Enterprises performed well above the 26.0 percent benchmark level in 2022–2024, when mortgage rates were high, and FHFA does not expect Enterprise performance to decline significantly due to a lowered benchmark level if mortgage rates remain elevated.³⁹ Considering that the Enterprises have performed well above the benchmark level in the current high-interest rate environment, FHFA believes the 21.0 percent benchmark level in the final rule is reasonable and

will enable the Enterprises to remain focused on both affordability and safety and soundness, even if mortgage rates decline significantly. Additionally, FHFA believes that setting the benchmark level where the market performed when mortgage rates were low eliminates the need for a measurement buffer for this goal.

In response to comments and after reassessing the historical performance and market trends, FHFA has determined that a benchmark level

lower than 26.0 percent for the low-income refinance goal is appropriate. The Agency believes that this decision is responsive to concerns expressed by commenters in this rule and in response to the 2025–2027 proposed housing goals rule, and that a lower benchmark goal will be a more reasonable and achievable, yet still difficult, target if interest rates decline significantly. Therefore, in this final rule FHFA is setting the benchmark level for the low-income refinance goal at 21.0 percent,

³⁴ Refinance activity is significantly more sensitive to market interest rate changes than mortgages for new home purchases. This is because refinancing is discretionary—homeowners only proceed when prevailing rates are low enough to offer a clear financial benefit over their current

mortgage. In contrast, purchase money mortgages are necessary for a transaction to occur, making their volume less sensitive to short-term rate fluctuations.

³⁵ See “2026–2028 Enterprise Housing Goals,” 90 FR 47652 (Oct. 2, 2025).

³⁶ *Ibid.*

³⁷ *Ibid.*

³⁸ *Ibid.*

³⁹ See “2026–2028 Enterprise Housing Goals,” 90 FR 47651 (Oct. 2, 2025).

which was the market performance during the 2020 refinance boom when mortgage rates were low.

V. Multifamily Housing Goals and Subgoal

A. Factors Considered in Setting the Multifamily Housing Goal Benchmark Levels

The Safety and Soundness Act requires FHFA to consider the following six factors in setting the multifamily housing goals:

1. National multifamily mortgage credit needs and the ability of the Enterprises to provide additional liquidity and stability for the multifamily mortgage market;
2. The performance and effort of the Enterprises in making mortgage credit available for multifamily housing in previous years;
3. The size of the multifamily mortgage market for housing affordable to low-income and very low-income families, including the size of the multifamily markets for housing of a smaller or limited size;
4. The ability of the Enterprises to lead the market in making multifamily mortgage credit available, especially for multifamily housing affordable to low-income and very low-income families;
5. The availability of public subsidies; and
6. The need to maintain the sound financial condition of the Enterprises.⁴⁰

FHFA has considered each of these six statutory factors in setting the benchmark levels for each of the multifamily housing goals in this final rule.

B. Multifamily Housing Goals Comments and FHFA Determinations

FHFA received comments on the multifamily housing goals recommendations from seven

commenters, including trade associations, nonprofit organizations, and letters signed by multiple organizations. Nearly all of the commenters that provided feedback on the proposed multifamily housing goals benchmark levels supported the proposal to maintain the current multifamily low-income goal benchmark at 61.0 percent, maintain the current very low-income goal benchmark at 14.0 percent, and maintain the current small multifamily low-income subgoal benchmark at 2.0 percent. One trade association stated that the proposed housing goals appropriately reflect past performance of the Enterprises and maintain their focus on serving the low- and very low-income renter community. Another trade association stated that the proposed benchmarks strike an appropriate balance, ensuring the Enterprises fulfill their mission to promote affordability while continuing to provide liquidity across the broader multifamily market. These two trade associations strongly supported the proposal to maintain the small multifamily low-income subgoal at 2.0 percent, noting that this segment already benefits from robust private capital participation. Regarding the proposed very low-income goal, one trade association expressed support for the 14.0 percent benchmark given the past performance of the Enterprises and the critical need for housing for this income cohort.

Of the remaining commenters on the multifamily housing goals, one trade association suggested increasing the low-income goal due to the Enterprises' track record of exceeding the 61 percent benchmark and ongoing national shortages of affordable rental housing for low-income households. The group noted that the need for affordable rental

housing is well-documented and growing. Another trade association stated that the low-income goal should only be increased if the single-family housing goals are similarly increased, so as not to create an imbalance between rental and homeownership opportunities.

All the comments on the proposed multifamily housing goal benchmark levels emphasized the importance of the role of the multifamily housing goals in the affordable rental housing finance market. One letter submitted on behalf of 28 organizations stated that the multifamily housing goals are important in addressing the affordable rental housing crisis. Another letter submitted on behalf of 17 organizations noted that the Enterprises back more than 40 percent of multifamily mortgage debt, giving them a critical role in supporting affordable rental housing.

Additionally, a trade association recommended that FHFA help the Enterprises balance their multifamily housing goals with providing liquidity support for market-rate units. The Agency agrees that the Enterprises should support both affordable and market-rate units. FHFA considers market-rate units when setting the cap on multifamily purchase volume (the Multifamily Volume Cap) and the percent of loans purchased that must be "mission-driven" affordable housing.⁴¹ The Enterprise housing goals, however, are focused on families at or below specific AMI levels.

The recent performance of the Enterprises on each of the multifamily housing goals and subgoal is shown in the tables below. Note that for each of the multifamily goals and subgoal, starting in 2023, the benchmark metrics changed from the number of low-income units to the share of low-income units.

TABLE 5—MULTIFAMILY LOW-INCOME HOUSING GOAL

Year	Historical performance				2025	2026	2027	2028
	2021	2022	2023	2024				
Low-Income Multifamily Benchmark	315,000	415,000	61.0%	61.0%	61.0%	61.0%	61.0%	61.0%
Fannie Mae Performance								
Low-Income Multifamily Units	384,488	419,361	317,032	270,357				
Total Multifamily Units	557,152	542,347	415,513	398,661				
Low-Income % Total	69.0%	77.3%	76.3%	68.0%				
Freddie Mac Performance								
Low-Income Multifamily Units	373,225	420,107	231,968	302,324				
Total Multifamily Units	540,541	567,249	345,702	463,113				
Low-Income % of Total Units	69.0%	74.1%	67.1%	65.3%				

⁴⁰ 12 U.S.C. 4563(a)(4).

⁴¹ FHFA establishes an annual cap on the multifamily purchase volume of each Enterprise. FHFA also establishes a percentage of multifamily

purchases within the cap that must be "mission-driven," a defined term, that generally encompasses affordable and underserved market segments.

Table 5 shows the number and share of goal-qualifying low-income multifamily units in properties backing mortgages acquired by each Enterprise

from 2021 through 2024.⁴² In addition, the historical performance share average for the pre-pandemic years of 2017–2019 would have been 65.1 percent for

Fannie Mae and 67.3 percent for Freddie Mac.⁴³

TABLE 6—MULTIFAMILY VERY LOW-INCOME HOUSING GOAL

Year	Historical performance				2025	2026	2027	2028
	2021	2022	2023	2024				
Very Low-Income Multifamily Benchmark	60,000	88,000	12.0%	12.0%	14.0%	14.0%	14.0%	14.0%
Fannie Mae Performance								
Very Low-Income Multifamily Units	83,459	127,905	77,509	57,796				
Total Multifamily Units	557,152	542,347	415,513	398,661				
Very Low-Income % of Total Units	15.0%	23.6%	18.7%	14.5%				
Freddie Mac Performance								
Very Low-Income Multifamily Units	87,854	127,733	71,217	70,795				
Total Multifamily Units	540,541	567,249	345,702	463,113				
Very Low-Income % of Total Units	16.3%	22.5%	20.6%	15.3%				

Table 6 shows the number and share of goal-qualifying very low-income multifamily units as a percentage of the total goal-eligible units in properties

backing mortgages acquired by each Enterprise from 2021 through 2024. In addition, the historical performance share average for the pre-pandemic

years of 2017–2019 would have been 13.1 percent for Fannie Mae and 15.6 percent for Freddie Mac.⁴⁴

TABLE 7—SMALL (5–50 UNITS) MULTIFAMILY LOW-INCOME SUBGOAL

Year	Historical performance				2025	2026	2027	2028
	2021	2022	2023	2024				
Fannie Mae Small Low-Income Multifamily Benchmark	10,000	17,000	2.5%	2.5%	2.0%	2.0%	2.0%	2.0%
Freddie Mac Small Low-Income Multifamily Benchmark	10,000	23,000	2.5%	2.5%	2.0%	2.0%	2.0%	2.0%
Fannie Mae Performance								
Small Low-Income Multifamily Units	14,409	21,436	13,241	11,182				
Total Multifamily Units	557,152	542,347	415,513	398,661				
Low-Income % of Total Multifamily Units	2.6%	4.0%	3.2%	2.8%				
Freddie Mac Performance								
Small Low-Income Multifamily Units	31,913	27,103	14,006	15,639				
Total Multifamily Units	540,541	567,249	345,702	463,113				
Low-Income % of Total Multifamily Units	5.9%	4.8%	4.1%	3.4%				

Table 7 shows Enterprise performance on this subgoal, including the previous numeric benchmark levels applicable through 2022 and the percentage-based metric that began in 2023. FHFA recognizes that the Enterprises have different business approaches to the small multifamily market segment, and that each Enterprise sets its own credit risk tolerance for these products. As a result, each Enterprise has performed very differently on this subgoal. Since 2021, Freddie Mac has exceeded Fannie Mae in terms of percentage share of total units and volume of low-income units in small (5–50) multifamily properties.

Based on the comments received and FHFA's consideration of the statutory factors, including the recent performance of the Enterprises and the market forecasts shown in the tables above, FHFA has determined that the benchmark levels for each of the multifamily housing goals and subgoal should be established at the levels proposed. FHFA believes that this approach will appropriately balance the objectives of the housing goals and the Multifamily Volume Cap. FHFA also agrees with commenters that maintaining the three multifamily goals at current levels is appropriate and

believes that the benchmark levels support affordable housing.

C. Simplify Enterprise Multifamily Goals and Targets

One trade association encouraged FHFA to work towards harmonizing the multifamily affordable and mission-related goals of the Enterprises (including the housing goals that are the subject of this final rule and the annual “mission-driven” requirements associated with the Multifamily Volume Cap). According to the trade association, the Enterprises' multifamily businesses operate to meet two affordable housing targets every year, one based on unit

⁴² 12 CFR 1282.16 (Special Counting Requirements).

⁴³ See “2023–2024 Multifamily Enterprise Housing Goals,” (Proposed Rule), 87 FR 50794, 50800 (Aug. 18, 2022), available at <https://www.federalregister.gov/documents/2022/08/18/2022-17868/2023-2024-multifamily-enterprise-housing-goals>.

⁴⁴ See “2023–2024 Multifamily Enterprise Housing Goals,” (Proposed Rule), 87 FR 50794,

50801 (Aug. 18, 2022), available at <https://www.govinfo.gov/content/pkg/FR-2022-08-18/pdf/2022-17868.pdf>.

count and the other based on a dollar volume limit with required minimum percentages. The commenter stated that this is a confusing process whereby each Enterprise must meet two different affordability frameworks.

FHFA has already taken measures to assist the Enterprises in coordinating their efforts with respect to these requirements. Both of these requirements help ensure that the Enterprises fulfill a different aspect of their statutory mission and charters, and each requirement serves low- and moderate-income families and underserved markets in different ways. For example, FHFA's 2023–2024 Multifamily Enterprise Housing Goals final rule established the benchmark levels for the multifamily housing goals based on a different methodology—the percentage of affordable units in multifamily properties financed by mortgages purchased by the Enterprise each year. FHFA believes this change simplifies the multifamily housing goals in a way that complements the Multifamily Volume Cap and enables the Enterprises to meet both targets more seamlessly. FHFA will continue to explore ways to coordinate and streamline the requirements of the various multifamily affordable and mission-related goals of the Enterprises while ensuring these goals are achieved.

VI. Other Issues

A. 12866 Regulatory Impact & Single-Family Market Forecast Recommendations

Five commenters responded to FHFA's regulatory impact analysis and 12866 significance determination. Overall, commenters expressed concern about evidence provided in FHFA's regulatory impact analysis. Advocacy groups opposed FHFA's estimated decrease in goal-qualified loans under the proposed rule, stating that the estimate is inaccurate and should incorporate the assumption that lenders will stop making loans to low-income borrowers if the housing goals were lowered. Additionally, nonprofit policy advocacy groups and trade associations asserted the regulatory impact analysis included insufficient data and over-relied on anecdotal evidence. For example, groups argued that several arguments lacked credible evidence, including claims by FHFA in the proposed rule that FHA, VA, and USDA loans may better meet borrowers' needs than Enterprise loans, and that the Enterprises have been turning away middle-class borrowers to meet housing goals.

One commenter, representing 28 national and state advocacy groups, believed FHFA included contradictory reasoning within the regulatory impact analysis. Specifically, the commenter noted, FHFA states that the Enterprises' acquisition of goal loans under the proposed rule will not change from current levels, yet also acknowledges a factor that could dissuade the Enterprises from acquiring the same volume of goal loans: the lower returns the Enterprises receive on housing-goal-qualifying loans. Other commenters urged FHFA to conduct further data-driven analysis of the proposed rule's impact to housing goal acquisitions. Advocacy groups also urged FHFA to study the effectiveness of housing goals in accomplishing statutory intent and provide empirical evidence to support FHFA's anecdotal claims before making further regulatory decisions. Some individual commenters suggested FHFA evaluate the effectiveness of the proposed rule post-implementation to learn and adjust for future rulemakings.

State and national policy advocacy groups also raised a series of data concerns with the market forecast model for single-family goals. First, groups recommended that FHFA avoid setting the benchmarks below historic and expected mortgage market level without sufficient evidence and model data to support the decisioning. Additional market forecast-related concerns include claims that the rule relies on the same data and market forecast used in the 2025–2027 rule, which set higher single-family benchmarks, but now reaches the opposite conclusion by lowering benchmarks. Individual commenters, advocacy groups, and trade associations urged FHFA to maintain a data-driven approach to setting the benchmarks, respecting the data integrity and analytical rigor in goal setting.

Responding to the first concern raised by advocacy groups that FHFA's regulatory impact analysis shows an inaccurate decrease in the number of loans to low-to moderate-income households over the next three years, FHFA considered impacts to loan deliveries across likely and unlikely scenarios. In accordance with OMB's Circular No. A–4, Executive Order 12866, 44 U.S.C. 3501–3521, and 31 U.S.C. 1105, FHFA provided an estimate of impact under a range of scenarios, to account for unforeseen factors including market uncertainty. While FHFA acknowledges stakeholder concerns regarding the estimated likely and unlikely impact as identified in the regulatory impact analysis, the Agency provided this analysis using the most up to date and accurate data available.

Addressing the concern that lenders may not make loans to low- to moderate-income households without Enterprise backing, FHFA anticipates no reduction in Enterprise support for such loans and, as such, no adverse changes in lender activity. As articulated in the preamble to the proposed rule, both Enterprises have a statutory mandate to provide these loans, regardless of established benchmark levels.⁴⁵ Further, lenders have an economic incentive to purchase these loans due to pricing benefits, and these loans are profitable for the Enterprises to purchase.⁴⁶ Lastly, historical performance data demonstrates that the Enterprises are likely to deliver above the benchmark number, and more similar to the market.⁴⁷ Therefore, FHFA believes that the current benchmark levels will not lead to a reduction in support and instead will best promote homeownership.

FHFA acknowledges that certain statements in the proposed rule, when taken in isolation can be perceived as “contradictory.” However, FHFA finds it inappropriate to isolate these statements and not consider the full arguments articulated. For example, given the argument that FHFA makes contradictory statements about whether the Enterprises will purchase loans to low-income borrowers, the fact that goal qualifying loans can be less profitable for the Enterprises should not lead to the conclusion that the Enterprises will stop providing liquidity. Lenders and the Enterprises have clear statutory obligations and economic incentives to deliver loans to low- and moderate-income borrowers, such as spec pool trading pay-ups.⁴⁸ Addressing the concern about the lack of sufficient data on the benefit of the VA/RHS and FHA for low-income borrowers in comparison to Enterprise loans, FHFA provided a summary of how many low-income borrowers were served by VA/RHS and FHA loans in 2024 in the preamble to the proposed rule.⁴⁹ This evidence makes clear that non-Enterprise players have a valuable stake in serving low to moderate income borrowers. Concerning sentiments that FHA mortgages are not cheaper alternatives than Enterprise loans, FHFA does not agree that FHA loans are always a more expensive or less

⁴⁵ See “2026–2028 Enterprise Housing Goals,” 90 FR 47644 (Oct. 2, 2025).

⁴⁶ *Ibid.*

⁴⁷ *Ibid.*

⁴⁸ For further discussion please reference: See “2026–2028 Enterprise Housing Goals,” 90 FR 47644 (Oct. 2, 2025).

⁴⁹ See “2026–2028 Enterprise Housing Goals,” 90 FR 47642–3 (Oct. 2, 2025).

attractive alternative. Borrower costs and loan decisions depend on multiple factors that include credit risk, loan structure, expected tenure, down payment or closing cost constraints, and prevailing market conditions. For some borrowers, FHA products may be more attractive due to lower upfront cash requirements, underwriting flexibility, or other alignments with their financial circumstances. However, FHFA does acknowledge that there may be, on-net, increased costs for the group of borrowers shifting from Enterprise-backed mortgages to non-conventional mortgages as a result of this rule. FHA loans play a critical role in expanding access to mortgage credit and, along with VA/RHS, operate as part of a diverse system of federal housing finance programs rather than one with direct competitors or substitutes for Enterprise-backed products.

FHFA considered commenters' concerns about reliance on anecdotal evidence within 12866. FHFA acknowledges that empirical evidence provides a scientific basis for decision-making. However, the Agency notes that qualitative and anecdotal evidence can be an important source of decisioning, especially with limited data available on a problem.⁵⁰ FHFA intends to use its observations of how aggressively high housing goals lead to market distortions, crowding-out effects, and "denominator-management," to spark further investigation and empirical research into these claims, although it is not prepared to commit to publishing any specific research or review at this time. Further, as noted above, FHFA's regulatory impact analysis did provide empirical evidence for the denominator management effect based on all available agency data which includes entire portfolio information from both Enterprises as well as a nationally representative sample of all residential mortgages in the United States.⁵¹ This indicates that, on the margins, lenders may be turning away middle-class borrowers. Performance under the proposed benchmarks will provide FHFA with the additional empirical data necessary to further study the

impact of the lowered benchmarks and gain more insight into the nature of our preliminary observations. Since 2013, FHFA has consistently increased the benchmarks for most single-family goals,⁵² yet housing affordability continues to be a challenge for Americans. The Agency believes that this alternative approach may best meet the Agency's policy goals to ensure a liquid housing market for all Americans, while continuing to support lower-income families.

FHFA's decisioning behind setting the benchmarks below the historical and expected market delivery is aimed at addressing current market uncertainty with predictions. By setting most benchmarks at the low end of the model confidence interval, or just below the model estimates, FHFA provides flexibility for the Enterprises while still holding them to statutory obligations. FHFA considered the seven statutory factors in establishing the benchmarks, including the market forecast. However, FHFA weighed the evidence of the past performance of the Enterprises in achieving the benchmarks and the ability of the Enterprises to lead the industry, more heavily in its decisioning given Agency priorities. Instead of relying primarily on the uncertain single-family market forecast model, as in previous rulemakings, FHFA considered the model as one of many factors considered when setting the final benchmark levels. It is important to note that the Agency has never relied solely on the model output to set goals, and has set the housing goal benchmarks in the context of all the statutory factors. Therefore, FHFA finds the benchmarks appropriately balance flexibility and market forecast data to set the benchmarks at the proposed level.

B. Regulatory Capacity & Accountability Mechanisms

The agency received comments on how the proposed rule impacts regulatory capacity and function. Individual commenters and trade associations commended FHFA for its efforts to reduce regulatory burden, streamline processes, and enhance operational efficiency. They argued that the lower benchmarks appropriately balance statutory obligations with the need for greater efficiency in loan pricing and the minimization of duplication across the secondary mortgage market. Trade associations also praised FHFA's holistic approach

in the proposed rule, highlighting the importance of ensuring optimal loan execution for borrowers in the market. In contrast, advocacy groups contended that there is insufficient evidence to demonstrate that the proposed changes will meaningfully improve operational efficiency or reduce regulatory burden for FHFA, the Enterprises, or the broader housing market.

National, state, and local advocacy groups emphasized that housing goals are a critical accountability mechanism for FHFA to ensure the Enterprises serve low- to moderate-income borrowers. These groups argued that the proposed single-family benchmarks weaken FHFA's regulatory authority and asserted that this accountability mechanism should be strengthened, not diminished, given current affordability challenges. Nonprofits and advocacy organizations also encouraged FHFA to take a more active role in adjusting policy in real time to reflect public needs and current housing conditions.

FHFA finds that the proposed rule will reduce regulatory burden. The Enterprises are likely to save on expenses associated with meeting and monitoring housing goals and responding to regulatory requests under a housing plan, as the lower benchmarks are more achievable given current and projected market conditions. By removing the complexity of multiple low-income area subgoals, the proposed rule provides the Enterprises with a clearer framework for underwriting, investment, pricing, and reporting. Evidence of the rule's potential to improve operational efficiency is presented in FHFA's regulatory impact analysis, which shows that the Enterprises are expected to issue approximately \$72 billion in additional goal-eligible financing over 2026–2028 without incurring any expenses beyond those already anticipated under the 2025–2027 housing goal benchmark levels.⁵³

The Agency agrees that the housing goals are a critical accountability mechanism to ensure the Enterprises serve low- to moderate-income borrowers. However, FHFA disagrees with commenters who suggested that lower benchmarks would diminish the Agency's ability to hold the Enterprises accountable for fulfilling statutory mandates. While FHFA acknowledges that the proposed single-family

⁵⁰ See Lim, W.M. "What Is Qualitative Research? An Overview and Guidelines." (2024), available at <https://journals.sagepub.com/doi/10.1177/14413582241264619>, & Limb CJ. "The Need for Evidence in an Anecdotal World. Trends Amplif." (2011), available at <https://pmc.ncbi.nlm.nih.gov/articles/PMC4040832/>.

⁵¹ Significant Regulatory Action Assessment and Regulatory Impact Analysis for 2026–2028 Enterprise Housing Goals Proposed Rule (p. 13). Federal Housing Finance Agency, available at <https://www.fhfa.gov/sites/default/files/2025-10/2026-2028-enterprise-housing-goals-proposed-rule-regulatory-impact-analysis.pdf>.

⁵² See U.S. Federal Housing, "Housing Goals Performance Page," available at <https://www.fhfa.gov/programs/affordable-housing/housing-goals-performance>.

⁵³ Significant Regulatory Action Assessment and Regulatory Impact Analysis for 2026–2028 Enterprise Housing Goals Proposed Rule (p. 19). Federal Housing Finance Agency, available at <https://www.fhfa.gov/sites/default/files/2025-10/2026-2028-enterprise-housing-goals-proposed-rule-regulatory-impact-analysis.pdf>.

benchmarks are lower than recent single-family benchmarks, the rule maintains existing enforcement mechanisms to ensure that the Enterprises continue to support low- to moderate-income borrowers.⁵⁴ These mechanisms include civil money penalties, housing plans, final and preliminary determinations of compliance, ongoing monitoring of the Enterprises, and annual reporting requirements. FHFA, as conservator, also has additional tools to ensure the Enterprises are supporting liquidity for low- to moderate-income families and it is FHFA's intention that the housing goal benchmarks do not represent a cap on loan purchases.

FHFA also agrees with commenters that FHFA should adjust policy in real time to reflect public needs and current housing conditions. FHFA is committed to actively evaluating policy and the benchmarks to reflect public needs and current housing conditions, as demonstrated by the decision to issue the proposed rule. The Agency plans to assess the impact of the proposed single-family benchmarks on borrowers and will adjust future policy decisions accordingly. FHFA will also assess whether more frequent rulemakings for housing goals benchmark setting would be appropriate and better reflect changing market conditions and respond to market uncertainty.

C. Measurement Buffer Recommendations

The Agency received comments regarding the application of measurement buffers and the setting of benchmarks within the housing goals framework. An industry trade group strongly urged the retention of measurement buffers, arguing that they are essential to mitigate market distortions and the challenges posed by using lagged, potentially year-old data to set static goals. The group noted the housing industry's sensitivity to rapid shifts in interest rates, volumes, and macroeconomic conditions, asserting that buffers help ensure goal compliance when goal levels and actual market production are misaligned, specifically suggesting the benefit for the single-family low-income refinance goal. Similarly, an advocacy coalition voiced concern over removal of the measurement buffers and factored increasing the benchmark and maintaining the buffers to ensure lower-income borrowers have reduced access

to liquidity. The coalition believed that lowering the benchmark could permit the Enterprises to allocate a significantly smaller share of activity to goals-eligible loans than the market overall.

The Agency agrees that misalignment between the goal levels and actual market production may result in unintended consequences, particularly for the low-income refinance goal due to its heightened sensitivity to outside changes. Based on commenters' feedback, as discussed above, FHFA has adjusted the low-income refinance goal to the same level that was in place in prior periods of low-interest rates. Additionally, the Enterprises may be in compliance with housing goals if they meet the market, which is determined retrospectively, is not static, and accurately represents overall market performance. FHFA believes that having a market-level compliance standard and implementing the revised benchmark will mitigate any unintended market distortions. FHFA disagrees that the benchmarks will result in the Enterprises purchasing a smaller share of goal qualifying loans. Based on historical data, and, as discussed in the preamble to the proposed rule and above, the Enterprises have performed above benchmarks and have incentives to continue to purchase loans made to low-income borrowers.

D. Notice of Determination of Compliance With Housing Goals

The current housing goals regulation requires FHFA to provide each Enterprise with a preliminary determination of the Enterprise's performance each year, whether the Enterprise has met its housing goals or not. The proposed rule sought to simplify FHFA's process for issuing preliminary and final determination letters by eliminating the requirement for FHFA to issue a preliminary determination letter if an Enterprise has met all of the housing goals for that year. As revised, FHFA would be required to provide a preliminary determination to an Enterprise only if the Enterprise failed to meet one or more of its housing goals for the year.

FHFA did not receive any substantive comments on the proposed revision to the process for issuing preliminary and final determination letters. If an Enterprise has met the housing goals, it is not necessary for the Enterprise to provide additional information in order for FHFA to reach a final determination. Issuing a preliminary determination letter in that situation creates unnecessary paperwork, without a corresponding procedural benefit. The final rule therefore revises section

1282.20(b) so that a preliminary determination letter is required only if an Enterprise has failed, or that there is a substantial probability that an Enterprise will fail, to meet any housing goal or subgoal.

E. Technical Changes

The proposed rule included several technical changes to conform the language used in the regulation with FHFA's current processes and with commonly-used terminology. FHFA did not receive any substantive comments on the proposed technical changes. For the reasons stated in the preamble to the proposed rule and summarized below, the final rule adopts each of the proposed technical changes.

FHFA often uses the terms "low-income home purchase goal" and "very low-income home purchase goal" to refer to the low-income families housing goal and the very low-income families housing goal, respectively, described in 12 CFR 1282.12(c) and (d). Similarly, FHFA uses the term "low-income areas home purchase goal" to refer to the low-income areas housing goal described in 12 CFR 1282.12(e). FHFA typically refers to the refinancing housing goal in 12 CFR 1282.12(h) as the "low-income refinance goal." The final rule adopts each of these changes to the names of the various housing goals in the relevant paragraphs.

The final rule also revises section 1282.12(e) to specify that FHFA will publish the annual notice establishing the benchmark level for the low-income areas home purchase goal on FHFA's website. This change is consistent with FHFA's current practice for notices and determinations related to the Enterprise housing goals.

Finally, the final rule updates how the benchmark levels are expressed in the regulation. The current regulation does not include any decimals in the benchmark levels. For example, the benchmark for the low-income families home purchase goal is expressed as "25 percent" rather than "25.0 percent." FHFA has an established practice has been to determine Enterprise performance on the housing goals at the first decimal. Updating the numeric expression of the benchmark levels in the regulation is a technical, non-substantive change that better aligns the rule language with existing practice, and reduces the possibility of confusion. The final rule therefore updates the numeric expression of each benchmark level to include the first digit after the decimal for each of the single-family and multifamily benchmark levels.

⁵⁴ See U.S. Federal Housing, "Housing Goals Performance Page," available at <https://www.fhfa.gov/programs/affordable-housing/housing-goals-performance>.

F. Required Adjustments To Maximum Civil Money Penalty Amounts

The Safety and Soundness Act authorizes FHFA to seek civil money penalties to enforce several requirements related to the Enterprise and Bank housing goals. These civil money penalties are subject to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Adjustment Improvements Act),

which amended the Federal Civil Penalties Inflation Adjustment Act of 1990 by establishing a mechanism for regular adjustment for inflation of civil money penalties.⁵⁵

The proposed rule would have made explicit the mandatory inflation adjustments required by law. Additional detail on the calculation method used by FHFA to determine the new maximum civil money penalty amounts.

FHFA did not receive any substantive comments on the proposed changes related to the maximum amounts for any civil money penalties that may be assessed in connection with the Bank or Enterprise housing goals. The final rule adopts the changes to the relevant sections as proposed. The new maximum civil money penalty amounts are set out in this table, summarizing the changes made by this final rule:

U.S. Code citation	Description	Adjusted maximum penalty amount
12 U.S.C. 4585(b)(1)	Maximum penalty for failure described in 1345(a)(1), for each day that the failure occurs	145,754
12 U.S.C. 4585(b)(2)	Maximum penalty for failure described in 1345(a)(2), (3), or (4), for each day that the failure occurs	72,876

These new maximum civil money penalty amounts will apply prospectively to any civil money penalty action initiated in connection with the Bank or Enterprise housing goals after the effective date of this final rule. The final rule revises sections 1209.1(c)(4), 1209.80, 1209.81, 1281.15(f), and 1282.22 to make clear that the new maximum penalty amounts above apply to any civil money penalties in connection with the Enterprise or Bank housing goals.

VII. Considerations of Differences Between the Banks and the Enterprises

When promulgating regulations relating to the Banks, section 1313(f) of the Safety and Soundness Act requires the Director of FHFA to consider the differences between the Banks and the Enterprises with respect to the Banks' cooperative ownership structure; mission of providing liquidity to members; affordable housing and community development mission; capital structure; and joint and several liability. FHFA, in preparing this final rule, considered the differences between the Banks and the Enterprises as they relate to the above factors. FHFA also considered these differences in light of section 10C of the Bank Act, which requires that the Bank housing goals be consistent with the Enterprise housing goals, with consideration of the unique mission and ownership structure of the Banks.

VIII. Regulatory Impact

A. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA), the Office of Management and Budget (OMB) must "review and approve proposed agency

collections of information." See 44 U.S.C. 3504(c)(1). OMB has determined that the Enterprise reporting requirements in Subpart D of Part 1282 constitute a "collection of information" for purposes of the PRA. FHFA has submitted a request for emergency authorization for the information collection pursuant to 5 CFR 1320.13, and OMB has approved the request. FHFA may publish additional notice via a separate **Federal Register** notice following the issuance of this final rule.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires that a regulation that has a significant economic impact on a substantial number of small entities, small businesses, or small organizations must include an initial regulatory flexibility analysis describing the regulation's impact on small entities. Such an analysis need not be undertaken if the agency has certified that the regulation will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b). FHFA has considered the impact of the final rule under the Regulatory Flexibility Act. FHFA certifies that the final rule will not have a significant economic impact on a substantial number of small entities because the rule applies to Fannie Mae, Freddie Mac, and the Federal Home Loan Banks, which are not small entities for purposes of the Regulatory Flexibility Act.

C. Congressional Review Act and Executive Order 12866, Regulatory Planning and Review

The Office of Management and Budget, Office of Information and

Regulatory Affairs (OIRA) has determined the final rule meets the definition of "major rule" in the Congressional Review Act at 5 U.S.C. 804(2). OIRA also has determined that this rule is economically significant under subsection 3(f)(1) of Executive Order 12866. FHFA submitted a regulatory impact analysis to OIRA, which reviewed the potential costs and benefits of the final rule. The analysis is available on FHFA's rulemaking website <https://www.fhfa.gov/regulation/rulemaking> and is part of the docket file for this final rule.

D. Executive Order 13563: Improving Regulation and Regulatory Review

Executive Order 13563 directs agencies to analyze regulations that are "outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned." Executive Order 13563 also directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. FHFA has developed this final rule in a manner consistent with these requirements.

E. Executive Order 14192: Unleashing Prosperity Through Deregulation

Executive Order 14192 requires that for each new regulation issued, at least 10 existing regulations be identified for elimination. Executive Order 14192 also directs that any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by

⁵⁵ Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Public Law 114–74,

title VII, sec. 701, 129 Stat. 599 (28 U.S.C. 2461 note) (2015), available at <https://www.govinfo.gov/>

<content/pkg/PLAW-114publ74/pdf/PLAW-114publ74.pdf>.

the elimination of existing costs associated with at least 10 prior regulations. FHFA's implementation of these requirements will be informed by M-25-20, Guidance Implementing Section 3 of Executive Order 14192, Titled "Unleashing Prosperity Through Deregulation" (March 26, 2025). This final rule is expected to be an Executive Order 14192 deregulatory action although the cost savings are unquantified.

IX. Severability

The final rule makes explicit FHFA's intent that all provisions of the Enterprise housing goals regulation be severable by adding a severability clause, as new 12 CFR 1282.11(c). The regulation contains many thematically related but ultimately independent regulatory requirements, each of which can function independently. For example, FHFA establishes each goal and subgoal independently from one another, utilizing separate formulas and consideration of differing statutory factors. If one goal or subgoal is found to be invalid or unenforceable for any reason, it is FHFA's intention that the remaining goals continue in effect. Adding a severability clause to the

regulation ensures that each of the distinct policy objectives in the regulation will be realized to the greatest extent possible.

List of Subjects

12 CFR Part 1209

Administrative practice and procedure, Penalties.

12 CFR Part 1281

Credit, Federal home loan banks, Housing, Mortgages, Reporting and recordkeeping requirements.

12 CFR Part 1282

Mortgages, Reporting and recordkeeping requirements.

Accordingly, for the reasons stated in the preamble, under the authority of 12 U.S.C. 4526, FHFA amends parts 1209, 1281, and 1282 of title 12 of the Code of Federal Regulations, as follows:

PART 1209—RULES OF PRACTICE AND PROCEDURE

- 1. The authority citation for part 1209 continues to read as follows:

Authority: 5 U.S.C. 554, 556, 557, and 701 *et seq.*; 12 U.S.C. 1430c(d); 12

U.S.C. 4501, 4502, 4503, 4511, 4513, 4513b, 4517, 4526, 4566(c)(1) and (c)(7), 4581–4588, 4631–4641; and 28 U.S.C. 2461 note.

- 2. Revise § 1209.1(c)(4) to read as follows:

§ 1209.1 Scope.

* * * * *

(c) * * *

(4) Enforcement proceedings under sections 1341 through 1348 of the Safety and Soundness Act, as amended (12 U.S.C. 4581 through 4588), and section 10C of the Federal Home Loan Bank Act, as amended (12 U.S.C. 1430c), except where the Rules of Practice and Procedure in subpart C are inconsistent with such statutory provisions or with part 1281 or 1282 of this title, in which case the statutory or regulatory provisions shall apply.

- 3. Revise § 1209.80 to read as follows:

§ 1209.80 Inflation adjustments.

The maximum amount of each civil money penalty within FHFA's jurisdiction, as set by the Safety and Soundness Act and thereafter adjusted in accordance with the Inflation Adjustment Act, is as follows:

TABLE 1 TO § 1209.80

U.S. Code citation	Description	Catch-up adjusted maximum penalty amount
12 U.S.C. 4636(b)(1)	First Tier	\$14,575
12 U.S.C. 4636(b)(2)	Second Tier	72,876
12 U.S.C. 4636(b)(4)	Third Tier (Regulated Entity or Entity-Affiliated party)	2,915,057
12 U.S.C. 4585(b)(1)	Maximum penalty for failure described in section 1345(a)(1), for each day that the failure occurs	145,754
12 U.S.C. 4585(b)(2)	Maximum penalty for failure described in section 1345(a)(2), (3), or (4), for each day that the failure occurs.	72,876

- 4. Revise § 1209.81 to read as follows:

§ 1209.81 Applicability.

(a) *Applicability to penalties under 12 U.S.C. 4636.* The inflation adjustments set out in § 1209.80 for 12 U.S.C. 4636 shall apply to civil money penalties assessed in accordance with the provisions of the Safety and Soundness Act, 12 U.S.C. 4636, and subparts B and C of this part, for violations occurring on or after January 15, 2025.

(b) *Applicability to penalties under 12 U.S.C. 4585.* The inflation adjustments set out in § 1209.80 for 12 U.S.C. 4585 shall apply to civil money penalties assessed under the provisions of the Safety and Soundness Act, 12 U.S.C. 4585 and subpart C of this part. The inflation adjusted maximum civil money penalty amounts shall apply to

violations occurring on or after the effective date of this section.

PART 1281—FEDERAL HOME LOAN BANK HOUSING GOALS

- 5. The authority citation for part 1281 continues to read as follows:

Authority: 12 U.S.C. 1430, 1430b, 1430c, 1431.

§ 1281.15 [Amended]

- 6. In § 1281.15(f), add the phrase "and applicable provisions in part 1209 of this title" after "in 12 U.S.C. 4581 through 4588" in the last sentence.

PART 1282—ENTERPRISE HOUSING GOALS AND MISSION

- 7. The authority citation for part 1282 continues to read as follows:

Authority: 12 U.S.C. 4501, 4502, 4511, 4513, 4526, 4561–4566.

- 8. Amend § 1282.11 by:

- a. Revising paragraph (a)(1); and
■ b. Adding paragraph (c).

The revision and addition read as follows:

§ 1282.11 General.

(a) * * *

(1) Three single-family owner-occupied purchase money mortgage housing goals, a single-family owner-occupied purchase money mortgage housing subgoal, a single-family refinancing mortgage housing goal, two multifamily housing goals, and a multifamily housing subgoal;

* * * * *

(c) *Severability.* FHFA intends the various provisions of this part to be

separate and severable from one another. If any provision of this part, or any application of a provision, is stayed or determined to be invalid or unenforceable, the remaining provisions or applications will continue in effect.

■ 9. Amend § 1282.12 by:

- a. Revising the heading to paragraph (c) introductory text and paragraph (c)(2);
- b. Revising the heading to paragraph (d) introductory text and paragraph (d)(2);
- c. Revising the heading to paragraph (e) introductory text and paragraph (e)(2);
- d. Revising paragraph (f);
- e. Removing paragraph (g);
- f. Redesignating paragraph (h) as paragraph (g); and
- g. Revising the heading to newly designated paragraph (g) and paragraph (g)(2). The revisions read as follows:

§ 1282.12 Single-family housing goals.

* * * * *

(c) *Low-income home purchase goal.* * * *

(2) The benchmark level, which for 2026, 2027, and 2028 shall be 21.0 percent of the total number of purchase money mortgages purchased by that Enterprise in each year that finance owner-occupied single-family properties.

(d) *Very low-income home purchase goal.* * * *

(2) The benchmark level, which for 2026, 2027, and 2028 shall be 3.5 percent of the total number of purchase money mortgages purchased by that Enterprise in each year that finance owner-occupied single-family properties.

(e) *Low-income areas home purchase goal.* * * *

(2) A benchmark level which shall be set annually by FHFA by notice based on the benchmark level for the low-income areas home purchase subgoal, plus an adjustment factor reflecting the additional incremental share of mortgages for moderate-income families in designated disaster areas in the most recent year for which such data is available. FHFA will make the notice available on FHFA's website, www.fhfa.gov.

(f) *Low-income areas home purchase subgoal.* The percentage share of each Enterprise's total purchases of purchase money mortgages on owner-occupied single-family housing that consists of mortgages for families in low-income census tracts or for moderate-income families in minority census tracts shall meet or exceed either:

(1) The share of such mortgages in the market as defined in paragraph (b) of this section in each year; or

(2) The benchmark level, which for 2026, 2027, and 2028 shall be 16.0 percent of the total number of purchase money mortgages purchased by that Enterprise in each year that finance owner-occupied single-family properties.

(g) *Low-income refinance goal.* * * *

(2) The benchmark level, which for 2026, 2027, and 2028 shall be 21.0 percent of the total number of refinancing mortgages purchased by that Enterprise in each year that finance owner-occupied single-family properties.

* * * * *

§ 1282.13 [Amended]

■ 10. Amend § 1282.13 by:

- a. In paragraph (b), removing the phrase "61 percent" and adding in its place the phrase "61.0 percent", and removing the phrase "for 2025, 2026, and 2027" and adding in its place the phrase "for 2026, 2027, and 2028";
- b. In paragraph (c), removing the phrase "14 percent" and adding in its place the phrase "14.0 percent", and removing the phrase "for 2025, 2026, and 2027" and adding in its place the phrase "for 2026, 2027, and 2028"; and
- c. In paragraph (d), removing the phrase "2 percent" and adding in its place the phrase "2.0 percent", and removing the phrase "for 2025, 2026, and 2027" and adding in its place the phrase "for 2026, 2027, and 2028".

§ 1282.15 [Amended]

- 11. In § 1282.15(b)(2), remove the word "subgoals" and add in its place the word "subgoal".
- 12. Revise § 1282.20 to read as follows:

§ 1282.20 Preliminary determination of compliance with housing goals; notice of preliminary determination.

(a) *Preliminary determination.* On an annual basis, the Director will evaluate each Enterprise's performance under each single-family housing goal and subgoal and each multifamily housing goal and subgoal.

(b) *Notice of preliminary determination.* If the Director preliminarily determines that an Enterprise has failed, or that there is a substantial probability that an Enterprise will fail, to meet any housing goal or subgoal, the Director will provide written notice to the Enterprise of the preliminary determination of its performance under each housing goal and subgoal established by this subpart, before public disclosure of the preliminary determination. The written notice will include the reasons for such determination, and the information on

which the Director based the determination.

(c) *Response by Enterprise.* Any notification to an Enterprise of a preliminary determination under this section will provide the Enterprise with an opportunity to respond in writing in accordance with the procedures at 12 U.S.C. 4566(b)(1) and (2). Relevant information in a timely written response from an Enterprise will be included in the information the Director considers when making a determination of housing goals compliance under § 1282.21.

■ 13. Revise § 1282.21 to read as follows:

§ 1282.21 Determination of compliance with housing goals, notice of determination.

(a) *Determination.* On an annual basis, the Director will make a final determination of each Enterprise's performance under each single-family housing goal and subgoal and each multifamily housing goal and subgoal. The determination will address whether an Enterprise has failed, or there is a substantial probability that an Enterprise will fail, to meet any housing goal or subgoal and whether the achievement of that housing goal or subgoal was or is feasible.

(b) *Notice of determination.* The Director will provide each Enterprise with written notification of the determination in accordance with the procedures at 12 U.S.C. 4562(f) and 12 U.S.C. 4566(b)(3). If the Enterprise has met each of the housing goals and subgoals, the notification will provide the Enterprise with an opportunity to comment on the determination during the 30-day period beginning upon receipt of the notification by the Enterprise. If the Enterprise has failed, or there is a substantial probability that an Enterprise will fail, to meet any housing goal or subgoal that FHFA determines was or is feasible, the notification will specify whether the Enterprise is required to submit a housing plan for approval under § 1282.22.

§ 1282.22 [Amended]

■ 14. Amend § 1282.22 by:

- a. Removing paragraph (b);
- b. Redesignating paragraphs (c), (d), (e), (f), (g) as paragraphs (b), (c), (d), (e), (f); and
- c. In newly redesignated paragraph (f) removing "in accordance with 12 U.S.C. 4581," and adding in its place the word "or" and removing "12 U.S.C. 4585" and adding in its place "12 U.S.C. 4581

through 4585 and applicable provisions in part 1209 of this title”.

* * * * *

Clinton Jones,

General Counsel, Federal Housing Finance Agency.

[FR Doc. 2025–23746 Filed 12–22–25; 8:45 am]

BILLING CODE 8070–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2025–1159; Airspace
Docket No. 25–AGL–5]

RIN 2120–AA66

Amendment of VOR Federal Airway V–300; Northcentral United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Very High Frequency Omnidirectional Range (VOR) Federal Airway V–300 due to the relocation of the Wiarton, Ontario (ON), Canada, VOR/Distance Measuring Equipment (VOR/DME) navigational aid (NAVAID). This action is in support of NAV CANADA’s NAVAID Modernization Program.

DATES: Effective date 0901 UTC, March 19, 2026. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: A copy of the notice of proposed rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at www.regulations.gov using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from www.federalregister.gov.

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

FOR FURTHER INFORMATION CONTACT: Brian Vidis, Rules and Regulations Group, Policy Directorate, Federal

Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

History

The FAA published an NPRM for Docket No. FAA–2025–0141 in the **Federal Register** (90 FR 25173; June 16, 2025), proposing to amend VOR Federal Airway V–300 due to the planned relocation of the Wiarton, ON, Canada, VOR/DME NAVAID. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. One comment was received.

The commenter suggested the FAA validate the 25–AGL–5 Airspace Docket Number used in the NPRM to ensure it was correct. The commenter also suggested validating the distance of the Wiarton, ON, Canada, VOR/DME relocation that was published in the NPRM. Additionally, the commenter offered that the magnetic radial (called bearings in the comment) values listed to describe the RIBIR, IILND, and MRUCI fixes in the V–300 description in the NPRM were incorrect and should have been lower than the companion true radials they were listed with instead of being larger. Finally, the commenter stated the CFNKB computer navigation fix (CNF) on the United States (U.S.)/Canada border that was listed in the NPRM should have been spelled CYNKB as contained in FAA Order JO 7400.11 and on the Detroit sectional.

The FAA reviewed each of the items raised by the commenter and offers the following in response. The 25–AGL–5 Airspace Docket Number was assigned by the Central Service Center, Operations Support Group in accordance with FAA Order JO 7400.2

and was determined to be correct as published in the NPRM.

With respect to the distance the Wiarton, ON, Canada, VOR was relocated, the FAA received the geographic latitude and longitude coordinates from NAV CANADA for the original and new locations of the VOR. Upon review, the distance of the VOR relocation was calculated to be just over 135 feet West-Southwest from the original location instead of approximately 80 feet West of the original location as specified in the NPRM. That information has been updated.

In determining the true and magnetic radials for the RIBIR, IILND, and MRUCI fixes in the V–300 description, the FAA used the most recent magnetic variation values associated with the Sault Ste Marie, MI, VOR/DME and the Pellston, MI, VOR/Tactical Air Navigation (VORTAC) NAVAIDs. The magnetic variation for the Sault Ste Marie VOR/DME is 4° West and for the Pellston VORTAC is 6° West. When calculating magnetic radials using counterpart true radials, West magnetic variation values are added to the true radial value; whereas East magnetic variation values are subtracted from the true radial value. The true and magnetic radials listed for the RIBIR, IILND, and MRUCI fixes in the V–300 description in the NPRM were correct as published. However, for awareness, the FAA only publishes true radial values in final rules.

Lastly, the FAA verified that the CFNKB CNF located on the U.S./Canada border was spelled correctly in the NPRM and matches the CNF information currently contained in the FAA’s National Airspace System Resource database and as published on the IFR Enroute Low Altitude L–31 chart. CNFs are not published in FAA Order JO 7400.11 or on sectional charts.

Incorporation by Reference

VOR Federal Airways are published in paragraph 6010(a) of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11K, dated August 4, 2025, and effective September 15, 2025. These amendments will be published in the next update to FAA Order JO 7400.11. FAA Order JO 7400.11K, which lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points, is publicly available as listed in the **ADDRESSES** section of this document.

The Rule

This action amends 14 CFR part 71 by amending VOR Federal Airway V–300 due to the planned relocation of the Wiarton, ON, Canada, VOR/DME by NAV CANADA as part of its NAVAID Modernization Program. The airway action is described below.

V–300: Prior to this final rule, V–300 extended between the Sault Ste Marie, MI, VOR/DME and the Wiarton, ON, Canada, VOR/DME, excluding the airspace within Canada. The airway is amended to only describe the two airway segments that lie within U.S. airspace. The first segment extends between the Sault Ste Marie, MI, VOR/DME and the intersection of the Sault Ste Marie VOR/DME 125° and Pellston, MI, VORTAC 029° radials (RIBIR Fix). The second segment extends between the intersection of the Sault Ste Marie VOR/DME 125° and Pellston VORTAC 054° radials (ILND Fix), replacing the “CFNKB” CNF on the U.S./Canada border, and the intersection of the Sault Ste Marie VOR/DME 125° and Pellston VORTAC 067° radials (MRUCI Fix), replacing the “MKPDG” CNF on the U.S./Canada border. The two airway segments within U.S. airspace will continue to provide route continuity and cross-border connectivity with the V–300 airway segments being established by NAV CANADA within Canadian airspace.

The NAVAID radials listed in the VOR Federal Airway V–300 description above and in the regulatory text of this final rule are stated in degrees True north.

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action amending Very High Frequency

Omnidirectional Range (VOR) Federal Airway V–300 qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321, *et seq.*) and in accordance with FAA Order 1050.1G, *FAA National Environmental Policy Act Implementing Procedures*, paragraph B–2.5.(a) of FAA’s NEPA implementation policy and procedures which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points); and section B–2.5.(k), which categorically excludes from further environmental impact review publication of existing air traffic control procedures that do not essentially change existing tracks, create new tracks, change altitude, or change the concentration of aircraft on these tracks. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with the FAA’s NEPA implementation policy and procedures regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. The FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11K, Airspace Designations and Reporting Points, dated August 4, 2025, and effective September 15, 2025, is amended as follows:

Paragraph 6010(a) VOR Federal Airways.

* * * * *

V–300 [Amended]

From Sault Ste Marie, MI; to INT Sault Ste Marie 125° and Pellston, MI, 029° radials. From INT Sault Ste Marie 125° and Pellston 054° radials; to INT Sault Ste Marie 125° and Pellston 067° radials.

* * * * *

Issued in Washington, DC, on December 19, 2025.

Glenn L. Sigley,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2025–23739 Filed 12–22–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2025–0372; Airspace Docket No. 24–AAL–126]

RIN 2120–AA66

Amendment of Colored Federal Airway Green 8, Jet Route J–115, United States Area Navigation (RNAV) Route T–227 and Establishment of RNAV Route Q–188 in Alaska; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects a final rule published by the FAA in the **Federal Register** on November 18, 2025, amending Colored Federal Airway Green 8 (G–8), Jet Route J–115, and United States Area Navigation (RNAV) Route T–227; and establishing RNAV Route Q–188 in Alaska due to the pending decommissioning of the Shemya, AK, Nondirectional Radio Beacon (NDB). Specifically, this action administratively corrects errors within the description of G–8 and J–115 in the final rule as published on November 18, 2025.

DATES: The effective date of the final rule published in the **Federal Register** on November 18, 2025, remains 0901 UTC, January 22, 2026. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11K, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations

Group, Policy Directorate, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267-8783.

FOR FURTHER INFORMATION CONTACT: Steven Roff, Rules and Regulations Group, Policy Directorate, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267-8783.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule in the **Federal Register** (90 FR 51507; November 18, 2025) amending Colored Federal Airway G-8, Jet Route J-115, and RNAV Route T-227; and establishing RNAV Route Q-188. Subsequent to the publication of that final rule, the FAA discovered a final rule previously published in the **Federal Register** (90 FR 13060; March 20, 2025) amending J-115 in Alaska. The amendment revoked a segment of the airway between the Fairbanks, AK, Very High Frequency Omnidirectional Range/Tactical Air Navigation (VORTAC) and the Deadhorse, AK, VOR/Distance Measuring Equipment (DME). However, these changes were not reflected in the later-published final rule that is now being corrected. Specifically, in this now-corrected airspace action, the segment of J-115 between the Fairbanks, AK, VORTAC and the Deadhorse, AK, VOR/DME was included in the description despite having been previously revoked. This action corrects this error by removing the segment of J-115 between the Fairbanks, AK, VORTAC and the Deadhorse, AK, VOR/DME from the airspace description. No other portion of J-115 is affected by this rule.

Additionally, the FAA discovered a final rule previously published in the **Federal Register** (90 FR 20232; May 13, 2025) amending G-8 in Alaska. The amendment revoked a segment of the airway between the Elfee, AK, NDB and the Kachemak, AK, NDB. However, these changes were not reflected in the later-published final rule that is now being corrected. Specifically, in this now-corrected airspace action, the segment of G-8 between the Elfee, AK, NDB and the Kachemak, AK, NDB was included in the description despite having been previously revoked. This action corrects this error by removing the segment of G-8 between the Elfee, AK, NDB and the Kachemak, AK, NDB from the airspace description. No other portion of G-8 is affected by this rule.

Correction to the Final Rule

Accordingly, pursuant to the authority delegated to me, in Docket No.

FAA-2025-0372 as published in the **Federal Register** on November 18, 2025 (90 FR 51507), FR Doc. 2025-20134, is corrected as follows:

■ 1. On page 51508, in the third column, in the line directly below the bolded text “G-8 [Amended]”, delete the text “From Mount Moffet, AK, NDB, 20 AGL; Dutch Harbor, AK, NDB, 20 AGL; INT Dutch Harbor, AK, NDB 041° and Elfee, AK, NDB 253° bearings, 20 AGL; Elfee, AK, NDB, 20 AGL; Chinook, AK, NDB; INT Chinook, AK, NDB 054° and Kachemak, AK, NDB 269° bearings; to Kachemak, AK, NDB” and replace it with “From Mount Moffet, AK, NDB, 20 AGL; Dutch Harbor, AK, NDB, 20 AGL; INT Dutch Harbor, AK, NDB 041° and Elfee, AK, NDB 253° bearings, 20 AGL; Elfee, AK, NDB, 20 AGL.”.

■ 2. On page 51508, in the third column, in the line directly below the bolded text “J-115 [Amended]”, delete the text “From Mount Moffett, AK, NDB; Dutch Harbor, AK, NDB; Cold Bay, AK; King Salmon, AK; INT King Salmon 053° and Kenai, AK, 239° radials; Kenai, AK; Anchorage, AK; Big Lake, AK; Fairbanks, AK; Chandalar, AK, NDB; to Deadhorse, AK” and replace it with “From Mount Moffett, AK, NDB; Dutch Harbor, AK, NDB; Cold Bay, AK; King Salmon, AK; INT King Salmon 053° and Kenai, AK, 239° radials; Kenai, AK; Anchorage, AK; Big Lake, AK; Fairbanks.”.

Issued in Washington, DC, on December 19, 2025.

Glenn L. Sigley,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2025-23738 Filed 12-22-25; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-1143]

Schedules of Controlled Substances: Placement of N-Desethyl Isotonitazene and N-Piperidinyl Etonitazene in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Final amendment; final order.

SUMMARY: With the issuance of this final order, the Administrator of the Drug Enforcement Administration is permanently placing *N*-ethyl-2-(4-isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine (other name: *N*-desethyl isotonitazene) and 2-

(4-ethoxybenzyl)-5-nitro-1-(2-(piperidin-1-yl)ethyl)-1*H*-benzimidazole (other names: *N*-piperidinyl etonitazene; etonitazepipine), including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts are possible within the specific chemical designation, in schedule I under the Controlled Substances Act. This scheduling action discharges the United States' obligations under the Single Convention on Narcotic Drugs (1961). This action imposes permanent regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research or conduct instructional activities with or possess), or handle *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene.

DATES: Effective January 22, 2026.

ADDRESSES: 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362-3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the United Nations Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407, 520 U.N.T.S. 151 (Single Convention), as amended by the 1972 Protocol. Article 3, paragraph 7 of the Single Convention requires that if the Commission on Narcotic Drugs (Commission) adds a substance to one of the schedules of such Convention, and the United States receives notification of such scheduling decision from the Secretary-General of the United Nations (Secretary-General), the United States, as a signatory Member State, is obligated to control the substance under its national drug control legislation. Under 21 U.S.C. 811(d)(1) of the Controlled Substances Act (CSA), if control of a substance is required “by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970,” the Attorney General must issue an order controlling such drug under the schedule she deems most appropriate to carry out such obligations, without regard to the findings required by 21 U.S.C. 811(a) or 812(b), and without regard to the procedures prescribed by 21 U.S.C. 811(a) and (b). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the

Drug Enforcement Administration (DEA).¹

Background

On July 29, 2024, DEA issued a temporary scheduling order, placing *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene temporarily in schedule I of the CSA.² That order for *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene (codified at 21 CFR 1308.11(h)(68) and (69)) was based on findings by the then-Administrator that the temporary scheduling was necessary to avoid an imminent hazard to public safety.³

On November 21, 2024, the Director-General of the World Health Organization recommended to the Secretary-General that *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene be placed in Schedule I of the Single Convention, as these substances have pharmacological effects similar to other opioid drugs that are controlled in Schedule I of the Single Convention. On June 9, 2025, the Secretariat of the United Nations informed the United States Government, by letter, that the Commission voted to place *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene in Schedule I of the Single Convention during its 68th session on March 12, 2025 (CND Mar 68/4 and 68/3).

N-Desethyl Isotonitazene and *N*-Piperidinyl Etonitazene

N-Desethyl isotonitazene and *N*-piperidinyl etonitazene are temporarily controlled in schedule I of the CSA because they pose imminent hazard to the public safety. Both *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene belong to the benzimidazole-opioid drug class, similar to etonitazene and isotonitazene. Substances of the benzimidazole-opioid drug class share similar pharmacological profile with other opioids such as morphine and fentanyl. *N*-Desethyl isotonitazene and *N*-piperidinyl etonitazene, similar to morphine and fentanyl, act as mu-opioid receptor agonists. Adverse health effects have been associated with the abuse of these benzimidazole-opioids. The abuse of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene has been associated with several toxicology cases in the United States and in Europe. Several substances belonging to the benzimidazole-opioid drug class have

been controlled in the United States, and as a class of drug in China, Canada, and the United Kingdom. The appearance of benzimidazole-opioids on the illicit drug market is similar to other synthetic opioids that are trafficked and abused for their psychoactive effects.

Law enforcement reports demonstrate that *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene are being illicitly distributed and abused. According to the National Forensic Laboratory Information System (NFLIS-Drug)⁴ database, which collects drug identification results from drug cases submitted to and analyzed by Federal, State and local forensic laboratories, there have been 151 reports for *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene between January 2022 and July 2025 (query date: July 17, 2025). Benzimidazole-opioids have been identified in counterfeit prescription tablets in the United States and other countries, including Sweden and the United Kingdom. The identification of these substances in counterfeit prescription drug products is of significant concern due to benzimidazole-opioids high potency.

N-Desethyl isotonitazene and *N*-piperidinyl etonitazene have no currently accepted medical use in treatment in the United States. The Department of Health and Human Services (HHS) advised DEA, by letter dated May 11, 2023, that based on a review by the Food and Drug Administration (FDA), there were no investigational new drug applications (IND) or approved new drug applications (NDA) for *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene in the United States. Since this letter, HHS has not advised DEA of any new IND or NDA for these substances. Because *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene are not formulated or available for clinical use as approved medicinal products, all current use of these substances by individuals is based on their own initiative, rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs.

Consistent with 21 U.S.C. 811(d)(1), DEA concludes that *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene have no currently accepted medical use in treatment in the United States⁵ and are most appropriately placed permanently in schedule I of the CSA, the same schedule in which they temporarily reside at present. Because control is required under the Single Convention, DEA will not be initiating regular rulemaking proceedings to permanently schedule *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene pursuant to 21 U.S.C. 811(a).

Conclusion

In order to meet the United States' obligation under the Single Convention and because *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene have no currently accepted medical use in

⁵ There is no evidence suggesting that *N*-desethyl isotonitazene or *N*-piperidinyl etonitazene have a currently accepted medical use in treatment in the United States. To determine whether a drug or other substance has a currently accepted medical use, DEA has traditionally applied a five-part test to a drug or substance that has not been approved by the FDA: i. The drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. See *Marijuana Scheduling Petition; Denial of Petition; Remand*, 57 FR 10499 (Mar. 26, 1992), pet. for rev. denied, *Alliance for Cannabis Therapeutics v. Drug Enforcement Admin.*, 15 F.3d 1131, 1135 (D.C. Cir. 1994). DEA applied the traditional five-part test and concluded the test was not satisfied. In a recent published letter in a different context, HHS applied an additional two-part test to determine currently accepted medical use for substances that do not satisfy the five-part test: (1) whether there exists widespread, current experience with medical use of the substance by licensed health care providers operating in accordance with implemented jurisdiction-authorized programs, where medical use is recognized by entities that regulate the practice of medicine, and, if so, (2) whether there exists some credible scientific support for at least one of the medical conditions for which part (1) is satisfied. On April 11, 2024, the Department of Justice's Office of Legal Counsel (OLC) issued an opinion, which, among other things, concluded that HHS's two-part test would be sufficient to establish that a drug has a currently accepted medical use. Office of Legal Counsel, Memorandum for Merrick B. Garland Attorney General Re: Questions Related to the Potential Rescheduling of Marijuana at 3 (April 11, 2024). For purposes of this scheduling order, there is no evidence that health care providers have widespread experience with medical use of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene or that the use of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene are recognized by entities that regulate the practice of medicine, so the two-part test also is not satisfied. By letter dated May 11, 2023, DEA has been advised by HHS that there are currently no approved new drug applications or investigational new drug applications for *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene. Additionally, HHS communicated no objections to the temporary placement of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene into schedule I of the CSA.

¹ 28 CFR 0.100.

² *Schedules of Controlled Substances: Temporary Placement of N-desethyl isotonitazene and N-piperidinyl etonitazene in Schedule I*, 89 FR 60817 (July 29, 2024).

³ *Id.*

⁴ NFLIS-Drug represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS-Drug is a comprehensive information system that includes data from forensic laboratories that handle more than 96 percent of an estimated 1 million distinct annual federal, state, and local drug analysis cases. NFLIS-Drug includes drug chemistry results from completed analyses only. While NFLIS-Drug data are not direct evidence of abuse, these can lead to an inference that a drug has been diverted and abused. See *Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV*, 76 FR 77330, 77332 (Dec. 12, 2011).

treatment in the United States, the Administrator has determined that *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, and salts are possible within the specific existence of such isomers, esters, ethers, and salts are possible within the specific chemical designation, should be placed permanently in schedule I of the CSA.

Requirements for Handling

As discussed above, *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene have been temporarily controlled in schedule I of the CSA since July 29, 2024. Upon the effective date of this final order, *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene will be permanently subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, engagement in research or conduct of instructional activities with, and possession of, schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, *N*-desethyl isotonitazene or *N*-piperidinyl etonitazene must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of these substances in a manner not authorized by the CSA is unlawful and those in possession of any quantity of these substances may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* *N*-Desethyl isotonitazene and *N*-piperidinyl etonitazene must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security.* *N*-Desethyl isotonitazene and *N*-piperidinyl etonitazene are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and in accordance with 21 CFR 1301.71 through 1301.76. Non-practitioners handling *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene must comply with the screening requirements of 21 CFR 1301.90 through 1301.93.

4. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene must comply with 21 U.S.C. 825 and 958(e) and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene in accordance with a quota assigned pursuant to 21 U.S.C. 826, and in accordance with 21 CFR part 1303.

6. *Inventory.* Any person registered with DEA to handle *N*-desethyl isotonitazene or *N*-piperidinyl etonitazene must have an initial inventory of all stocks of controlled substances (including these substances) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene) on hand every two years pursuant to 21 U.S.C. 827 and 958(e) and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports with respect to *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1301.74(b) and (c), 1301.76(b), and 1307.11 and parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* Every DEA registrant who distributes *N*-desethyl isotonitazene or *N*-piperidinyl etonitazene must continue to comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene must continue to comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving *N*-desethyl isotonitazene or *N*-piperidinyl etonitazene not authorized by, or in violation of the CSA or its implementing regulations, is unlawful, and may subject the person to

administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866, 13563, 14192, and 14294

This action is not a significant regulatory action as defined by Executive Order (E.O.) 12866 (Regulatory Planning and Review), and the principles reaffirmed in E.O. 13563 (Improving Regulation and Regulatory Review). DEA scheduling actions are not subject to E.O. 14192, Unleashing Prosperity Through Deregulations, or E.O. 14294, Fighting Overcriminalization in Federal Regulations. This action makes no change in the status quo, as *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene are already listed as schedule I controlled substances.

Executive Order 12988, Civil Justice Reform

This action meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This action does not have federalism implications warranting the application of E.O. 13132. This action does 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.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications warranting the application of E.O. 13175. It 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.

Administrative Procedure Act

The CSA provides for an expedited scheduling action where control is required by the United States' obligations under international treaties, conventions, or protocols.⁶ If control is required pursuant to such international treaty, convention, or protocol, the Attorney General, as delegated to the Administrator, must issue an order

⁶ 21 U.S.C. 811(d)(1).

controlling such drug under the schedule he deems most appropriate to carry out such obligations, and “without regard to” the findings and rulemaking procedures otherwise required for scheduling actions in 21 U.S.C. 811(a) and (b). *Id.*

In accordance with 21 U.S.C. 811(d)(1), scheduling actions for drugs that are required to be controlled by the United States’ obligations under international treaties, conventions, or protocols in effect on October 27, 1970, shall be issued by order, as opposed to scheduling by rule pursuant to 21 U.S.C. 811(a). Therefore, DEA believes that the notice-and-comment requirements of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this scheduling action.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under the APA or any other law. As explained above, the CSA exempts this final order from notice and comment. Consequently, the RFA does not apply to this action.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995.⁷ Also, this action does not impose

new or modify existing recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. However, this action does require compliance with the following existing OMB collections: 1117–0003, 1117–0004, 1117–0006, 1117–0008, 1117–0009, 1117–0010, 1117–0012, 1117–0014, 1117–0021, 1117–0023, 1117–0029, and 1117–0056. 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.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the “Regulatory Flexibility Act” section above, DEA has determined pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.*) that this final rule would not result in any Federal mandate that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year” Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This order is not a major rule as defined by the Congressional Review

Act (CRA), 5 U.S.C. 804. However, DEA is submitting reports under the CRA to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11:

■ a. Redesignate paragraphs (b)(76) through (117) as paragraphs (b)(78) through (119);

■ b. Redesignate paragraphs (b)(72) through (75) as paragraphs (b)(73) through (76);

■ c. Add new paragraphs (b)(72), (77); and

■ h. Remove and reserve paragraphs (h)(68) and (h)(69).

The additions to read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(72) <i>N</i> -Desethyl isotonitazene (<i>N</i> -ethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1 <i>H</i> -benzimidazol-1-yl)ethan-1-amine)	9760
(77) <i>N</i> -Piperidinyl etonitazene (2-(4-ethoxybenzyl)-5-nitro-1-(2-(piperidin-1-yl)ethyl)-1 <i>H</i> -benzimidazole (other names: etonitazepipne)	9761

* * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on December 17, 2025, by Administrator Terrance Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this

document upon publication in the Federal Register.

Leslie Mayer,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2025–23717 Filed 12–22–25; 8:45 am]

BILLING CODE 4410–09–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4044

Allocation of Assets in Single-Employer Plans; Valuation of Benefits and Assets; Expected Retirement Age; Missing Participants Mortality Assumption

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This rule amends the Pension Benefit Guaranty Corporation’s regulation on Allocation of Assets in Single-Employer Plans by substituting a

⁷ 44 U.S.C. 3501–3521.

new table for determining expected retirement ages for participants in pension plans undergoing distress or involuntary termination with valuation dates falling in 2026. This table is needed to compute the value of early retirement benefits and, thus, the total value of benefits under a plan. This rule also provides the mortality assumption for use with PBGC's missing participants program for determination dates in 2026.

DATES: This rule is effective January 1, 2026.

FOR FURTHER INFORMATION CONTACT:

Andrew Wilson (wilson.andrew1@pbgc.gov), Attorney (202–860–8354), or Joseph Krettek (krettek.joseph@pbgc.gov), Assistant General Counsel (202–229–6772), Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024–2101. 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:

Background

The Pension Benefit Guaranty Corporation (PBGC) administers the pension plan termination insurance program under title IV of the Employee Retirement Income Security Act of 1974 (ERISA). PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) sets forth (in subpart B) the methods for valuing plan benefits of terminating single-employer plans covered under title IV. Guaranteed benefits and benefit liabilities under a plan that is undergoing a distress termination must be valued in accordance with subpart B of part 4044. In addition, when PBGC terminates an underfunded plan involuntarily pursuant to ERISA section 4042(a), it uses the subpart B valuation rules to determine the amount of the plan's underfunding.

Expected Retirement Age Low, Medium, High Tables

Under § 4044.51(b) of the asset allocation regulation, early retirement benefits are valued based on the annuity starting date, if a retirement date has been selected, or the expected retirement age, if the annuity starting date is not known on the valuation date. Sections 4044.55 through 4044.58 set forth rules for determining the expected retirement ages for plan participants entitled to early retirement benefits. Section 4044.58 contains tables to be

used in determining the expected early retirement ages.¹

Table I to § 4044.58 (Selection of Retirement Rate Category) is used to determine whether a participant has a low, medium, or high probability of retiring early. The determination is based on the year a participant would reach “unreduced retirement age” (URA) (*i.e.*, the earlier of the normal retirement age or the age at which an unreduced benefit is first payable) and the participant's monthly benefit at the unreduced retirement age. The table applies only to plans with valuation dates in the current year and is updated annually by PBGC to reflect changes in the cost of living.

Tables II–A, II–B, and II–C (Expected Retirement Ages for Individuals in the Low, Medium, and High Categories respectively) are used to determine the expected retirement age after the probability of early retirement has been determined using Table I. These tables establish, by probability category, the expected retirement age based on both the earliest age a participant could retire under the plan and the unreduced retirement age. This expected retirement age is used to compute the value of the early retirement benefit and, thus, the total value of benefits under the plan.

This document amends § 4044.58 to replace Table I–25 with Table I–26 to provide an updated correlation, appropriate for calendar year 2026, between the amount of a participant's benefit and the probability that the participant will elect early retirement. Table I–26 will be used to value benefits in plans with valuation dates during calendar year 2026.

Missing Participants Mortality Assumptions

PBGC's regulation on Missing Participants (29 CFR part 4050) provides that the mortality assumption used to determine certain amounts to be transferred on behalf of a missing participant from a terminating defined benefit plan to PBGC is the mortality table in § 4044.53(h). The table currently provides the mortality assumption for benefit determination dates on or after July 31, 2024, but before January 1,

¹ In June 2024, PBGC issued a final rule at 89 FR 48291 updating the interest, mortality, and expense assumptions used to determine the present value of a single-employer plan's benefits when it terminates in a distress or involuntary termination. This rule moved the expected retirement ages tables from Appendix D in part 4044 to § 4044.58.

2026.² This rule updates the table to provide the mortality assumption for benefit determination dates in 2026.

Compliance With Regulatory Requirements

PBGC has determined that notice of, and public comment on, this rule are impracticable, unnecessary, and contrary to the public interest. PBGC's update of § 4044.58 and § 4044.53(h) for calendar year 2026 are routine. If a plan has a valuation date in 2026, the plan administrator needs the updated table in § 4044.58 being promulgated in this rule to value benefits. Similarly, if a plan is transferring amounts on behalf of missing participants under part 4050, the plan administrator needs the updated mortality table in § 4044.53(h) for benefit determination dates in 2026. Accordingly, PBGC finds that the public interest is best served by issuing these tables expeditiously, without an opportunity for notice and comment, and that good cause exists for making the table set forth in this amendment effective less than 30 days after publication to allow the use of the proper tables to determine the value benefits for dates in early 2026.

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 regulation, the Regulatory Flexibility Act of 1980 does not apply (5 U.S.C. 601(2)).

List of Subjects in 29 CFR Part 4044

Employee benefit plans, Pension insurance.

In consideration of the foregoing, 29 CFR part 4044 is amended 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 § 4044.53 by revising table 4 to paragraph (h) to read as follows:

§ 4044.53 Mortality assumptions.

* * * * *

(h) * * *

² PBGC's June 2024 final rule does not apply to calculations where the valuation date is before July 31, 2024.

TABLE 4 TO PARAGRAPH (h)—MISSING PARTICIPANTS UNISEX MORTALITY TABLE

Age	Benefit determination dates in 2024	Benefit determination dates in 2025	Benefit determination dates in 2026
0	0.00207	0.00204	0.00202
1	0.00015	0.00014	0.00014
2	0.00010	0.00009	0.00009
3	0.00008	0.00007	0.00007
4	0.00006	0.00006	0.00006
5	0.00006	0.00005	0.00005
6	0.00005	0.00005	0.00005
7	0.00005	0.00005	0.00005
8	0.00004	0.00004	0.00004
9	0.00004	0.00004	0.00003
10	0.00004	0.00004	0.00004
11	0.00004	0.00004	0.00004
12	0.00005	0.00005	0.00005
13	0.00006	0.00006	0.00006
14	0.00008	0.00007	0.00007
15	0.00009	0.00009	0.00008
16	0.00010	0.00010	0.00010
17	0.00012	0.00012	0.00012
18	0.00014	0.00014	0.00014
19	0.00016	0.00015	0.00015
20	0.00016	0.00016	0.00016
21	0.00017	0.00016	0.00016
22	0.00017	0.00017	0.00017
23	0.00018	0.00018	0.00018
24	0.00019	0.00019	0.00019
25	0.00020	0.00019	0.00019
26	0.00021	0.00020	0.00020
27	0.00022	0.00021	0.00021
28	0.00023	0.00022	0.00022
29	0.00023	0.00023	0.00023
30	0.00025	0.00025	0.00024
31	0.00026	0.00026	0.00026
32	0.00028	0.00027	0.00027
33	0.00030	0.00030	0.00030
34	0.00032	0.00031	0.00031
35	0.00034	0.00034	0.00033
36	0.00036	0.00036	0.00035
37	0.00038	0.00038	0.00037
38	0.00040	0.00040	0.00039
39	0.00043	0.00042	0.00041
40	0.00044	0.00044	0.00043
41	0.00046	0.00045	0.00044
42	0.00048	0.00047	0.00046
43	0.00049	0.00049	0.00048
44	0.00052	0.00051	0.00050
45	0.00054	0.00053	0.00052
46	0.00058	0.00057	0.00056
47	0.00061	0.00060	0.00059
48	0.00065	0.00064	0.00064
49	0.00070	0.00069	0.00068
50	0.00076	0.00076	0.00075
51	0.00085	0.00084	0.00083
52	0.00095	0.00094	0.00092
53	0.00106	0.00105	0.00103
54	0.00120	0.00118	0.00117
55	0.00143	0.00141	0.00139
56	0.00177	0.00174	0.00172
57	0.00205	0.00202	0.00200
58	0.00239	0.00235	0.00232
59	0.00276	0.00273	0.00269
60	0.00321	0.00317	0.00313
61	0.00370	0.00365	0.00360
62	0.00441	0.00434	0.00428
63	0.00514	0.00507	0.00500
64	0.00577	0.00570	0.00562
65	0.00658	0.00650	0.00641
66	0.00748	0.00738	0.00729
67	0.00834	0.00823	0.00813
68	0.00928	0.00916	0.00904
69	0.01034	0.01021	0.01008

TABLE 4 TO PARAGRAPH (h)—MISSING PARTICIPANTS UNISEX MORTALITY TABLE—Continued

Age	Benefit determination dates in 2024	Benefit determination dates in 2025	Benefit determination dates in 2026
70	0.01155	0.01141	0.01127
71	0.01294	0.01278	0.01262
72	0.01452	0.01435	0.01417
73	0.01631	0.01611	0.01592
74	0.01837	0.01815	0.01794
75	0.02073	0.02049	0.02025
76	0.02345	0.02317	0.02291
77	0.02656	0.02626	0.02596
78	0.03012	0.02979	0.02945
79	0.03417	0.03382	0.03345
80	0.03899	0.03862	0.03823
81	0.04395	0.04356	0.04315
82	0.04959	0.04916	0.04872
83	0.05595	0.05549	0.05502
84	0.06317	0.06267	0.06217
85	0.07138	0.07083	0.07029
86	0.08063	0.08005	0.07947
87	0.09107	0.09044	0.08982
88	0.10286	0.10220	0.10154
89	0.11596	0.11526	0.11457
90	0.13036	0.12962	0.12889
91	0.14540	0.14463	0.14387
92	0.16090	0.16012	0.15933
93	0.17679	0.17601	0.17522
94	0.19284	0.19206	0.19127
95	0.20898	0.20822	0.20745
96	0.22620	0.22545	0.22467
97	0.24386	0.24311	0.24234
98	0.26196	0.26123	0.26048
99	0.28059	0.27986	0.27912
100	0.29960	0.29887	0.29814
101	0.31891	0.31817	0.31746
102	0.33825	0.33748	0.33676
103	0.35757	0.35673	0.35595
104	0.37670	0.37583	0.37502
105	0.39521	0.39436	0.39354
106	0.41327	0.41245	0.41166
107	0.43080	0.42999	0.42921
108	0.44743	0.44667	0.44595
109	0.46339	0.46271	0.46204
110	0.47628	0.47568	0.47508
111	0.48468	0.48417	0.48366
112	0.49268	0.49226	0.49184
113	0.49666	0.49634	0.49602
114	0.49795	0.49773	0.49751
115	0.49928	0.49915	0.49903
116	0.49960	0.49953	0.49945
117	0.49978	0.49973	0.49968
118	0.49995	0.49993	0.49990
119	0.50000	0.50000	0.50000
120	1.00000	1.00000	1.00000

■ 3. Amend § 4044.58 by revising table 1 to the section to read as follows:

§ 4044.58 Tables used to determine expected retirement age.

* * * * *

TABLE 1 TO § 4044.58—TABLE I-26—SELECTION OF RETIREMENT RATE CATEGORY

[For valuation dates in 2026 ¹]

If participant reaches URA in year—	Participant's retirement rate category is—			
	Low ² if monthly benefit at URA is less than—	Medium ³ if monthly benefit at URA is—		High ⁴ if monthly benefit at URA is greater than—
		From—	To—	
2027	849	849	3,587	3,587
2028	869	869	3,670	3,670

TABLE 1 TO § 4044.58—TABLE I-26—SELECTION OF RETIREMENT RATE CATEGORY—Continued
[For valuation dates in 2026 ¹]

If participant reaches URA in year—	Participant's retirement rate category is—			
	Low ² if monthly benefit at URA is less than—	Medium ³ if monthly benefit at URA is—		High ⁴ if monthly benefit at URA is greater than—
		From—	To—	
2029	888	888	3,750	3,750
2030	908	908	3,833	3,833
2031	928	928	3,917	3,917
2032	948	948	4,003	4,003
2033	969	969	4,092	4,092
2034	990	990	4,182	4,182
2035	1,012	1,012	4,274	4,274
2036 or later	1,034	1,034	4,368	4,368

¹ Applicable tables for valuation dates before 2026 are available on PBGC's website (www.pbgc.gov).
² Table II-A.
³ Table II-B.
⁴ Table II-C.

* * * * *

Joseph Krettek,
Assistant General Counsel, Pension Benefit Guaranty Corporation.
[FR Doc. 2025-23799 Filed 12-22-25; 8:45 am]
BILLING CODE 7709-02-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2025-1110]

RIN 1625-AA00

Safety Zone; West of Cyril E. King Airport, St. Thomas, VI

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the vicinity of the waters off the Cyril E. King Airport in St. Thomas, USVI. This action is necessary to protect personnel, vessels, and the marine environment from potential hazards created by the proximity of low flying aircrafts. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector San Juan.

DATES: This rule is effective from January 1, 2026, through March 31, 2026.

ADDRESSES: To view available documents go to <https://www.regulations.gov> and search for USCG-2025-1110.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule,

contact Lieutenant Commander Rachel E. Thomas, Sector San Juan, Waterways Management Division Chief, Coast Guard; telephone (571) 613-1417, email Rachel.E.Thomas@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background and Authority

On August 25, 2025, the Coast Guard established a temporary final rule establishing a safety zone for the runway of Cyril E. King Airport in St. Thomas, USVI.¹ The Coast Guard originally published the temporary final rule to be effective through September 30, 2025. Later in October 2025 we promulgated a temporary interim rule to keep the zone open until December 31, 2025.² We are now implementing another temporary safety zone until March 31, 2026, to provide an opportunity for comment before we establish a permanent safety zone. The Captain of the Port (COTP) San Juan has determined that potential hazards associated low flying aircrafts to vessels in the vicinity of the waters off the Cyril E. King Airport in St. Thomas, USVI includes wake turbulence, collision risk, restricted visibility, and emergency maneuvers. Therefore, the COTP is issuing this rule under the authority in 46 U.S.C. 70034, which is needed to protect personnel, vessels, and the

marine environment in the navigable waters within the safety zone.

The Coast Guard is issuing this rule without prior notice and comment. As is authorized by 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this temporary rule because there is an immediate need to mitigate the risk of vessels transiting between private port authority managed yellow buoys and the end of the St. Thomas Cyril E. King runway due to the proximity to low flying aircrafts. Prompt action is needed to respond to the potential safety hazards associated with vessels transiting in the proximity of the runway of Cyril E. King Airport in St. Thomas, USVI. It is impracticable and contrary to the public interest to publish an NPRM because we must establish this safety zone by January 1, 2026.

For the same reasons, the Coast Guard finds that under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

III. Discussion of the Rule

This rule establishes a temporary safety zone for navigable waters west of the Cyril E. King Airport in St. Thomas, U.S. Virgin Islands. This temporary rule is effective through March 31, 2026, to give an opportunity for comment before the Coast Guard establishes a permanent safety zone. The temporary safety zone covers all navigable waters within 400 yards from shore directly west of the airport's runway within the two private port authority managed yellow buoys. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. No vessel or person will be permitted to enter the

¹ 90 FR 41301.
² 90 FR 52565.

safety zone without obtaining permission from the COTP or their designated representative.

IV. 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. Impact on Small Entities

The regulatory flexibility analysis provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to rules that are not subject to notice and comment. Because the Coast Guard has, for good cause, waived the notice and comment requirement that would otherwise apply to this rulemaking, the Regulatory Flexibility Act's flexibility analysis provisions do not apply here.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), if this rule will affect your small business, organization, or governmental jurisdiction and you have questions, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards by calling 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.

B. 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).

C. Federalism and Indian Tribal Governments

We have analyzed this rule under Executive Order 13132, Federalism, and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in that Order.

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.

D. Unfunded Mandates Reform Act

As required by The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the Coast Guard certifies that this rule will not result in an annual expenditure of \$100,000,000 or more (adjusted for inflation) by a State, local, or tribal government, in the aggregate, or by the private sector.

E. 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 is a safety zone. 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. See the Record of Environmental Consideration supporting this determination is available in the docket under USCG–2025–1105.

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.T07–1110 to read as follows:

§ 165.T07–1110 Safety Zone; West of Cyril E. King Airport, St. Thomas, VI.

(a) *Location.* The following area is a safety zone: The following area is a safety zone: All navigable waters within 400 yards from shore directly west of the airport's runway within the two private port authority managed yellow buoys located at 18°20.288' N–64°59.343' W and 18°20.116' N–64°59.343' 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 Sa Juan (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 by telephone at (787) 289–2041, or a designated representative via VHF–FM radio on channel 16 to request authorization. If authorization is granted, all persons and vessels receiving such authorization must comply with the instructions of the COTP San Juan or a designated representative. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from 12:01 a.m. on January 1, 2026, through 11:59 p.m. on March 31, 2026.

Luis J. Rodríguez,

Captain, U.S. Coast Guard, Captain of the Port Sector San Juan.

[FR Doc. 2025–23685 Filed 12–22–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 9

[Docket No. VA–2024–VBA–0014]

RIN 2900–AS12

Servicemembers' Group Life Insurance Traumatic Injury Protection Program Amendments

AGENCY: Department of Veterans Affairs.
ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its regulations that govern the Servicemembers' Group Life Insurance (SGLI) Traumatic Injury Protection (TSGLI) program to correct an unintended amendment to the TSGLI Schedule of Losses for payments for inability to perform at least two activities of daily living (ADL) for 15, 30, 60, and 90 consecutive day periods as a result of a traumatic injury other than a traumatic brain injury.

DATES: This final rule is effective January 22, 2026.

FOR FURTHER INFORMATION CONTACT: Samantha Yerdon, Program Analyst, Insurance Service, Veterans Benefits Administration, (215) 842–2000, ext. 5494.

SUPPLEMENTARY INFORMATION: On March 15, 2023, VA published a final rule in the **Federal Register** that amended its regulations governing the TSGLI program. 88 FR 15907. As part of this rulemaking, VA recodified the TSGLI Schedule of Losses and amended the eligibility standards for certain losses covered under the schedule. Following publication of the final rule, VA discovered that it had inadvertently changed the Schedule of Losses for inability to perform at least two ADLs as a result of a traumatic injury other than a traumatic brain injury. Neither the preamble to the proposed rule nor the preamble to the final rule addressed this change to the TSGLI regulation. See 85 FR 50973; 88 FR 15907. On July 24, 2024, VA published a proposed rule to correct this inadvertent change. 89 FR 59865. VA received one comment from the National Veterans Legal Services Program (NVLSP), which we address below.

The comments submitted by NVLSP assert that VA should leave the inadvertent change in the Schedule of Losses for the following reasons: (1) the TSGLI program is in good financial health as evidenced by the fact that VA has not needed to increase the TSGLI premium since inception; therefore, more generous benefits for this loss will not hurt the program; (2) the TSGLI program's focus should be on caring for wounded Service members and should not distinguish between temporary and permanent injuries; and (3) VA is not legally required to consult with the Department of Defense (DoD) in updating the TSGLI regulations published in March 2023.

Financial Health of TSGLI

TSGLI became effective on December 1, 2005. The program provides payments to Service members and Veterans who are insured by SGLI and suffer a serious traumatic injury in service resulting in a loss that qualifies for payment under TSGLI. TSGLI benefits are also payable retroactively to any member who suffered a traumatic injury from October 7, 2001, to November 30, 2005, resulting in a qualifying injury, regardless of whether they had SGLI coverage at the time of the injury. TSGLI premiums are \$1.00 per month and are intended to cover only the civilian incidence of such injuries. The uniformed services fund the cost of claims in excess of premiums

collected, with such claims attributed to the extra hazards of military service. Extra hazards funding in TSGLI was needed during periods of U.S. military involvement in Iraq and Afghanistan. In addition, the uniformed services pay for the total cost of retroactive claims. The TSGLI fund balance as of June 30, 2024, was \$60.1 million. Of this, \$28 million was contributed by DoD as start-up funds when the program began and is therefore earmarked for extra hazards costs. In addition, a portion of the remaining fund balance must be set aside to account for the lag in reporting of claims.

An analysis of the claims experience for policy years 2015 to 2024 indicates that TSGLI payments using the shorter time periods for the TSGLI Schedule of Losses for Other Traumatic Injury (OTI) resulting in inability to perform ADLs (15, 30, 60, 90 days) would have resulted in an additional 1,385 claims and an increase of \$34.6 million in payout. Additionally, the shorter time period for payment would have resulted in claims and administrative expenses exceeding premium collections for eight of the past 10 policy years. The additional claim payments using the shorter timeframes average approximately \$3.5 million per year over the past 10 policy years. Assuming that OTI ADL loss experience trends similarly going forward, premium collections will cover only about 81% of claims and administrative expenses. Consequently, use of the shorter time periods for the Schedule of Losses for OTI would put upward pressure on the TSGLI premium rate in the long term. While program surplus can be used to supplement this deficit in the short term, it is necessary for the program to maintain a sufficient fund balance to guard against the risk of future conflicts or events resulting in significant injuries that may cause spikes in claims.

Temporary and Permanent Injuries

VA explained in the proposed rulemaking that leaving the shorter payment intervals as they currently are codified could “potentially result in higher payout amounts to individuals with severe but temporary injuries than those paid to injured servicemembers who have permanent injuries.” 89 FR at 59866. As required by 38 U.S.C. 1980A(j), VA has consulted with the uniformed services, and DoD does not support the inadvertent change to the payment standard. VA and DoD note that in the original TSGLI interim final rulemaking published on December 22, 2005 (70 FR 75940, 75943), VA stated, “As required by 38 U.S.C. 1980A(d), the amount of the payment in the schedule

. . . is based on the severity of the member's loss.” Severity includes not only the length of recovery period for the loss but the nature of the injury itself, such as its permanence. Program experience demonstrates that the time periods of 15, 30, 60, and 90 days of loss of ADL due to traumatic brain injury (TBI) clearly indicate a severe injury with lasting impacts on the member's functions. However, the same cannot be said for the time period of 15 days of loss of ADL due to OTI. Since the inception of the program, denied claims that do not meet the time period of 30 days' loss of ADL due to OTI show less severe injuries of a more temporary nature, including bone fractures, lacerations, and torn ligaments. DoD and VA both agree that the initial justification for the payment standard should remain as valid rationale for maintaining the standard at the lower, instead of higher, payment amount.

VA Consultation With DoD Not Required

NVLSP also commented that there was no legal mandate that VA follow DoD guidance following consultation with the uniformed services under 38 U.S.C. 1980A(j), and even if such consultation was required, there is no evidence that DoD has publicly stated their opposition to the change in standard from the 2023 final rulemaking.

First and foremost, 38 U.S.C. 1980A(j) does not require DoD to provide public statements as to the nature of the consultation or position prior to VA implementing TSGLI rulemaking. VA supports DoD's ongoing consultation on the TSGLI regulations as the program evolves because, although VA may promulgate TSGLI regulations, it is within the exclusive purview of the uniformed services to certify TSGLI claims, and VA plays no role in the adjudication process under 38 U.S.C. 1980A(f). Furthermore, DoD staff meet with VA staff and other Department officials each year as required by statute (38 U.S.C. 1974), and DoD involvement in TSGLI warrants a fair measure of deference from VA when evaluating and responding to feedback from DoD. Adopting regulations that contradict DoD feedback may not only be costly and inconsistent with actuarially sound business principles but also would not be aligned with improvements to the customer experience for the TSGLI program, which were implicit in the purpose, design, and intent of the TSGLI Year Ten Review.

Additionally, in the case of the regulatory publication error in March 2023, the uniformed services under DoD

were the first to identify the issue in late Spring 2023 and raise the concern to VA that this change was never contemplated during the intensive collaboration with DoD and the services in the TSGLI Year Ten Review. Their concern arose from whether VA had made a change in OTI vs. TBI losses related to severity of injury in opposition to the long-standing rationale of the program they understood and supported. VA assured DoD and the uniformed services that the change was an inadvertent typographical error, and no change had been intended.

Based on the foregoing, VA adopts the proposed rule, without change, as a final rule.

Executive Orders 12866, 13563, and 14192

VA examined the impact of this rulemaking as required by Executive Orders 12866 (Sept. 30, 1993) and 13563 (Jan. 18, 2011), which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. The Office of Information and Regulatory Affairs has determined that this final rule is not a significant regulatory action under E.O. 12866.

Through this rulemaking, VA will restore the intended payment schedule for TSGLI benefits, thereby preventing confusion and unnecessary re-processing of claims. Absent this rulemaking, VA staff would continue to spend more time adjudicating appeals and handling inconsistencies from the current payment structure. While VA is unable to quantify measurable cost savings, these qualitative benefits will generate positive outcomes to society, such as reductions in burden and confusion among stakeholders. This final rule is a deregulatory action under Executive Order 14192 as it removes an unintended burden and provides a net positive benefit to society.

Economic Impact: There are no costs or savings associated with this final rule. This rule ensures the TSGLI is managed according to actuarially sound principles, maintaining the TSGLI premium at a low rate. TSGLI is funded by the premiums that Service members pay for TSGLI coverage, and as such, there will be no cost to the Government with this final rulemaking.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act

(5 U.S.C. 601–612). The overall impact of this final rule would be of no benefit or detriment to small businesses. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Unfunded Mandates

This final rule will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year.

Paperwork Reduction Act

Although this final rule contains collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), there are no provisions associated with this rulemaking constituting any new collection of information or any revisions to the existing collection of information. The collection of information for 38 CFR 9.21 is currently approved by the Office of Management and Budget (OMB) and have been assigned OMB control number 2900–0919.

Assistance Listing

The Assistance Listing number and title for the program affected by this document is 64.103, Life Insurance for Veterans.

Congressional Review Act

Pursuant to Congressional Review Act) (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

List of Subjects in 38 CFR Part 9

Life insurance, Military personnel, Veterans.

Signing Authority

Douglas A. Collins, Secretary of Veterans Affairs, approved this document on October 8, 2025, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Taylor N. Mattson,

*Alternate Federal Register Liaison Officer,
Department of Veterans Affairs.*

For the reasons stated in the preamble, VA amends 38 CFR part 9 as set forth below:

PART 9—SERVICEMEMBERS' GROUP LIFE INSURANCE AND VETERANS' GROUP LIFE INSURANCE

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

Authority: 38 U.S.C. 501, 1965–1980A, unless otherwise noted.

■ 2. Amend § 9.21 by revising paragraphs (c)(20)(i) through (iv) to read as follows:

§ 9.21 Schedule of Losses.

* * * * *

(c) * * *

(20) * * *

(i) The amount payable at the 30th consecutive day of ADL loss is \$25,000.

(ii) The amount payable at the 60th consecutive day of ADL loss is an additional \$25,000.

(iii) The amount payable at the 90th consecutive day of ADL loss is an additional \$25,000.

(iv) The amount payable at the 120th consecutive day of ADL loss is an additional \$25,000.

* * * * *

[FR Doc. 2025–23682 Filed 12–22–25; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 27

[AU Docket No. 25–117; DA 25–1075; FR ID 323537]

Auction of Advanced Wireless Services (AWS–3) Licenses; Filing Requirements, Minimum Opening Bids, Upfront Payments, and Other Procedures for Auction 113

AGENCY: Federal Communications Commission.

ACTION: Final action; requirements and procedures.

SUMMARY: In this document, the Federal Communications Commission (Commission) summarizes the procedures, deadlines, and upfront payment and minimum opening bid amounts for the upcoming auction of 200 Advanced Wireless Services licenses for spectrum in the Federal Communications Commission's inventory in the 1695–1710 MHz, 1755–1780 MHz, and 2155–2180 MHz bands (AWS–3 bands). This document provides details regarding the procedures, terms, conditions, dates, and deadlines governing participation in Auction 113 bidding, as well as overview of the post-auction application and payment processes.

DATES: Applications to participate in Auction 113 must be submitted before 6:00 p.m. Eastern Time (ET) on February 11, 2026. Upfront payments for Auction 113 must be received by 6:00 p.m. ET on April 8, 2026. Bidding in Auction 113 is scheduled to start on June 2, 2026.

FOR FURTHER INFORMATION CONTACT:

General Auction 113 Information: FCC Auctions Hotline at (888) 225-5322, option two; or (717) 338-2868. *Auction 113 Legal Information:* Valerie Barrish or Yasiman Montgomery at (202) 418-0660. *AWS-3 Bands Licensing Information:* Madelaine Maior at (202) 418-1466 or Jeffery Tignor at (202) 418-0774.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document (*Auction 113 Procedures Public Notice*) in AU Docket No. 25-117; DA 25-1075; adopted and released on December 18, 2025. The complete text of this document, including attachments and any related documents, are available on the Commission's website at <https://docs.fcc.gov/public/attachments/DA-25-1075A1.pdf> or by using the search function for AU Docket No. 25-117, on the Commission's Electronic Comment Filing System (ECFS) web page at www.fcc.gov/ecfs. To request materials in accessible formats for people with disabilities, send an email to FCC504@fcc.gov or by call the Consumer & Governmental Affairs Bureau at (202) 418-0530.

I. General Information

A. Introduction

In the *Auction 113 Procedures Public Notice*, the Office of Economics and Analytics (OEA), jointly with the Wireless Telecommunications Bureau (WTB), establishes the procedures to be used for Auction 113, the auction of 200 Advanced Wireless Services licenses for spectrum in the Commission's inventory in the 1695-1710 MHz, 1755-1780 MHz, and 2155-2180 MHz bands (collectively, the "AWS-3" bands). Auction 113, which marks the Federal Communications Commission's (Commission) first auction since its authority to use competitive bidding lapsed in 2023, will bring unused, valuable 5G-ready spectrum to market, and proceeds will fund the Commission's ongoing efforts to protect American networks from untrustworthy and insecure foreign equipment.

Bidding in Auction 113 is scheduled to commence on June 2, 2026. Auction 113 will be conducted using an ascending clock auction with a supply of one in each category of frequency-specific channel blocks, referred to as

the "clock-1" auction format. The *Auction 113 Procedures Public Notice* provides details regarding the procedures, terms, conditions, dates, and deadlines governing participation in Auction 113 bidding, as well as an overview of the post-auction application and payment processes.

B. Background and Relevant Authority

The Commission is offering licenses in Auction 113 pursuant to the Spectrum and Secure Technology and Innovation Act of 2024 (Spectrum and Secure Technology and Innovation Act). The Spectrum and Secure Technology and Innovation Act directs the Commission to initiate a system of competitive bidding under 47 U.S.C. 309(j) to grant licenses for spectrum in its inventory in the AWS-3 bands as of December 23, 2024. See Servicemember Quality of Life Improvement and National Defense Authorization Act for Fiscal Year 2025, Public Law 118-159, Div. E, Title LIV, §§ 5401-5405, § 5403. Auction proceeds will support the Commission's Supply Chain Reimbursement Program, which implements the Secure and Trusted Communications Networks Act of 2019 by reimbursing eligible advanced communications service providers for their costs to remove, replace, and dispose of Huawei Technologies Company or ZTE Corporation equipment and services obtained on or before June 30, 2020.

On March 11, 2025, in accordance with 47 U.S.C. 309(j)(3), OEA and WTB released the *Auction 113 Comment Public Notice*, 90 FR 13117 (March 20, 2025), seeking comment on certain competitive bidding and other various procedures to be used in Auction 113. Ten parties filed comments in response to the *Auction 113 Comment Public Notice*, and six parties filed reply comments.

One commenter recommends that funds from spectrum auctions and licenses be strategically and primarily directed towards expanding rural Tribal cellular services and communications infrastructure support on Tribal lands rather than for incumbent reimbursement. No parties commented on this recommendation. Even if this recommendation did not conflict with Congress's express direction for the Auction 113 proceeds, the use of auction proceeds is outside the scope of this proceeding on auction procedures as well as outside the scope of OEA's and WTB's delegated authority.

The Commission's rules and decisions provide the underlying authority for the procedures OEA and WTB adopt for Auction 113. As specified in 47 CFR

27.1105, any auction of licenses for spectrum in the AWS-3 band is to be governed by the bidding procedures set forth in 47 CFR part 1, subpart Q. The Commission has also adopted rules regarding the AWS-3 bands, as well as the licensing and operating rules that are applicable to all 47 CFR part 27 services. See *2014 AWS-3 Report and Order*, 79 FR 32366 (June 4, 2014). On July 24, 2025, the Commission adopted the *2025 AWS-3 Report and Order*, 90 FR 36385 (August 4, 2025), in which it updated the designated entity provisions of the 47 CFR part 27 rules that had applied to the Commission's first auction of AWS-3 spectrum in 2014. One commenter requests that OEA and WTB adopt an accelerated two-year buildout deadline for Auction 113 winning bidders because it claims that doing so will favor bidders with the financial capacity, operational readiness, and technical sophistication to promptly deploy service as well as discourage "speculative bidding." Four commenters oppose this request. The Commission adopted buildout rules for the AWS-3 bands in the *2014 AWS-3 Report and Order*, and any amendments to those rules require a rulemaking proceeding and cannot be made in the context of establishing the procedures for Auction 113 because such action is outside the scope of OEA's and WTB's delegated authority.

Prospective applicants should familiarize themselves with the 47 CFR part 1, subpart Q rules, including amendments and clarifications thereto, as well as Commission decisions regarding competitive bidding procedures, application requirements, and obligations of Commission licensees. In addition, applicants must be thoroughly familiar with the procedures, terms, and conditions contained in the *Auction 113 Procedures Public Notice* and any future public notices that may be released in this proceeding.

The terms contained in the Commission's rules, relevant orders, and public notices are not negotiable. OEA and WTB may amend or supplement the information contained in their public notices at any time, and may issue public notices to convey any new or supplemental information that may generally apply to applicants. Pursuant to the Commission's rules, OEA and WTB also retain the authority to implement further procedures during the course of this auction. It is the responsibility of all applicants to remain current with all Commission rules and with all public notices pertaining to Auction 113.

C. Description of Licenses To Be Offered in Auction 113

The AWS-3 spectrum available in Auction 113 will be licensed on a geographic area basis. Of the 200 licenses offered in Auction 113, the 48 licenses located in the A1 block (1695–1700 MHz), B1 block (1700–1710 MHz), H block (1760–1765/2160–2165), I block (1765–1770/2165–2170), and J block (1770–1780 MHz/2170–2180 MHz) are based on Economic Areas (EAs) and the 152 located in the G block (1755–1760/2155–2160) are based on Cellular Market Areas (CMAs). The AWS-3 frequencies will be licensed in five and ten megahertz blocks, with each license having a total bandwidth of five, ten, or twenty megahertz. The list of licenses to be offered in Auction 113 is available in the Attachment A file on the Auction

113 website at www.fcc.gov/auction/113.

One commenter requests that Block G be redefined using county level geographic areas for Auction 113, rather than on a CMA basis, as specified in 47 CFR part 27. However, implementing such a change would require an amendment to the Commission's part 27 rules that must be adopted in a rulemaking proceeding. A Commission rule cannot be amended in the context of this proceeding establishing the procedures for Auction 113 because such action is outside the scope of OEA's and WTB's delegated authority.

OEA and WTB did not seek comment on establishing a Tribal licensing window for AWS-3 spectrum inventory in the *Auction 113 Comment Public Notice*, however five parties commented on this topic. The Commission declined in the *2025 AWS-3 Report and Order* to

implement a Tribal licensing window for Auction 113, and has therefore resolved this issue.

The 1695–1710 MHz band will be licensed in an unpaired configuration for low-power mobile transmit (*i.e.*, uplink) operations. The 1755–1780 MHz band will be licensed paired with the 2155–2180 MHz band, with the 1755–1780 MHz band authorized for low-power mobile transmit (*i.e.*, uplink) operations and the 2155–2180 MHz band authorized for base station and fixed (*i.e.*, downlink) operations.

Figure 1 in the *Auction 113 Comment Public Notice* shows the band plan for the 1695–1710 MHz band. Figure 2 in the *Auction 113 Comment Public Notice* shows the band plans for the 1755–1780 MHz and 2155–2180 MHz bands. Table 1 contains summary information regarding the AWS-3 licenses available in Auction 113:

TABLE 1—AWS-3 LICENSE SUMMARY
[Auction 113]

Block	Frequencies (MHz)	Total bandwidth (MHz)	Pairing	Geographic area type	Number of licenses
A1	1695–1700 MHz	5	unpaired	EA	1
B1	1700–1710 MHz	10	unpaired	EA	1
G	1755–1760/2155–2160 MHz	10	2 × 5 MHz	CMA	152
H	1760–1765/2160–2165 MHz	10	2 × 5 MHz	EA	14
I	1765–1770/2165–2170 MHz	10	2 × 5 MHz	EA	29
J	1770–1780/2170–2180 MHz	20	2 × 10 MHz	EA	3

Each potential bidder is solely responsible for investigating and evaluating all technical and marketplace factors that may have a bearing on the potential uses of a license that it may seek in Auction 113. In addition to the typical due diligence considerations that the Commission encourages of bidders in all auctions, OEA and WTB call particular attention in Auction 113 to the incumbency issues in the 1695–1710 MHz, 1755–1780 MHz, and 2155–2180 MHz bands and protection of Federal and non-Federal incumbent operations described herein. Each applicant should closely follow releases from the Commission concerning these issues and consider carefully the technical and economic implications for commercial use of the AWS-3 band. The Commission makes no representations or warranties about the use of this spectrum for particular services, or about the information in Commission databases that is furnished by outside parties.

D. Incumbency Issues

The AWS-3 bands are currently being used for a variety of government and

non-government services. In the *2014 AWS-3 Report and Order*, the Commission allocated the 1695–1710 MHz band for non-Federal fixed and mobile (except aeronautical mobile) commercial use and the 1755–1780 MHz band for non-Federal fixed and mobile commercial use. Licenses in the 1695–1710 MHz band are being made available on a shared basis with incumbent Federal meteorological-satellite (MetSat) data users. The Commission adopted twenty-seven Protection Zones for the 1695–1710 MHz band in the *2014 AWS-3 Report and Order*, and the forty-seven Federal earth stations located in these Protection Zones will operate on a co-equal, primary basis with commercial AWS-3 licensees. All other Federal earth stations operate on a secondary basis. In order to facilitate coordination, uplink/mobile transmit devices in the 1695–1710 MHz band must be under the control of, or associated with, a base station as a means to facilitate shared use of the band and prevent interference to Federal operations.

Licenses in the 1755–1780 MHz band are being made available on a shared

basis with a limited number of Federal incumbents indefinitely, and some Federal systems that have or will over time relocate out of the band. The Federal systems located in the Protection Zones adopted by the Commission for the 1755–1780 MHz band in the *2014 AWS-3 Report and Order* will operate on a co-equal, primary basis with commercial AWS licensees. The Federal systems that will relocate from the band pursuant to an approved transition plan will operate on a primary basis until they are reaccommodated. In order to facilitate coordination, uplink/mobile transmit devices in the 1755–1780 MHz band must be under the control of, or associated with, a base station as a means to facilitate shared use of the band and prevent interference to Federal operations. NTIA issues annual reports on the status of the transitions of spectrum in the 1695–1710 MHz and 1755–1780 MHz bands. *See, e.g.*, <https://www.ntia.doc.gov/report/2024/2023-commercial-spectrum-enhancement-act-csea-report>. *See also* <https://www.ntia.doc.gov/category/aws-3-transition>.

Licenses to operate in the 1695–1710 MHz and 1755–1780 MHz bands are subject to the condition that the licensee must not cause harmful interference to an incumbent Federal entity relocating from these bands under an approved Transition Plan. This condition remains in effect until the National Telecommunications and Information Administration (NTIA) terminates the applicable authorization of the incumbent Federal entity. Although this license condition does not apply to the permanent sharing scenario, the Commission's rules require successful coordination to avoid causing harmful interference to these Federal incumbents. In addition, AWS–3 licensees in the 1755–1780 MHz band must agree to accept interference from incumbent Federal users while they remain authorized to operate in the band. The 2155–2180 MHz band is already allocated for exclusive non-Federal, commercial use. Although no Federal users are currently licensed or operating in the 2155–2180 MHz band, AWS–3 licensees may have to protect or relocate and/or share in the cost of relocating non-Federal incumbent Fixed Microwave and Broadband Radio Service licensees in the band.

AWS–3 licensees in the 1695–1710 MHz and 1755–1780 MHz bands are required to successfully coordinate with Federal incumbent users in these bands prior to operating in designated protection zones. The *2014 AWS–3 Report and Order* established that 1695–1710 MHz licensees operating at certain power levels are required to coordinate with Federal incumbents in those protection zones, and higher-powered operations would generally require nationwide coordination. Similarly, operations in the 1755–1780 MHz band are subject to successful coordination with Federal incumbents in the protection zones adopted for that band, with the default coordination zone being nationwide. Prior to commencing operations in the 1755–1780 MHz band, an AWS–3 licensee must reach a coordination arrangement on an operator-to-operator basis with each Federal agency that has an assignment with United States and Possessions authority. The *FCC/NTIA Coordination Procedures Public Notice*, 79 FR 54710 (September 12, 2014), contains various refinements to the previously-defined protection zones for each of these bands. The *FCC/NTIA Coordination Procedures Public Notice* also provides information and guidance on the overall coordination process for these bands, as contemplated by the *2014 AWS–3 Report and Order*, including informal

pre-coordination discussion and the formal process of submitting coordination requests to, and receiving responses from, relevant Federal agencies. OEA and WTB encourage each potential applicant to carefully review these coordination requirements and the policies and procedures adopted by the Commission to implement them, and to consider the impact of those requirements and policies on the potential applicant's business plans.

One commenter expresses opposition to Federal spectrum sharing and coordination requirements for the AWS–3 bands because he contends that they create challenges for bidders and could deter participation or lead to underutilized spectrum. These arguments are outside the scope of this proceeding, and as such, OEA and WTB do not address them. The Commission adopted rules for the spectrum sharing and coordination requirements for the AWS–3 bands in the *2014 AWS–3 Report and Order*. Amendments to those rules require a rulemaking proceeding and cannot be adopted in the context of establishing the procedures for Auction 113 because such action is outside the scope of OEA's and WTB's delegated authority.

E. Auction Specifics

1. Auction Title and Start Date

The auction of licenses for spectrum in the Commission's inventory in the AWS–3 bands will be referred to as "Auction 113." Bidding in Auction 113 will begin on June 2, 2026. The initial schedule for bidding rounds in Auction 113 will be announced by public notice at least one week before bidding begins. Unless otherwise announced, bidding on all licenses will be conducted on each business day until bidding has stopped on all licenses.

2. Auction Dates and Deadlines

The following pre-bidding dates and deadlines apply to Auction 113:

Auction Application System Publicly

Available: Expected January 7, 2026
Auction Application Tutorial Available (via internet): No later than January 12, 2026

Short-Form Application (FCC Form 175) Filing Window Opens: January 26, 2026, 12:00 p.m. Eastern Time (ET)

Short-Form Application (FCC Form 175) Filing Window Deadline: February 11, 2026, 6:00 p.m. ET

Upfront Payments (via wire transfer): April 8, 2026, 6:00 p.m. ET

Bidding Tutorial Available (via internet): No later than May 1, 2026
Mock Auction: May 29, 2026

Bidding Begins in Auction 113: June 2, 2026

3. Auction Delay, Suspension, or Cancellation

OEA and WTB adopt their proposal that at any time before or during the bidding process, OEA, in conjunction with WTB, may delay, suspend, or cancel bidding in Auction 113 in the event of a natural disaster, technical obstacle, network interruption, administrative or weather necessity, evidence of an auction security breach or unlawful bidding activity, or for any other reason that affects the fair and efficient conduct of competitive bidding. This approach has proven effective in resolving exigent circumstances in previous auctions, and OEA and WTB find no reason to depart from it here. OEA will notify participants of any such delay, suspension, or cancellation by public notice and/or through the FCC Auction Bidding System's (bidding system) announcement function. If the bidding is delayed or suspended, then OEA may, in its sole discretion, elect to resume the auction starting from the beginning of the current round or from some previous round, or cancel the auction in its entirety. OEA and WTB emphasize that they will exercise the authority to delay, suspend, or cancel bidding in Auction 113 solely at their discretion.

4. Requirements for Participation

Those wishing to participate in Auction 113 must:

- Submit a short-form application (FCC Form 175) electronically prior to 6:00 p.m. ET on February 11, 2026, following the electronic filing procedures and other instructions set forth in the *Auction 113 Procedures Public Notice* and in the FCC Form 175 Instructions.

- Submit a sufficient upfront payment and an FCC Remittance Advice Form (FCC Form 159) by 6:00 p.m. ET on April 8, 2026, following the procedures and instructions set forth in the *Auction 113 Procedures Public Notice*.

- Comply with all provisions outlined in the *Auction 113 Procedures Public Notice* and applicable Commission rules.

F. Educational Materials

Before the opening of the short-form filing window for Auction 113, detailed educational information will be provided in various formats to potential participants on the Auction 113 web page. Specifically, OEA will provide various materials on the pre-bidding processes in advance of the opening of the short-form application window, beginning with the release of step-by-

step instructions for completing the FCC Form 175 in the FCC's Auction Application System (AAS), which is the Commission's newly developed system that will be used for the first time in Auction 113. These materials will be available in the Education section on the Auction 113 website at www.fcc.gov/auction/113. In addition, OEA will provide an online application procedures tutorial for the auction, covering information on pre-bidding preparation, completing short-form applications, and the application review process. Applicants should carefully review both the Auction 113 application tutorial and the FCC Form 175 filing instructions, paying close attention to any departures from previous application processes as a result of the use of the new AAS for Auction 113.

In advance of the start of the mock auction, OEA will provide educational materials on the bidding procedures for Auction 113, including a user guide for the bidding system, bidding system file formats, and an online bidding procedures tutorial. These materials will provide detailed information on bidding features specific to the ascending clock auction format, including intra-round bidding and proxy bids. OEA and WTB recognize the importance of these materials to applicants' and bidders' comprehension of the bidding procedures OEA and WTB adopt herein. Accordingly, the educational materials will be released as soon as reasonably possible to provide potential applicants and bidders with time to understand them and ask questions of Commission staff before bidding begins.

OEA and WTB believe that parties interested in participating in Auction 113 will find the interactive, online tutorials an efficient and effective way to further their understanding of the application and bidding processes. The online tutorials will allow viewers to navigate the presentation outline, review written notes, and listen to audio of the notes. Additional features of these web-based tools include links to auction-specific Commission releases, email links for contacting Commission staff, and screen shots of the online application and bidding systems. The online tutorials will be accessible in the Education section on the Auction 113 website at www.fcc.gov/auction/113. Once posted, the tutorials will remain continuously accessible.

One commenter advocates for additional educational support in the form of personalized and interactive tools for less experienced participants, claiming that the educational resources the Commission makes available to participants are often too generalized for

bidders to apply to their particular circumstances. The Commission currently offers a wide variety of educational materials, demonstrations, educational opportunities, and other information and resources to assist prospective applicants and bidders with understanding the FCC's auction application system and the bidding system. Moreover, individual prospective applicants and bidders can address specific questions to Commission staff well in advance of all auction deadlines. As a result, OEA and WTB conclude that the added benefit, if any, of developing personalized and interactive educational tools in time for Auction 113 is outweighed by the time and expense that Commission would incur to customize such resources.

II. Pre-Bidding Activities and Considerations

A. Due Diligence

OEA and WTB remind each potential bidder that it is solely responsible for investigating and evaluating all technical and marketplace factors that may have a bearing on the value of the licenses that it is seeking in Auction 113 and that it is required to certify, under penalty of perjury, that it has read the *Auction 113 Procedures Public Notice* and has familiarized itself with the auction procedures and the service rules for the AWS-3 bands. The Commission makes no representations or warranties about the use of this spectrum or these licenses for particular services. Each applicant should be aware that a Commission auction represents an opportunity to become a Commission licensee, subject to certain conditions and regulations. This includes the established authority of the Commission to alter the terms of existing licenses by rulemaking, which is equally applicable to licenses awarded by auction. A Commission auction does not constitute an endorsement by the Commission of any particular service, technology, or product, nor does a Commission license constitute a guarantee of business success.

An applicant should perform its due diligence research and analysis before proceeding, as it would with any new business venture. In particular, OEA and WTB encourage each potential bidder to perform technical analyses and/or refresh its previous analyses to assure itself that, should it become a winning bidder for any Auction 113 license, it will be able to build and operate facilities that will fully comply with all applicable technical and legal requirements. OEA and WTB urge each applicant to inspect any prospective

sites for communications facilities located in, or near, the geographic area for which it plans to bid, confirm the availability of such sites, and to familiarize itself with the Commission's rules regarding the National Environmental Policy Act (NEPA), the National Historic Preservation Act (NHPA), and any other environmental statutes that may apply.

In August 2025, the Commission released the *Modernizing the Commission's National Environmental Policy Act Rules NPRM*, 90 FR 40295 (August 19, 2025), to consider updates to its rules implementing NEPA. Potential bidders in Auction 113 should be mindful that if the Commission amends its NEPA rules, AWS-3 licensees will be subject to the amended rules.

OEA and WTB also encourage each applicant in Auction 113 to continue to conduct its own research throughout the auction in order to determine the existence of pending or future administrative or judicial proceedings that might affect its decision on continued participation in the auction. Each applicant is responsible for assessing the likelihood of the various possible outcomes and for considering the potential impact on licenses available in an auction. The due diligence considerations mentioned in the *Auction 113 Procedures Public Notice* do not constitute an exhaustive list of steps that should be undertaken prior to participating in Auction 113. As always, the burden is on the potential bidder to determine how much research to undertake, depending upon the specific facts and circumstances related to its interests. For example, applicants should pay particular attention to the requirements presented by the temporary and indefinite sharing of portions of the AWS-3 bands by incumbent Federal users and AWS-3 licensees, which may vary by geography and frequency. The *FCC/NTIA Coordination Procedures Public Notice* contains additional information regarding the extent of sharing in the AWS-3 bands, refinements to the protection zones adopted in the *2014 AWS-3 Report and Order*, and information and guidance on the overall coordination process between commercial and Federal users. OEA and WTB expect that the information in both the *FCC/NTIA Coordination Procedures Public Notice* and federal agencies' approved transition plans will be material to an applicant's potential participation in Auction 113. Therefore, OEA and WTB strongly encourage each applicant to closely review these materials, as well as future releases from

the Commission and NTIA concerning these issues, and to carefully consider the technical and economic implications for commercial use of the AWS-3 bands.

Applicants are solely responsible for identifying associated risks and for investigating and evaluating the degree to which such matters may affect their ability to bid on, otherwise acquire, or make use of the licenses available in Auction 113. Each potential bidder is responsible for undertaking research to ensure that any licenses won in the auction will be suitable for its business plans and needs. Each potential bidder must undertake its own assessment of the relevance and importance of information gathered as part of its due diligence efforts.

The Commission makes no representations or guarantees regarding the accuracy or completeness of information in its databases or any third-party databases, including, for example, court docketing systems. To the extent the Commission's databases may not include all information deemed necessary or desirable by an applicant, it must obtain or verify such information from independent sources or assume the risk of any incompleteness or inaccuracy in said databases. Furthermore, the Commission makes no representations or guarantees regarding the accuracy or completeness of information that has been provided by incumbent licensees and incorporated into its databases.

B. Licensing Considerations

In addition to the incumbency issues discussed in the *Auction 113 Procedures Public Notice*, potential bidders should be aware of the following licensing considerations concerning the use of the AWS-3 frequencies they acquire in Auction 113.

1. International Coordination

Potential bidders seeking licenses for geographic areas adjacent to the Canadian and Mexican borders should be aware that the use of the AWS-3 frequencies they acquire in Auction 113 are subject to current and future agreements with the governments of Canada and Mexico.

The Commission routinely works with the United States Department of State and Canadian and Mexican government officials to ensure the efficient use of the spectrum as well as interference-free operations in the border areas near Canada and Mexico. Until such time as any adjusted agreements, as needed, between the

United States, Mexico, and/or Canada can be agreed to, operations in the AWS-3 bands must not cause harmful interference across the border, consistent with the terms of the agreements currently in force.

2. Environmental Review Requirements

Licensees must comply with the Commission's rules for environmental review under the NEPA, the NHPA, and any other environmental statutes that may apply. Licensees and other applicants that propose to build certain types of communications facilities for licensed service must follow Commission procedures implementing obligations under NEPA and NHPA prior to constructing the facilities. Under NEPA, a licensee or applicant must assess if certain environmentally sensitive conditions specified in the Commission's rules are relevant to the proposed facilities, and prepare an environmental assessment when applicable. If an environmental assessment is required, then facilities may not be constructed until environmental processing is completed. Under NHPA, a licensee or applicant must follow the procedures in 47 CFR 1.1320, as well as the *Nationwide Programmatic Agreement for Collocation of Wireless Antennas* and the *Nationwide Programmatic Agreement Regarding the Section 106 National Historic Preservation Act Review Process* (see 47 CFR pt. 1, Appendices B and C). Compliance with section 106 of the NHPA requires Tribal consultation, and if construction of the communications facilities would have adverse effects on historic or Tribally significant properties, an environmental assessment must be prepared.

3. Mobile Spectrum Holdings

OEA and WTB remind bidders of the Commission's mobile spectrum holdings policies applicable to the AWS-3 band. Specifically, the Commission did not impose a pre-auction bright-line limit on acquisitions of the AWS-3 band. The Commission also determined that it would perform case-by-case review of proposed secondary market transactions once AWS-3 was found suitable and available for the provision of mobile telephony/broadband services. All 65 megahertz of AWS-3 spectrum have been found suitable and available and are currently included in the spectrum screen.

4. Quiet Zones

AWS-3 licensees must individually apply for and receive a separate license for each transmitter if the proposed operation will affect the radio quiet zones set forth in the Commission's rules.

C. Short-Form Applications: Due Before 6:00 p.m. ET on February 11, 2026

In order to be eligible to bid in Auction 113, an applicant must first follow the procedures to submit a short-form application (FCC Form 175) electronically via the FCC's Auction Application Portal, following the instructions set forth in the FCC Form 175 Instructions. The short-form application will become available with the opening of the initial filing window and must be submitted prior to 6:00 p.m. ET on February 11, 2026. Late applications will not be accepted. No application fee is required for short-form applications. However, in *Amendment of the Schedule of Application Fees*, 86 FR 15026 (March 19, 2021), the Commission adopted a long-form application filing fee that includes an amount to recover costs for processing the short-form application, and each Auction 113 winning bidder must submit the filing fee prescribed in 47 CFR 1.1102 with each separate long-form application.

Applications may be filed at any time beginning at 12:00 p.m. ET on January 26, 2026, until the filing window closes at 6:00 p.m. ET on February 11, 2026. Applicants are strongly encouraged to file early and are responsible for allowing adequate time for filing their applications. There are no limits or restrictions on the number of times an application can be updated or amended until the initial filing deadline on February 11, 2026.

An applicant must always click on the CERTIFY & SUBMIT button on the *Certify & Submit* screen to successfully submit its FCC Form 175 and any modifications; otherwise, the application or changes to the application will not be received or reviewed by Commission staff. Additional information about accessing, completing, and viewing the FCC Form 175 is provided in the FCC Form 175 Instructions. Applicants requiring technical assistance should contact FCC Auctions Technical Support using the contact information provided in the *Auction 113 Procedures Public Notice*. In order to provide better service to the public, all calls to Technical Support are recorded.

D. Application Processing and Minor Modifications

1. Public Notice of Applicants' Initial Application Status and Opportunity for Minor Modifications

After the deadline for filing auction applications, the Commission will process all timely submitted applications to determine whether each applicant has complied with the application requirements and provided all information concerning its qualifications for bidding. OEA will issue a public notice with applicants' initial application status, identifying: (1) those that are complete; and (2) those that are incomplete or deficient because of defects that may be corrected. The public notice will include the deadline for resubmitting corrected applications and an electronic copy will be sent by email to the contact address listed in the FCC Form 175 for each applicant. In addition, each applicant with an incomplete application will be sent information on the nature of the deficiencies in its application, along with the name and contact information of a Commission staff member who can answer questions specific to the application.

After the initial application filing deadline on February 11, 2026, applicants can make only minor modifications to their applications. Minor amendments include any changes that are not major, such as: the deletion or addition of authorized bidders (to a maximum of three); revision of addresses and telephone numbers of the applicant, its responsible party, and its contact person; correcting typographical errors; and supplying or correcting information as requested to support the certifications made in the application. Major modifications (*e.g.*, change of license selection, change in ownership that would constitute an assignment or transfer of control of the applicant, change in the required certifications, change in applicant's legal classification that results in a change in control, or change in claimed eligibility for a higher percentage of bidding credit) will not be permitted. If an amendment reporting changes is a "major amendment," as described in 47 CFR 1.2105(b)(2), the major amendment will not be accepted and may result in the dismissal of the application. After the deadline for resubmitting corrected applications, an applicant will have no further opportunity to cure any deficiencies in its application or provide any additional information that may affect Commission staff's ultimate determination of whether and to what extent the applicant is qualified to participate in

Auction 113 and whether the applicant may be eligible to pursue any bidding credit claim.

Commission staff will communicate only with an applicant's contact person or certifying official, as designated on the applicant's FCC Form 175, unless the applicant's certifying official or contact person notifies Commission staff in writing that another representative is authorized to speak on the applicant's behalf. Authorizations may be sent by email to auction113@fcc.gov.

2. Public Notice of Applicants' Final Application Status After Upfront Payment Deadline

After Commission staff reviews resubmitted applications and upfront payments, OEA will release a *Qualified Bidders Public Notice* identifying applicants that have become qualified bidders for the auction. The *Qualified Bidders Public Notice* will be issued before bidding in the auction begins. Qualified bidders are those applicants with submitted FCC Form 175 applications that are deemed timely filed and complete and that have made a timely and sufficient upfront payment.

E. Upfront Payments

In order to be eligible to bid in Auction 113, a sufficient upfront payment and a complete and accurate FCC Remittance Advice Form (FCC Form 159, Revised 2/03) must be submitted before 6:00 p.m. ET on April 8, 2026. After completing its short-form application, an applicant will have access to an electronic blank version of the FCC Form 159. An accurate and complete FCC Form 159 must accompany each payment. Proper completion of this form is critical to ensuring correct crediting of upfront payments. Payers are responsible for ensuring that all information entered on the FCC Form 159, including payment amounts, is accurate. Instructions for completing FCC Form 159 for Auction 113 are provided below.

1. Making Upfront Payments by Wire Transfer for Auction 113

All upfront payments for Auction 113 must be transmitted by electronic wire transfer directly from a bank or other financial institution to the proper account at the U.S. Treasury. Wire transfer payments for Auction 113 must be received before 6:00 p.m. ET on April 8, 2026. No other payment method is acceptable. To avoid untimely payments, applicants should discuss arrangements (including bank closing schedules and other specific bank wire transfer requirements, such as an in-person written request before a specified

time of day) with their bankers several days before they plan to make the wire transfer, and must allow sufficient time for the transfer to be initiated and completed before the deadline. The following information will be needed:
ABA Routing Number: 021030004
Receiving Bank: TREAS NYC, 33 Liberty Street, New York, NY 10045
BENEFICIARY: FCC, 45 L Street NE, 3rd Floor, Washington, DC 20554
ACCOUNT NUMBER: 827000001001
Originating Bank Information (OBI Field): (Skip one space between each information item)

"AUCTIONPAY"

APPLICANT FCC REGISTRATION

NUMBER (FRN): (use the same FRN as used on the applicant's FCC Form 159, block 21)

PAYMENT TYPE CODE: (same as FCC Form 159, block 24A: "U113")

Note: The beneficiary account number (BNF Account Number) is specific to the upfront payments for Auction 113. Do not use a BNF Account Number from a previous auction.

At least one hour before placing the order for the wire transfer (but on the same business day), applicants must print and fax a completed FCC Form 159 (Revised 2/03) to the FCC at (202) 418-2843. Alternatively, the completed form can be scanned and sent as an attachment to an email to RROGWireFaxes@fcc.gov. On the fax cover sheet or in the email subject header, write "Wire Transfer—Auction Payment for Auction 113." To meet the upfront payment deadline, an applicant's payment must be credited to the Commission's account for Auction 113 before the deadline.

Each applicant is responsible for ensuring the timely submission of its upfront payment and for timely filing an accurate and complete FCC Form 159. An applicant should coordinate with its financial institution well ahead of the due date regarding its wire transfer and allow sufficient time for the transfer to be initiated and completed prior to the deadline. The Commission repeatedly has cautioned auction participants about the importance of planning ahead to prepare for unforeseen last-minute difficulties in making payments by wire transfer. Each applicant also is responsible for obtaining confirmation from its financial institution that its wire transfer to the U.S. Treasury was successful and from Commission staff that its upfront payment was timely received and that it was deposited into the proper account. As a regulatory requirement, the U.S. Treasury screens all payments from all financial institutions before deposits are made

available to specified accounts. If wires are suspended, the U.S. Treasury may direct questions regarding any transfer to the financial institution initiating the wire. Each applicant must take care to assure that any questions directed to its financial institution(s) are addressed promptly. To receive confirmation from Commission staff, contact Scott Radcliffe of the Office of Managing Director's Revenue & Receivables Operations Group/Auctions at (202) 418-7518 or Theresa Meeks at (202) 418-2945.

Please note the following information regarding upfront payments:

- All payments must be made in U.S. dollars.

- All payments must be made by wire transfer.

- Upfront payments for Auction 113 go to an account number different from the accounts used in previous FCC auctions.

Failure to deliver a sufficient upfront payment as instructed herein by the upfront payment deadline will result in dismissal of the short-form application and disqualification from participation in the auction.

2. Completing and Submitting FCC Form 159

The following information supplements the standard instructions for FCC Form 159 (Revised 2/03) and is

provided to help ensure the correct completion of FCC Form 159 for upfront payments for Auction 113. Applicants need to complete FCC Form 159 carefully because:

- Mistakes may affect bidding eligibility; and
- Lack of consistency between information provided in FCC Form 159 (Revised 2/03), FCC Form 175, long-form application (FCC Form 601), and correspondence about an application may cause processing delays.

Therefore, appropriate cross-references between the FCC Form 159 Remittance Advice and the short-form application (FCC Form 175) are described in the following chart:

Block No.	Required information
1	LOCKBOX #—Leave Blank.
2	Payer Name—Enter the name of the person or company making the payment. If the applicant itself is the payer, this entry would be the same name as in FCC Form 175.
3	Total Amount Paid—Enter the amount of the upfront payment associated with the FCC Form 159 (Revised 2/03).
4–8	Street Address, City, State, ZIP Code—Enter the street mailing address (not post office box number) where mail should be sent to the payer. If the applicant is the payer, these entries would be the same as FCC Form 175 from the Applicant Information section.
9	Daytime Telephone Number—Enter the telephone number of a person knowledgeable about this upfront payment.
10	Country Code—For addresses outside the United States, enter the appropriate postal country code (available from the Mailing Requirements Department of the U.S. Postal Service).
11	Payer FRN—Enter the payer's 10-digit FCC Registration Number (FRN) registered in the Commission Registration System (CORES).
21	Applicant FRN (Complete only if applicant is different than payer)—Enter the applicant's 10-digit FRN registered in CORES.
24A	Payment Type Code—Enter "U113".
25A	Quantity—Enter the number "1".
26A	Fee Due—Amount of Upfront Payment.
27A	Total Fee—Will be the same amount as 26A.
28A	FCC Code 1—Enter the number "113" (indicating Auction 113).

Notes:

- Do not use Remittance Advice (Continuation Sheet), FCC Form 159-C, for upfront payments.
- If the applicant is different from the payer, complete blocks 13 through 21 for the applicant, using the same information shown on FCC Form 175. Otherwise leave them blank.
- No signature is required on FCC Form 159 for auction payments.
- Since credit card payments will not be accepted for upfront payments for an auction, leave Section E blank.

3. Upfront Payments and Bidding Eligibility

An upfront payment is a refundable deposit made by each applicant seeking to participate in bidding to establish its eligibility to bid on licenses. Upfront payments that are related to the inventory of licenses being auctioned protect against frivolous or insincere bidding and provide the Commission with a source of funds from which to collect payments owed at the close of bidding.

Applicants that are former defaulters must pay upfront payments 50% greater

than non-former defaulters. For purposes of classification as a former defaulter or a former delinquent, defaults and delinquencies of the applicant itself and its controlling interests are included.

An applicant must make an upfront payment sufficient to obtain bidding eligibility on the licenses on which it will bid. OEA and WTB adopt the proposals in the *Auction 113 Comment Public Notice* to set upfront payments based on the MHz-pops of each license offered in the auction and to determine an applicant's initial bidding eligibility, the maximum number of bidding units on which a bidder may place bids in any single round, based on the amount of the upfront payment. In order to bid for a license, qualified bidders must have a current eligibility level that meets or exceeds the number of bidding units assigned to that license. At a minimum, therefore, an applicant's total upfront payment must be enough to establish eligibility to bid on at least one license in a market selected on its FCC Form 175 for Auction 113, or else the applicant will not become qualified to

participate in the auction. The total upfront payment does not affect the total dollar amount the bidder may bid.

The Commission has authority to determine appropriate upfront payments for each license being auctioned, taking into account such factors as the efficiency of the auction process and the potential value of similar licenses. In the *Auction 113 Comment Public Notice*, OEA and WTB proposed to base upfront payments for the paired licenses on dollars per MHz-pop in three population tiers: \$0.005 per MHz-pop for the paired licenses in areas with a population of less than 300,000, \$0.01 per MHz-pop for the paired licenses in areas with a population of at least 300,000 and less than 1,000,000, \$0.025 per MHz-pop for the paired licenses in areas with a population of at least 1,000,000, and \$0.005 per MHz-pop for the unpaired licenses and sought comment on this proposal. OEA and WTB received no comment on this proposal. OEA and WTB believe that this methodology is appropriate here and therefore adopt it. For all licenses, upfront payments will be subject to a

minimum of \$500 per license. The upfront payment amount per license is set forth in the Attachment A file on the Auction 113 website at www.fcc.gov/auction/113.

Additionally, for the reasons set forth in the *Auction 113 Comment Public Notice*, OEA and WTB adopt the proposal to assign each license a specific number of bidding units, equal to one bidding unit per \$100 of the upfront payment, which is necessary for

implementing the activity requirement described in the *Auction 113 Procedures Public Notice*, and facilitates the efficient conduct of the auction. The number of bidding units for a given license is fixed and does not change during the auction as prices change. Thus, in calculating its upfront payment amount, an applicant should determine the maximum number of bidding units on which it may wish to bid in any single round, and submit an upfront

payment amount covering that number of bidding units. In order to make this calculation, an applicant should add together the bidding units for the licenses on which it seeks to be active in any given round. Applicants should check their calculations carefully, as there is no provision for increasing a bidder's eligibility after the upfront payment deadline.

EXAMPLE—UPFRONT PAYMENTS AND BIDDING ELIGIBILITY

License	Description	Bidding units	Upfront payment
CMA117-G	Colorado Springs, CO	760	\$76,000
CMA118-G	Reading, PA	430	43,000

Under the clock-1 format, if a bidder wishes to bid on both of the above licenses in a round, it must have selected both of the markets in which each of these licenses are located on its FCC Form 175 and have purchased at least 1,190 bidding units (760 + 430) of bidding eligibility. If a bidder only wishes to bid on one license, but not both, purchasing 760 bidding units would allow the bidder to bid on either license, but not both at the same time. If the bidder purchased only 430 bidding units, the bidder would have enough eligibility to bid for the license in Reading but not for the one in Colorado Springs.

If an applicant is a former defaulter, it must calculate its upfront payment for the maximum number of licenses on which it plans to bid by multiplying the number of bidding units on which it wishes to be active by 1.5. In order to calculate the number of bidding units to assign to former defaulters, the Commission will calculate the number of bidding units a non-former defaulter would get for the upfront payment received, divide that number by 1.5, and round the result up to the nearest bidding unit. If a former defaulter fails to submit a sufficient upfront payment to establish eligibility to bid on at least one license, the applicant will not be eligible to bid in Auction 113.

F. Auction Registration

All qualified bidders for Auction 113 are automatically registered for the auction. Registration materials will be distributed prior to the auction by overnight delivery. The mailing will be sent only to the contact person at the contact address listed in the FCC Form 175 and will include the SecurID® tokens that will be required to place bids.

Qualified bidders that do not receive this registration mailing will not be able to submit bids. Therefore, any qualified bidder for Auction 113 that has not received this mailing by noon on May 15, 2026, should call the Auctions Hotline at (717) 338-2868. Receipt of this registration mailing is critical to participating in the auction, and each applicant is responsible for ensuring it has received all the registration materials.

In the event that a SecurID® token is lost or damaged, only a person who has

been designated as an authorized bidder, the contact person, or the certifying official on the applicant's short-form application may request a replacement. To request a replacement, call the Auction Bidder Line at the telephone number provided in the registration materials or the Auction Hotline at (717) 338-2868.

G. Remote Electronic Bidding Via the Bidding System

Bidders will be able to participate in Auction 113 over the internet using the bidding system. In addition, bidders will have the option of placing bids by telephone through a dedicated auction bidder line. Please note that telephonic bid assistants are required to use a script when entering bids placed by telephone. Telephonic bidders are therefore reminded to allow sufficient time to bid by placing their calls well in advance of the close of a round. The length of a call to place a telephonic bid may vary; please allow a minimum of 10 minutes. The toll-free telephone number for the auction bidder line will be provided to qualified bidders prior to the start of bidding in the auction.

Only qualified bidders are permitted to bid. Each authorized bidder must have his or her own SecurID® token, which the Commission will provide at no charge. Each applicant will be issued three SecurID® tokens. A bidder cannot bid without his or her SecurID® token. In order to access the bidding function of the bidding system, bidders must be logged in during the bidding round using the passcode generated by the SecurID® token and a personal identification number (PIN) created by the bidder. For security purposes, the

SecurID® tokens and a telephone number for bidding questions are only mailed to the contact person at the contact address listed on the FCC Form 175. Each SecurID® token is tailored to a specific auction. SecurID® tokens issued for other auctions or obtained from a source other than the FCC will not work for Auction 113. Please note that the SecurID® tokens can be recycled, and the Commission requests that bidders return the tokens to the FCC. Pre-addressed envelopes will be provided to return the tokens once the auction has ended.

The Commission makes no warranties whatsoever and shall not be deemed to have made any warranties, with respect to the bidding system, including any implied warranties of merchantability or fitness for a particular purpose. In no event shall the Commission, or any of its officers, employees, or agents, be liable for any damages whatsoever (including, but not limited to, loss of business profits, business interruption, loss of use, revenue, or business information, or any other direct, indirect, or consequential damages) arising out of or relating to the existence, furnishing, functioning, or use of the bidding system. Moreover, no obligation or liability will arise out of the Commission's technical, programming, or other advice or service provided in connection with the bidding system.

To the extent an issue arises with the bidding system itself, the Commission will take all appropriate measures to resolve such issues quickly and equitably. Should an issue arise that is outside the bidding system or attributable to a bidder, including, but

not limited to, a bidder's hardware, software, or internet access problem that prevents the bidder from submitting a bid prior to the end of a round, the Commission shall have no obligation to resolve or remediate such an issue on behalf of the bidder. Similarly, if an issue arises due to bidder error using the bidding system, the Commission shall have no obligation to resolve or remediate such an issue on behalf of the bidder. Accordingly, after the close of a bidding round, the results of bid processing will not be altered absent evidence of any failure in the bidding system.

H. Mock Auction

All qualified bidders will be eligible to participate in a mock auction. The mock auction, which will begin on May 29, 2026, will enable qualified bidders to become familiar with the bidding system and to practice submitting bids prior to the auction. OEA and WTB recommend that all qualified bidders, including all their authorized bidders, participate to assure that they can log in to the bidding system and gain experience with the bidding procedures. Participating in the mock auction may reduce the likelihood of a bidder making a mistake during the auction. Details regarding the mock auction will be announced in the *Qualified Bidders Public Notice* for Auction 113.

I. Fraud Alert

As is the case with many business investment opportunities, some unscrupulous parties may attempt to use Auction 113 to deceive and defraud unsuspecting investors. Common warning signals of fraud include the following:

- The first contact is a "cold call" from a telemarketer or is made in response to an inquiry prompted by a radio or television infomercial.
- The offering materials used to invest in the venture appear to be targeted at IRA funds, for example, by including all documents and papers needed for the transfer of funds maintained in IRA accounts.
- The amount of investment is less than \$25,000.
- The sales representative makes verbal representations that: (a) the Internal Revenue Service, Federal Trade Commission (FTC), Securities and Exchange Commission (SEC), FCC, or other government agency has approved the investment; (b) the investment is not subject to state or federal securities laws; or (c) the investment will yield unrealistically high short-term profits. In addition, the offering materials often include copies of actual FCC releases, or

quotes from FCC personnel, giving the appearance of FCC knowledge or approval of the solicitation.

Information about deceptive telemarketing investment schemes is available from the FCC, as well as the FTC and SEC. Additional sources of information for potential bidders and investors may be obtained from the following sources:

- the FCC's Consumer Call Center at (888) 225-5322 or by visiting www.fcc.gov/general/frauds-scams-and-alerts-guides.
- the FTC at (877) FTC-HELP ((877) 382-4357) or by visiting <https://consumer.ftc.gov/>.
- the SEC at (800) 732-0330 or by visiting <https://www.investor.gov/>.

Complaints about specific deceptive telemarketing investment schemes should be directed to the FTC, the SEC, or the National Consumer League's Fraud Center at <https://fraud.org/> or (202) 835-3323, Ext. 815.

III. Short-Form Application Contents and Certifications

A. General Information Regarding Short-Form Applications

An application to participate in Auction 113, referred to as a short-form application or FCC Form 175, provides information concerning the applicant's legal, technical, and/or financial qualifications to participate in a Commission auction for spectrum licenses or permits. The short-form application is the first part of the Commission's two-phased auction application process. In the first phase, a party seeking to participate in Auction 113 must file a short-form application in which it certifies, under penalty of perjury, that it is qualified to participate. Eligibility to participate in Auction 113 is determined based on an applicant's short-form application and certifications and on the applicant's upfront payment. Pursuant to 47 CFR 1.2105, each applicant must make a series of certifications under penalty of perjury on its FCC Form 175 related to the information provided in its application and its participation in the auction, and it must confirm that it is legally, technically, financially, and otherwise qualified to hold a Commission license. An auction applicant's failure to make the required certifications in its short-form application by the applicable filing deadline would render its application unacceptable for filing, its application would be dismissed with prejudice, and it would be ineligible to participate further in the auction. One commenter requests that the Commission "develop

and mandate a Certification of Tribal Spectrum Access for all licensees." No parties commented on this request, and the request is outside the scope of OEA's and WTB's delegated authority.

After bidding closes, in the second phase of the process, each winning bidder in Auction 113 must file a more comprehensive post-auction long-form application (FCC Form 601) for the licenses it wins in the auction, and it must have a complete and accurate ownership disclosure information report (FCC Form 602) on file with the Commission. OEA and WTB remind applicants that being deemed qualified to bid in Auction 113 does not constitute a determination that a party is qualified to hold a Commission license or is eligible for a designated entity bidding credit.

A party seeking to participate in Auction 113 must file an FCC Form 175 electronically via the Auction Application Portal (AAP) in the AAS prior to 6:00 p.m. ET on February 11, 2026, following the procedures prescribed in the FCC Form 175 Instructions. In order to access the AAP within the AAS to create a new auction application for an applicant, or save, edit, view, and/or withdraw an existing application for the applicant, an individual must: (1) have a unique email address associated with an FCC Username account that is associated with the applicant's FCC Registration Number (FRN) in the Commission Registration System (CORES), (2) be granted the appropriate permissions in CORES by an Administrator of that FRN, and (3) be assigned the appropriate Auctions Permissions in the AAP by the Administrator of that FRN. The AAS includes security features that are being implemented for the first time in Auction 113, including the use of multifactor authentication. The Commission expects to make the AAS available to the public for the Administrator(s) for an FRN to assign the appropriate Auctions Permissions in the AAP to each unique FCC Username associated with that FRN on January 7, 2026.

An Auction 113 applicant bears full responsibility for submitting an accurate, complete, and timely short-form application. Pursuant to the Commission's competitive bidding rules, an applicant must make a series of certifications under penalty of perjury on its FCC Form 175 related to the information provided in its application and its participation in the auction, and an applicant must confirm that it is legally, technically, financially, and otherwise qualified to hold a license. If an applicant claims eligibility for a

bidding credit, then the information provided in its FCC Form 175 will be used to determine whether the applicant appears to be eligible for the claimed bidding credit, with the final determination of bidding credit eligibility to occur based on a winning bidder's post-auction long-form application. Each participant in Auction 113 must also certify that it has read the *Auction 113 Procedures Public Notice* and familiarized itself both with the auction procedures and with the requirements for obtaining a license and operating facilities in the AWS-3 bands. If an Auction 113 applicant fails to make the required certifications in its FCC Form 175 by the filing deadline, then its application will be deemed unacceptable for filing and cannot be corrected after the filing deadline.

An applicant should note that submitting an FCC Form 175 (and any amendments thereto) constitutes a representation by the certifying official that he or she is an authorized representative of the applicant with authority to bind the applicant, that he or she has read the form's instructions and certifications, and that the contents of the application, its certifications, and any attachments are true and correct. Submitting a false certification to the Commission may result in penalties, including monetary forfeitures, license forfeitures, ineligibility to participate in future auctions, and/or criminal prosecution.

Applicants are cautioned that, because the required information submitted in FCC Form 175 bears on each applicant's qualifications, requests for confidential treatment will not be routinely granted. The Commission generally has held that it may publicly release confidential business information where the party has put that information at issue in a Commission proceeding or where the Commission has identified a compelling public interest in disclosing the information. In this regard, OEA and WTB have previously concluded that information submitted in support of receiving bidding credits in auction proceedings should be made available to the public.

An applicant must designate between one and three individuals as authorized bidders in its FCC Form 175. The Commission's rules prohibit an individual from serving as an authorized bidder for more than one auction applicant.

To access the bidding system, each authorized bidder will be required to have a unique email address associated with an FCC Username account that is associated with the applicant's FRN in CORES. The email address associated

with an FCC Username account is also the FCC Username for that account. If an authorized bidder does not provide an FCC Username that is associated with the applicant's FRN in the applicant's FCC Form 175, that bidder will be unable to place or submit bids. For further details, applicants should refer to the FCC Form 175 Instructions for Auction 113.

No individual or entity may file more than one short-form application or have a controlling interest in more than one short-form application. If a party submits multiple short-form applications for an auction, then only one application may form the basis for that party to become qualified to bid in that auction.

Similarly, and consistent with the Commission's general prohibition on joint bidding agreements, a party generally is permitted to participate in a Commission auction only through a single bidding entity. Accordingly, the filing of applications in Auction 113 by multiple entities controlled by the same individual or set of individuals generally will not be permitted. As noted by the Commission in adopting the prohibition on applications by commonly controlled entities, this rule, in conjunction with the prohibition against joint bidding agreements, protects the competitiveness of the Commission's auctions.

After the initial short-form application filing deadline, Commission staff will review each timely submitted application to determine whether it complies with the application requirements. Following this review, a public notice will be released announcing the status of the submitted applications and establishing an application resubmission filing window, during which an applicant may make minor modifications to its application to address identified deficiencies. To become a qualified bidder, an applicant must have a complete application (*i.e.*, have timely filed an application that is deemed complete after the deadline for correcting any identified deficiencies) and make a timely and sufficient upfront payment. Qualified bidders will be identified by public notice at least 10 days prior to the mock auction.

The *Auction 113 Procedures Public Notice* provides details regarding certain information required to be submitted in the FCC Form 175, however, an applicant should consult the Commission's rules to ensure that, in addition to the materials described in the *Auction 113 Procedures Public Notice*, all required information is included in its short-form application. To the extent the information in the

Auction 113 Procedures Public Notice does not address an applicant's specific operating structure, or if the applicant needs additional information or guidance concerning the described disclosure requirements, the applicant should review the educational materials for Auction 113 (see the Education section on the Auction 113 website at www.fcc.gov/auction/113) and use the contact information provided in the *Auction 113 Procedures Public Notice* to consult with Commission staff to better understand the information that it must submit in its short-form application.

B. Certification of Notice of Auction 113 Requirements and Procedures

For the reasons set forth in the *Auction 113 Comment Public Notice*, OEA and WTB adopt the proposal to require any applicant seeking to participate in Auction 113 to certify in its short-form application, under penalty of perjury, that it has read the *Auction 113 Procedures Public Notice* adopting procedures for Auction 113 and that it has familiarized itself with these procedures and with the requirements for obtaining a license and operating facilities in the AWS-3 bands.

This certification is designed to bolster applicants' efforts to educate themselves about the procedures for auction participation and to ensure that, prior to submitting their short-form applications, applicants understand their obligation to stay abreast of relevant information. Familiarity with the Commission's rules and procedures governing Auction 113 may also help bidders avoid the consequences to them associated with defaults, which also cause harm to other applicants and the public by reducing the efficiency of the auction process and reducing the likelihood that the license will be assigned to the bidder that values it the most. This certification, along with the other certifications required pursuant to 47 CFR 1.2105(a), will promote the submission of applications that meet the Commission's requirements, thereby leading to a more efficient application process.

A substantively similar requirement was instituted for Auctions 110, 108, and 112. This requirement furthers a long-standing policy under which the Commission expressly places a burden upon each applicant to be thoroughly familiar with the procedures, terms, and conditions contained in the relevant *Procedures Public Notice* and any future public notices that may be released in the auction proceeding. While the certification OEA and WTB add refers to information regarding auction procedures and licensing that is

available at the time of certification, potential auction applicants are on notice from the *Auction 113 Procedures Public Notice* that their educational efforts must continue even after their short-form applications are filed. Commission staff routinely makes available detailed educational materials, such as interactive, online tutorials and technical guides, to enhance interested parties' comprehension of the pre-bidding and bidding processes and to help applicants minimize their need to engage outside engineers, legal counsel, or other auction experts.

For these reasons, OEA and WTB will require each Auction 113 applicant to certify as follows in its short-form application:

that the applicant has read the public notice adopting procedures for the auction and that it has familiarized itself both with the auction procedures and with the requirements for obtaining a license and operating facilities in the AWS-3 bands.

An applicant must provide this certification under penalty of perjury, consistent with 47 CFR 1.2105(a). This certification must be provided in addition to the certifications already required under 47 CFR 1.2105. As with the other certifications required in the short-form application, an applicant's failure to make this certification in its FCC Form 175 by the February 11, 2026 short-form filing deadline will render its application unacceptable for filing, and its application will be dismissed with prejudice.

C. Acknowledgement Statement for Auction 113 Applicants

OEA and WTB adopt their proposal to require each applicant that selects on its short-form application any market in which there is a license in the 1755–1780 MHz band available for bidding to submit as an attachment to its short-form application a signed statement acknowledging that the applicant's operations in the 1755–1780 MHz band may be subject to interference from Federal systems, that the applicant must accept interference from incumbent Federal operations, and that the applicant has considered these risks before submitting any bids for applicable licenses in Auction 113. The specific text that must be included in the required acknowledgement statement is contained in Attachment B to the *Auction 113 Procedures Public Notice*. The acknowledgement statement must be signed by the same individual that signs the application on behalf of the applicant.

D. License Selection

Auction 113 will offer 200 licenses in 199 markets. An applicant must select all of the markets in which it may want to bid from the list of available markets on its FCC Form 175. One market, EA173, has two licenses available (one in frequency block H and one in frequency block I). An applicant that wishes to bid on either license in that market must select the market (and will be therefore eligible to bid on both licenses, assuming that it otherwise has sufficient bidding eligibility), even if it intends to bid on only one license and not the other. An applicant must carefully review and verify its selections before the FCC Form 175 filing deadline because those selections cannot be changed after the auction application filing deadline. An applicant is not required to place bids on any of the licenses in the markets it selects, but the bidding system will not accept bids for license(s) in a market that the applicant did not select in its FCC Form 175.

When two or more short-form applications are submitted selecting the same market in Auction 113, mutual exclusivity exists for auction purposes as to the license(s) in that market, and those license(s) must be awarded by competitive bidding procedures. Once mutual exclusivity exists for auction purposes, even if only one applicant is qualified to bid for a particular license, that applicant is required to submit a bid in order to obtain the license.

E. Disclosure of Agreements and Bidding Arrangements

An applicant must provide in its FCC Form 175 a brief description of, and identify each party to, any partnerships, joint ventures, consortia or other agreements, arrangements, or understandings of any kind relating to the licenses being auctioned, including any agreements that address or communicate directly or indirectly bids (including specific prices), bidding strategies (including the specific licenses on which to bid or not to bid), or the post-auction market structure, to which the applicant, or any party that controls or is controlled by the applicant, is a party. In connection with the agreement disclosure requirement, the applicant must certify under penalty of perjury in its FCC Form 175 that it has described, and identified each party to any such agreements, arrangements, or understandings to which it (or any party that controls it or that it controls) is a party. Moreover, since each applicant must maintain the accuracy and completeness of the information in its pending auction application, if it

enters into any agreement relating to the licenses being auctioned after the FCC Form 175 filing deadline, then that agreement is subject to these same disclosure requirements.

For purposes of making the required agreement disclosures on the FCC Form 175, if parties agree in principle on all material terms prior to the application filing deadline, then each party to the agreement that is submitting an auction application must provide a brief description of, and identify the other party or parties to, the agreement on its respective FCC Form 175, even if the agreement has not been reduced to writing. Parties that have not agreed in principle by the FCC Form 175 filing deadline should not describe, or include the names of parties to, the discussions on their applications.

The Commission's rules generally prohibit joint bidding and other arrangements involving auction applicants (including any party that controls or is controlled by such applicants). For purposes of the prohibition, a joint bidding arrangement includes any arrangement relating to the licenses being auctioned that addresses or communicates, directly or indirectly, bidding in the auction, bidding strategies, including arrangements regarding price or the specific licenses on which to bid, and any such arrangement relating to the post-auction market structure.

This prohibition applies to joint bidding arrangements involving two or more nationwide providers, as well as joint bidding arrangements involving a nationwide provider and one or more non-nationwide providers, where at least one party to the arrangement is an applicant for the auction. In the *Updating Part 1 Report and Order*, 80 FR 56764 (September 18, 2015), the Commission stated that entities that qualify as nationwide providers generally would be identified in procedures public notices released before each auction. To that end, in the *Auction 113 Comment Public Notice*, OEA and WTB proposed to identify AT&T, T-Mobile, and Verizon as “nationwide providers” for the purpose of implementing the competitive bidding rules in Auction 113, including 47 CFR 1.2105(c), the rule prohibiting certain communications, which is consistent with the Commission's decisions in recent spectrum auctions and the *2024 Communications Marketplace Report*, FCC 24–136 (released December 31, 2024).

One commenter requests that OEA and WTB also identify EchoStar Corporation (EchoStar), or any bidders “with whom EchoStar has agreements,”

as a “nationwide provider” for purposes of Auction 113, citing the public statements made by DISH Network (DISH) and EchoStar that have referred to DISH’s “nationwide 5G network” and because EchoStar’s Boost Mobile Network touts 99% coverage. OEA and WTB decline to adopt this suggestion for Auction 113. The Commission has historically relied, in part, on the *Communications Marketplace Report* among its justifications for a determination of which entities are considered to be “nationwide providers” for competitive bidding purposes, and the Commission’s most recent report, released in December 2024, did not identify EchoStar as a nationwide provider. In addition, EchoStar’s geographic coverage as reflected on the Commission’s National Broadband Map, is substantially less than that of AT&T, T-Mobile, and Verizon. Moreover, EchoStar’s Boost Mobile is partially a Mobile Virtual Network Operator (MVNO), and its purported “99%” coverage that this commenter refers to is based in part on the nationwide networks of its wholesale providers (e.g., AT&T and T-Mobile). OEA and WTB therefore adopt their proposal to identify only AT&T, T-Mobile, and Verizon as “nationwide providers” for purposes of implementing the competitive bidding rules in Auction 113.

Under certain circumstances, a non-nationwide provider may enter into an agreement to form a consortium or a joint venture (as applicable) that results in a single party applying to participate in an auction. Specifically, a designated entity can participate in one consortium or joint venture in an auction, and non-nationwide providers that are not designated entities may participate in an auction through only one joint venture. A non-nationwide provider may enter into only one agreement to form a consortium or joint venture (as applicable), and such consortium or joint venture shall be the exclusive bidding vehicle for its members in the auction. The general prohibition on joint bidding arrangements excludes certain agreements, including those that are solely operational in nature, as defined in 47 CFR 1.2105(a)(2)(ix)(A)–(C).

To implement the prohibition on joint bidding arrangements, the Commission’s rules require each applicant to certify in its short-form application that it has disclosed any arrangements or understandings of any kind relating to the licenses being auctioned to which it (or any party that controls or is controlled by it) is a party. The applicant must also certify that it

(or any party that controls or is controlled by it) has not entered and will not enter into any arrangement or understanding of any kind relating directly or indirectly to bidding at auction with, among others, any other applicant or a nationwide provider.

Although the Commission’s rules do not prohibit auction applicants from communicating about matters that are within the scope of an excepted agreement that has been disclosed in an FCC Form 175, OEA and WTB remind applicants that certain discussions or exchanges could nonetheless touch upon impermissible subject matters, and that compliance with the Commission’s rules will not insulate a party from enforcement of the antitrust laws.

Applicants should bear in mind that a winning bidder will be required to disclose in its post-auction long-form application, the specific terms, conditions, and parties involved in any agreement relating to the licenses being auctioned into which it had entered prior to the time bidding was completed. This applies to any bidding consortium, joint venture, partnership, or other agreement, arrangement, or understanding of any kind entered into relating to the competitive bidding process, including any agreements relating to the licenses being auctioned that address or communicate directly or indirectly bids (including specific prices), bidding strategies (including the specific licenses on which to bid or not to bid), or the post-auction market structure, to which the applicant, or any party that controls or is controlled by the applicant, is a party.

F. Ownership Disclosure Requirements

Each applicant must comply with the applicable part 1 ownership disclosure requirements and provide information required by 47 CFR 1.2105 and 1.2112, and, when applicable, 47 CFR 1.2110. Specifically, in completing FCC Form 175, an applicant must fully disclose information regarding the real party- or parties-in-interest in the applicant or application and the ownership structure of the applicant, including both direct and indirect ownership interests of 10% or more, as prescribed in 47 CFR 1.2105 and 1.2112 and, where applicable, 47 CFR 1.2110. Each applicant is responsible for ensuring that information submitted in its short-form application is complete and accurate.

In certain circumstances, an applicant may have previously filed an FCC Form 602 ownership disclosure information report or filed an application to participate in a previous auction in which ownership information was disclosed. If in that previous filing, the

applicant used the same FRN the applicant is using to create its FCC Form 175 for Auction 113, the applicant will have the option to pre-fill the most current ownership information contained in any such filing into certain ownership sections on the applicant’s FCC Form 175, if such information is in an electronic format compatible with FCC Form 175. Applicants who want to take advantage of the pre-fill option are encouraged to submit an FCC Form 602 ownership report or update any ownership information on file with the Commission in an FCC Form 602 ownership report prior to starting a short-form application for Auction 113 to ensure that their most recent ownership information is pre-filled into their short-form application. Each applicant must carefully review any ownership information that has been pre-filled into its FCC Form 175, including any ownership attachments, to confirm that all information supplied on FCC Form 175 is complete and accurate as of the application filing deadline. Any information that needs to be corrected or updated must be changed directly in FCC Form 175.

G. Foreign Ownership Disclosure Requirements

47 U.S.C. 310 requires the Commission to review foreign investment in radio station licenses and imposes specific restrictions on who may hold certain types of radio licenses. 47 U.S.C. 310 applies to applications for initial radio licenses, applications for assignments and transfers of control of radio licenses, and spectrum leasing arrangements under the Commission’s secondary market rules. In completing FCC Form 175, an applicant is required to disclose information concerning foreign ownership of the applicant. If an applicant has foreign ownership interests in excess of the applicable limit or benchmark set forth in 47 U.S.C. 310(b), then it may seek to participate in Auction 113 as long as it has filed a petition for declaratory ruling with the Commission prior to the FCC Form 175 filing deadline. An applicant must certify in its FCC Form 175 that, as of the deadline for filing its application to participate in the auction, the applicant either is in compliance with the foreign ownership provisions of 47 U.S.C. 310 or has filed a petition for declaratory ruling requesting Commission approval to exceed the applicable foreign ownership limit or benchmark in 47 U.S.C. 310(b) that is pending before, or has been granted by, the Commission.

H. Additional Disclosures for Small Businesses and Rural Service Providers Seeking Bidding Credits

In Auction 113, designated entity bidding credits will be available to applicants that demonstrate eligibility for a small business or a rural service provider bidding credit and are subsequently winning bidders in the auction. A bidding credit represents an amount by which an eligible small business or rural service provider bidder's overall payment across the licenses won may be discounted, subject to the specified caps on the total bidding credit discount they may receive adopted in the *Auction 113 Procedures Public Notice*. These bidding credits will not be cumulative—an applicant is permitted to request either a small business bidding credit or a rural service provider bidding credit, but not both.

The Commission's rules regarding designated entity bidding credits provide for, among other things: (1) a two-pronged standard for evaluating eligibility for small business benefits, (2) updated gross revenue requirements for determining whether a small business is eligible for a 15% or 25% bidding credit, (3) a bidding credit for eligible rural service providers, and (4) an attribution rule for certain disclosable interest holders of applicants claiming eligibility for bidding credits. An applicant seeking a designated entity bidding credit must disclose in its short-form application additional information demonstrating its eligibility for that bidding credit, and must also certify that it is eligible for the bidding credit it requests in its FCC Form 175.

In addition to the information provided in the *Auction 113 Procedures Public Notice*, each applicant should review carefully the Commission's decisions regarding eligibility for designated entity benefits as well as the part 1 rules. In particular, OEA and WTB remind applicants requesting bidding credits that they should take due account of the requirements of the Commission's rules and implementing orders regarding *de jure* and *de facto* control of such applicants. Nearly all of the spectrum associated with the licenses to be offered in Auction 113 is in the Commission's inventory in connection with two Auction 97 winning bidders having claimed small business bidding credits for which the Commission later determined they were ineligible. Applicants should be mindful that the Commission will closely examine qualifications of all applicant claims of bidding credit eligibility and strictly enforce its

designated entity eligibility requirements.

Moreover, the Commission's rules include a prohibition, which applies to all applicants (whether they seek bidding credits or not), against changes in ownership of the applicant that would constitute an assignment or transfer of control after the initial filing deadline for FCC Form 175. Applicants should not expect to receive any opportunities to revise their ownership structure after the filing of their short- and long-form applications, including making revisions to their agreements or other arrangements with interest holders, lenders, or others in order to address potential concerns relating to compliance with the designated entity bidding credit requirements.

This policy will help to ensure compliance with the Commission's rules applicable to the award of bidding credits prior to the conduct of the auction, which will involve competing bids from those that do and do not seek bidding credits, and thus preserves the integrity of the auction process. OEA and WTB also believe that this will meet the Commission's statutory objectives in awarding licenses through the competitive bidding process.

OEA and WTB did not make any proposals or seek comment in the *Auction 113 Comment Public Notice* on eligibility for bidding credits or the small business bidding credit levels for Auction 113, however, two parties offered comments on this topic, seeking to roll back to the small business definitions and bidding credits and other designated entity rules that had been used in Auction 97 held in 2014. These comments are not addressed in this proceeding because the Commission has already addressed those contentions and determined bidding credit eligibility and the levels of small business bidding credits available in Auction 113 in the *2025 AWS-3 Report and Order*.

1. Small Business Bidding Credit

For Auction 113, bidding credits will be available to eligible small businesses and consortia thereof, subject to the bidding credit caps adopted in the *Auction 113 Procedures Public Notice*. Under the service rules applicable to AWS-3 band licenses to be offered in Auction 113, the two-tiers of bidding credits available are determined as follows:

- A bidder that qualifies as a “small business”—*i.e.*, one with attributed average annual gross revenues that do not exceed \$55 million for the preceding five years—is eligible to receive a 15% discount on its overall payment.

- A bidder that qualifies as a “very small business”—*i.e.*, one with attributed average annual gross revenues that do not exceed \$20 million for the preceding five years—is eligible to receive a 25% discount on its overall payment.

Small business bidding credits are not cumulative; an eligible applicant may receive either the 15% or the 25% bidding credit on its overall payment, but not both. The Commission's unjust enrichment provisions also apply to a winning bidder that uses a bidding credit and subsequently seeks to assign or transfer control of its license within a certain period to an entity not qualifying for at least the same level of small business bidding credit.

Each applicant seeking a small business bidding credit must disclose the gross revenues for the preceding five years for each of the following: (1) the applicant, (2) its affiliates, (3) its controlling interests, and (4) the affiliates of its controlling interests. The applicant must also submit an attachment that lists all parties with which the applicant has entered into any spectrum use agreements or arrangements for any licenses that may be won by the applicant in Auction 113. In addition, to the extent that an applicant has an agreement with any disclosable interest holder for the use of more than 25% of the spectrum capacity of any license that may be won in Auction 113, the applicant must disclose the identity and the attributable gross revenues of any such disclosable interest holder. This attribution rule will be applied on a license-by-license basis. As a result, an applicant may be eligible for a bidding credit on some, but not all, of the licenses for which it is bidding in Auction 113. If an applicant is applying as a consortium of small businesses, then the disclosures described in this paragraph must be provided for each consortium member.

2. Rural Service Provider Bidding Credit

An eligible applicant may request a 15% discount on its overall payment using a rural service provider bidding credit, subject to the cap discussed below. To be eligible for a rural service provider bidding credit, an applicant must: (1) be a service provider that is in the business of providing commercial communications services and, together with its controlling interests, affiliates, and the affiliates of its controlling interests, has fewer than 250,000 combined wireless, wireline, broadband, and cable subscribers; and (2) serve predominantly rural areas. Rural areas are defined as counties with a population density of 100 or fewer

persons per square mile. An applicant seeking a rural service provider bidding credit must provide the number of subscribers served as of the short-form application deadline. An applicant may count any subscriber as a single subscriber even if that subscriber receives more than one service.

Each applicant seeking a rural service provider bidding credit must disclose the number of its subscribers, along with the number of subscribers of its affiliates, controlling interests, and the affiliates of its controlling interests. The applicant must also submit an attachment that lists all parties with which the applicant has entered into any spectrum use agreements or arrangements for any licenses that may be won by the applicant in Auction 113. In addition, to the extent that an applicant has an agreement with any disclosable interest holder for the use of more than 25% of the spectrum capacity of any license that may be won in Auction 113, the identity and the attributable subscribers of any such disclosable interest holder must be disclosed. Like applicants seeking eligibility for small business bidding credits, eligible rural service providers may also form a consortium. If an applicant is applying as a consortium of rural service providers, then the disclosures described in this paragraph, including the certification, must be provided for each consortium member.

3. Attributable Interests

Controlling Interests and Affiliates. Pursuant to 47 CFR 1.2110, an applicant's eligibility for bidding credits is determined by attributing the gross revenues (for those seeking small business benefits) or subscribers (for those seeking rural service provider benefits) of the applicant, its affiliates, its controlling interests, and the affiliates of its controlling interests. This information must therefore be disclosed in the short-form application of any auction participant seeking a small business or rural service provider bidding credit. Controlling interests of an applicant include individuals and entities with either *de facto* or *de jure* control of the applicant. Typically, ownership of greater than 50% of an entity's voting stock evidences *de jure* control. *De facto* control is determined on a case-by-case basis based on the totality of the circumstances. The following are some common indicia of *de facto* control:

- the entity constitutes or appoints more than 50% of the board of directors or management committee;
- the entity has authority to appoint, promote, demote, and fire senior

executives that control the day-to-day activities of the licensee; and

- the entity plays an integral role in management decisions.

Additionally, for attribution purposes, officers and directors of an applicant seeking a bidding credit are considered to have a controlling interest in the applicant. Applicants should refer to 47 CFR 1.2110(c)(2) and the FCC Form 175 Instructions to understand how certain interests are calculated in determining control for purposes of attributing gross revenues.

Affiliates of an applicant or controlling interest include an individual or entity that: (1) directly or indirectly controls or has the power to control the applicant, (2) is directly or indirectly controlled by the applicant, (3) is directly or indirectly controlled by a third party that also controls or has the power to control the applicant, or (4) has an "identity of interest" with the applicant. The Commission's definition of an affiliate of the applicant encompasses both controlling interests of the applicant and affiliates of controlling interests of the applicant. For more information on how to disclose information regarding controlling interests and affiliates, applicants should refer to 47 CFR 1.2110(c)(2) and (c)(5) respectively, as well as the FCC Form 175 Instructions.

An applicant seeking a small business bidding credit must demonstrate, through its disclosures, its eligibility for the bidding credit by: (1) meeting the applicable small business size standard, based on the Commission's controlling interest and affiliation rules; and (2) retaining control, on a license-by-license basis, over the spectrum associated with the licenses for which it seeks small business benefits. For purposes of the first prong of the standard, applicants should note that control and affiliation may arise through, among other things, ownership interests, voting interests, management and other operating agreements, or the terms of any other types of agreements—including spectrum lease agreements—that independently or together create a controlling, or potentially controlling, interest in the applicant's or licensee's business as a whole. In addition, once an applicant demonstrates eligibility as a small business under the first prong, it must also be eligible for benefits on a license-by-license basis under the second prong. As part of making the FCC Form 175 certification that it is qualified as a designated entity under 47 CFR 1.2110, an applicant is certifying that it does not have any spectrum use or other agreements that would confer either *de jure* or *de facto* control of any

license it seeks to acquire with bidding credits.

With respect to the retention of control over the spectrum associated with the licenses at issue, applicants should note that, under this standard for evaluating eligibility for small business bidding credits, if an applicant executes a spectrum use agreement that does not comply with the Commission's relevant standard of *de facto* control, then it will be subject to unjust enrichment obligations for the benefits associated with that particular license. If that spectrum use agreement (either alone or in combination with the Commission's designated entity controlling interest and attribution rules) goes so far as to confer control of the applicant's overall business, then the gross revenues of the additional interest holders will be attributed to the applicant, which could render the applicant ineligible for all current and future small business benefits on all licenses.

Limitation on Spectrum Use. Under 47 CFR 1.2110(c)(2)(ii)(J), the gross revenues (or the subscribers, in the case of a rural service provider) of an applicant's disclosable interest holder are attributable to the applicant, on a license-by-license basis, if the disclosable interest holder has an agreement with the applicant to use, in any manner, more than 25% of the spectrum capacity of any license won by the applicant and acquired with a bidding credit during the five-year unjust enrichment period for the applicable license. For purposes of this requirement, a disclosable interest holder of an applicant seeking designated entity benefits is defined as any individual or entity holding a 10% or greater interest of any kind in the applicant, including but not limited to, a 10% or greater interest in any class of stock, warrants, options, or debt securities in the applicant or licensee. Any applicant seeking a bidding credit for licenses won in Auction 113 will be subject to this attribution rule and must make the requisite disclosures.

Certain disclosable interest holders may be excluded from this attribution rule. Specifically, an applicant claiming the rural service provider bidding credit may have a spectrum license use agreement with a disclosable interest holder, without having to attribute the disclosable interest holder's subscribers, so long as the disclosable interest holder is independently eligible for a rural service provider credit and the disclosable interest holder's spectrum use and any spectrum use agreement is otherwise permissible under the Commission's existing rules. If applicable, the applicant must attach to

its FCC Form 175 any additional information as may be required to indicate any license that may be subject to this attribution rule or to demonstrate its eligibility for the exception from this attribution rule. Consistent with the Commission's limited information procedures, OEA and WTB intend to withhold from public disclosure all information contained in any such attachments until after the close of Auction 113.

Exceptions from Attribution Rules for Small Businesses and Rural Service Providers. Applicants claiming designated entity benefits may be eligible for certain exceptions from the Commission's attribution rules. For example, in calculating an applicant's gross revenues under the controlling interest standard, the Commission will not attribute to the applicant the personal net worth, including personal income, of its officers and directors. However, to the extent that the officers and directors of the applicant are controlling interest holders of other entities, the gross revenues of those entities will be attributed to the applicant. Moreover, if an officer or director operates a separate business, then the gross revenues derived from that business would be attributed to the applicant.

The Commission has also exempted from attribution to the applicant the gross revenues of the affiliates of a rural telephone cooperative's officers and directors, if certain conditions specified in 47 CFR 1.2110(b)(4)(iii) are met. An applicant claiming this exemption must provide, in an attachment, an affirmative statement that the applicant, affiliate, and/or controlling interest is an eligible rural telephone cooperative within the meaning of 47 CFR 1.2110(b)(4)(iii), and the applicant must supply any additional information as may be required to demonstrate eligibility for the exemption from the attribution rule.

An applicant claiming a rural service provider bidding credit may be eligible for an exception from the Commission's attribution rules as an existing rural partnership. To qualify for this exception, an applicant must be a rural partnership providing service as of July 16, 2015, and each member of the rural partnership must individually have fewer than 250,000 combined wireless, wireline, broadband, and cable subscribers. Because each member of the rural partnership must individually qualify for the bidding credit, by definition, a partnership that includes a nationwide provider as a member will not be eligible for the benefit.

Finally, a consortium of small businesses or rural service providers may seek an exception from the Commission's attribution rules. Under the Commission's rules, a consortium of small businesses or rural service providers is a conglomerate organization composed of two or more entities, each of which individually satisfies the definition of small business or rural service provider. A consortium must provide additional information for each member demonstrating each member's eligibility for the claimed bidding credit in order to show that the applicant satisfies the eligibility criteria for the bidding credit. The gross revenue or subscriber information of each consortium member will not be aggregated for purposes of determining the consortium's eligibility for the claimed bidding credit. This information must be provided, however, to ensure that each consortium member qualifies for the bidding credit sought by the consortium.

I. Provisions Regarding Former and Current Defaulters

Pursuant to the rules governing competitive bidding, each applicant must make certifications regarding whether it is a current or former defaulter or delinquent. A current defaulter or delinquent is not eligible to participate in Auction 113, but a former defaulter or delinquent may participate so long as it is otherwise qualified and makes an upfront payment that is 50% more than would otherwise be necessary. Accordingly, each applicant must certify under penalty of perjury on its FCC Form 175 that it, its affiliates, its controlling interests, and the affiliates of its controlling interests are not in default on any payment for a Commission construction permit or license (including down payments) and that they are not delinquent on any non-tax debt owed to any Federal agency. Additionally, an applicant must certify under penalty of perjury whether it (along with its controlling interests) has ever been in default on any payment for a Commission construction permit or license (including down payments) or has ever been delinquent on any non-tax debt owed to any Federal agency, subject to the specific exclusions provided in the Commission's rules. For purposes of making these certifications, the term "controlling interest" is defined in 47 CFR 1.2105(a)(4)(i).

Under the Commission's rule regarding applications by former defaulters, an applicant is considered a "former defaulter" or a "former delinquent" when, as of the FCC Form 175 filing deadline, the applicant or any

of its controlling interests has defaulted on any Commission construction permit or license or has been delinquent on any non-tax debt owed to any Federal agency, but has since remedied all such defaults and cured all the outstanding non-tax delinquencies. For purposes of the certification under 47 CFR 1.2105(a)(2)(xii), the applicant may exclude from consideration any cured default on a Commission construction permit or license or cured delinquency on a non-tax debt owed to a Federal agency for which any of the following criteria are met: (1) the notice of the final payment deadline or delinquency was received more than seven years before the FCC Form 175 filing deadline, (2) the default or delinquency amounted to less than \$100,000, (3) the default or delinquency was paid within two quarters (*i.e.*, six months) after receiving the notice of the final payment deadline or delinquency, or (4) the default or delinquency was the subject of a legal or arbitration proceeding and was cured upon resolution of the proceeding. With respect to the first exclusion, notice to a debtor may include notice of a final payment deadline or notice of delinquency and may be express or implied depending on the origin of any Federal non-tax debt giving rise to a default or delinquency. Additionally, for the third exclusion, the date of receipt of the notice of a final default deadline or delinquency by the intended party or debtor will be used for purposes of verifying receipt of notice.

In addition to the *Auction 113 Procedures Public Notice*, applicants are encouraged to review previous guidance on default and delinquency disclosure requirements in the context of the auction short-form application process. Parties are also encouraged to consult with Auctions Division staff if they have any questions about default and delinquency disclosure requirements.

The Commission considers outstanding debts owed to the United States Government, in any amount, to be a serious matter. The Commission has previously adopted rules, including a provision referred to as the "red light rule," that implement its obligations under the Debt Collection Improvement Act of 1996, which governs the collection of debts owed to the United States. Under the red light rule, applications and other requests for benefits filed by parties that have outstanding debts owed to the Commission will not be processed. When adopting that rule, the Commission explicitly declared, however, that its competitive bidding rules "are not affected" by the red light

rule. As a consequence, the Commission's adoption of the red light rule does not alter the applicability of any of its competitive bidding rules, including the provisions and certifications of 47 CFR 1.2105 and 1.2106, with regard to current and former defaults or delinquencies.

OEA and WTB remind each applicant, however, that any indication in the Commission's Red Light Display System, which provides information regarding debts currently owed to the Commission, may not be determinative of an auction applicant's ability to comply with the default and delinquency disclosure requirements of 47 CFR 1.2105. Thus, while the red light rule ultimately may prevent the processing of long-form applications by auction winners, an auction applicant's lack of current "red light" status is not necessarily determinative of its eligibility to participate in an auction (or whether it may be subject to an increased upfront payment obligation). Moreover, a prospective applicant in Auction 113 should note that any long-form applications filed after the close of bidding will be reviewed for compliance with the Commission's red light rule, and such review may result in the dismissal of a winning bidder's long-form application. OEA and WTB encourage each applicant to carefully review all records and other available Federal agency databases and information sources to determine whether the applicant, or any of its affiliates, or any of its controlling interests, or any of the affiliates of its controlling interests, owes or was ever delinquent in the payment of non-tax debt owed to any Federal agency.

J. Modifications to FCC Form 175

1. Duty To Maintain Accuracy and Completeness of FCC Form 175

Pursuant to 47 CFR 1.65, each applicant has a continuing obligation to maintain the accuracy and completeness of information furnished in a pending application, including a pending application to participate in Auction 113. Consistent with the requirements for prior spectrum auctions, an applicant for Auction 113 must furnish additional or corrected information to the Commission within five business days after a significant occurrence, or amend its FCC Form 175 no more than five business days after the applicant becomes aware of the need for the amendment. An applicant is obligated to amend its pending application even if a reported change may result in the dismissal of the application because it is

subsequently determined to be a major modification.

2. Modifying an FCC Form 175

A party seeking to participate in Auction 113 must file an FCC Form 175 electronically via the AAP in the AAS. During the initial filing window, an applicant will be able to make any necessary modifications to its FCC Form 175 in the AAP. An applicant that has certified and submitted its FCC Form 175 before the close of the initial filing window may continue to make modifications as often as necessary until the close of that window; however, the applicant must re-certify and re-submit its FCC Form 175 before the close of the initial filing window to confirm and effect its latest application changes. After each submission, a confirmation page will be displayed stating the submission time and submission date.

An applicant will also be allowed to modify its FCC Form 175 in the AAP, except for certain fields, during the resubmission filing window and after the release of the public notice announcing the qualified bidders for an auction. During these times, if an applicant needs to make permissible minor changes to its FCC Form 175 or must make changes in order to maintain the accuracy and completeness of its application pursuant to 47 CFR 1.65 and 1.2105(b)(4), then it must make the change(s) in the AAP and re-certify and re-submit its application to confirm and effect the change(s).

An applicant's ability to modify its FCC Form 175 in the AAP will be limited between the closing of the initial filing window and the opening of the application resubmission filing window, and between the closing of the resubmission filing window and the release of the public notice announcing the qualified bidders for an auction. During these periods, an applicant will be able to view its submitted application, but will be permitted to modify only the applicant's address, responsible party address, and contact information (e.g., name, address, telephone number) in the AAP. An applicant will not be able to modify any other pages of the FCC Form 175 in the AAP during these periods. If, during these periods, an applicant needs to make other permissible minor changes to its FCC Form 175, or changes to maintain the accuracy and completeness of its application pursuant to 47 CFR 1.65 and 1.2105(b)(4), then the applicant must submit a letter briefly summarizing the changes to its FCC Form 175 via email to auction113@fcc.gov. The email summarizing the changes must include a subject line

referring to Auction 113 and the name of the applicant, for example, "Re: Changes to Auction 113 Auction Application of XYZ Corp." Any attachments to the email must be formatted as Adobe® Acrobat® (PDF) or Microsoft® Word documents. An applicant that submits its changes in this manner must subsequently modify, certify, and submit its FCC Form 175 application(s) electronically in the AAP once it is again open and available to applicants.

Applicants should also note that even at times when the AAP is open and available to applicants, the system will not allow an applicant to make certain other permissible changes itself (e.g., correcting a misstatement of the applicant's legal classification). If an applicant needs to make a permissible minor change of this nature, then it must submit a written request by email to the Auctions Division Chief, via auction113@fcc.gov requesting that the Commission manually make the change on the applicant's behalf. Once Commission staff has informed the applicant that the change has been made in the Auction Application Portal, the applicant must then re-certify and re-submit its FCC Form 175 in the AAP to confirm and effect the change(s).

As with filing the FCC Form 175, any amendment(s) to the application and related statements of fact must be certified by an authorized representative of the applicant with authority to bind the applicant. Applicants should note that submission of any such amendment or related statement of fact constitutes a representation by the person certifying that he or she is an authorized representative with such authority and that the contents of the amendment or statement of fact are true and correct.

Applicants must not submit application-specific material through the Commission's Electronic Comment Filing System. Further, parties submitting information related to their applications should use caution to ensure that their submissions do not contain confidential information or communicate information that would violate 47 CFR 1.2105(c) or the limited information procedures adopted for Auction 113. An applicant seeking to submit, outside the AAP, information that might reflect non-public information, such as an applicant's license selection(s), upfront payment amount, or bidding eligibility, should consider including in its email a request that the filing or portions of the filing be withheld from public inspection until the end of the prohibition on certain communications pursuant to 47 CFR 1.2105(c).

Questions about FCC Form 175 amendments should be directed to the Auctions Division at auction113@fcc.gov or (202) 418-0660.

IV. Information Procedures and Prohibited Communications

A. Information Procedures During the Auction Process

Consistent with past practice in many prior spectrum license auctions, OEA and WTB adopt the proposal to limit information available during Auction 113 in order to prevent the identification of bidders placing particular bids until after the bidding has closed. Specifically, OEA and WTB will not make public until after bidding has closed: (1) the licenses that an applicant selects for bidding in its short-form application, (2) the amount of any upfront payment made by or on behalf of an applicant for Auction 113, (3) any applicant's bidding eligibility, and (4) any other bidding-related information that might reveal the identity of the bidder placing a bid. Moreover, OEA and WTB will not make public until after the close of the auction whether an applicant has submitted with its short-form application a signed acknowledgment statement regarding the acceptance of interference from Federal incumbents for operations in the 1755–1780 MHz.

OEA and WTB also adopt their proposal to make public after each bidding round, for each license, the aggregate demand, the posted price of the last completed round, and the clock price for the next round. The identities of bidders making specific bids will not be disclosed until after the close of bidding in the auction. Bids placed according to a bidder's proxy instructions will be made available, but a bidder's proxy instructions will not be disclosed because they may contain price information private to the bidder. The limited comment OEA and WTB received on this proposal largely supports adopting it.

Each bidder will have access to additional information related to its own bidding and bid eligibility. Specifically, after the bids of a round have been processed, the bidding system will inform each bidder of its processed demand for each license, its proxy instructions, and its eligibility for the next round. The identities of bidders placing specific bids will *not* be disclosed until after the close of bidding. After the close of bidding, bidders' license selections, upfront payment amounts, bidding eligibility, bids, and other bidding-related actions will be made publicly available.

The limited information procedures (sometimes also referred to as anonymous bidding) OEA and WTB adopt here have been effective in past auctions to safeguard against potential anticompetitive behavior such as retaliatory bidding and collusion. Commenters generally support adopting the limited information procedures as proposed. One commenter supports adopting limited information procedures generally to promote fair competition and discourage anticompetitive conduct, but suggests a more restrictive approach—*i.e.*, implementing phased disclosures of aggregate demand data, contending that in smaller markets with fewer licenses available, bidding patterns and price movements revealed by the proposed limited information procedures can indirectly reveal bidding strategies. Another commenter, however, asks OEA and WTB to reject these suggested enhancements, arguing that such additional procedures would complicate the development of Auction 113 bidding software and strategies and that there is no reason for the Commission “to stray from the tried-and-true bidding framework that has made its auctions a success.”

Because the commenter suggesting this more restrictive approach provides no evidence that the limited information procedures used in the Commission's past auctions have facilitated anticompetitive bidding behavior in any auction, OEA and WTB are not persuaded that they should depart from the Commission's now-established practice of implementing these procedures in wireless spectrum auctions, and they conclude that the competitive benefits associated with limiting information disclosure support adoption of such procedures and outweigh any potential benefits of full disclosure. OEA and WTB also agree that implementing the proposal for the phased disclosure of aggregate demand data would unnecessarily complicate Auction 113 bidding procedures.

OEA and WTB warn applicants that direct or indirect communication to other applicants or the public disclosure of non-public information (*e.g.*, reductions in eligibility, identities of bidders) could violate the Commission's rule prohibiting certain communications. Therefore, to the extent an applicant believes that such a disclosure is required by law or regulation, including regulations issued by the U.S. Securities and Exchange Commission (SEC), OEA and WTB strongly urge that the applicant consult with Commission staff in the Auctions Division before making such disclosure.

B. Prohibited Communications and Compliance With Antitrust Laws

The rules prohibiting certain communications set forth in 47 CFR 1.2105(c) apply to each “applicant” in Auction 113. 47 CFR 1.2105(c)(1) provides that, subject to specified exceptions, “[a]fter the short-form application filing deadline, all applicants are prohibited from cooperating or collaborating with respect to, communicating with or disclosing, to each other or any nationwide provider [of communications services] that is not an applicant, or, if the applicant is a nationwide provider, any non-nationwide provider that is not an applicant, in any manner the substance of their own, or each other's, or any other applicants' bids or bidding strategies (including post-auction market structure), or discussing or negotiating settlement agreements, until after the down payment deadline[.]” Any applicant found to have violated these communication prohibitions may be subject to sanctions.

1. Entities Subject to 47 CFR 1.2105(c)

An “applicant” for purposes of this rule includes all “controlling interests” in the entity submitting the FCC Form 175 auction application, as well as all holders of interests amounting to 10% or more of the entity (including institutional investors and asset management companies), and all officers and directors of that entity. Under 47 CFR 1.2105(c), a party that submits an application becomes an “applicant” under the rule, which goes into effect at the application deadline, and that status does not change based on later developments.

2. Prohibition Applies Until Down Payment Deadline

The prohibition in 47 CFR 1.2105(c) on certain communications begins at an auction's short-form application filing deadline and ends at the auction's down payment deadline after the auction closes, which will be announced in a future public notice. To be clear, communications that occur even after bidding has ended and the auction has closed, but before the down payment deadline, are still subject to 47 CFR 1.2105(c).

3. Scope of Prohibition on Certain Communications; Prohibition on Joint Bidding Agreements

47 CFR 1.2105(c) prohibits certain communications between applicants for an auction, regardless of whether the applicants seek permits or licenses in the same geographic area or market. The

rule also applies to communications by applicants with non-applicant nationwide providers of communications services and by nationwide applicants with non-applicant, non-nationwide providers. For purposes of the prohibited communications rule for Auction 113, OEA and WTB consider AT&T, T-Mobile, and Verizon to be “nationwide providers.” The rule further prohibits “joint bidding arrangements,” including arrangements relating to the permits or licenses being auctioned that address or communicate, directly or indirectly, bidding at the auction, bidding strategies, including arrangements regarding price or the specific permits or licenses on which to bid, and any such arrangements relating to the post-auction market structure. The rule allows for limited exceptions for communications within the scope of any arrangement consistent with the exclusion from the Commission’s rule prohibiting joint bidding, provided such arrangement is disclosed on the applicant’s auction application. Applicants may communicate pursuant to any pre-existing agreements, arrangements, or understandings relating to the licenses being auctioned that are solely operational or that provide for the transfer or assignment of licenses, provided that such agreements, arrangements, or understandings are disclosed on their applications and do not address or communicate bids (including amounts), bidding strategies, or the particular permits or licenses on which to bid or the post-auction market structure.

In addition to express statements of bids and bidding strategies, the prohibition against communicating “in any manner” includes public disclosures as well as private communications and indirect or implicit communications. Consequently, an applicant must take care to determine whether its auction-related communications may reach another applicant.

Parties subject to 47 CFR 1.2105(c) should take special care in circumstances where their officers, directors, and employees may receive information directly or indirectly relating to any applicant’s bids or bidding strategies, even if the officers, directors, or employees are not involved in their company’s participation in the auction or if the information received is wholly unsolicited. Such information may be deemed to have been received by the applicant under certain circumstances. For example, Commission staff have found that, where an individual serves as an officer

and director for two or more applicants, the bids and bidding strategies of one applicant are presumed to be conveyed to the other applicant through the shared officer, which creates an apparent violation of the rule.

Subject to the limited exceptions for communications within the scope of any arrangement consistent with the exclusion from the Commission’s rule prohibiting joint bidding, 47 CFR 1.2105(c)(1) prohibits applicants from communicating with specified other parties only with respect to “their own, or each other’s, or any other applicant’s bids or bidding strategies.” The *Prohibited Communications Guidance Public Notice*, 80 FR 63215 (October 19, 2015), released in advance of the Broadcast Incentive Auction (Auction 1000), reviewed the scope of the prohibition generally, as well as in that specific auction’s forward auction of spectrum licenses and reverse auction to relinquish broadcast licenses. As the Commission explained therein, a communication conveying “bids or bidding strategies (including post-auction market structure)” must also relate to the “licenses being auctioned” in order to be covered by the prohibition. Thus, the prohibition is limited in scope and does not apply to all communications between or among the specified parties. The Commission consistently has made clear that application of the rule prohibiting communications has never required total suspension of essential ongoing business. Entities subject to the prohibition may negotiate agreements during the prohibition period, provided that the communications involved do not relate to both: (1) the licenses being auctioned and (2) bids or bidding strategies or post-auction market structure.

Accordingly, business discussions and negotiations that do not convey information about the bids or bidding strategies, including the post-auction market structure, of an applicant are not prohibited by the rule. Moreover, not all auction-related information is covered by the prohibition. For example, communicating merely whether a party has or has not applied to participate in Auction 113 will not violate the rule. In contrast, communicating, among other things, how a party will participate, including specific geographic areas selected, specific bid amounts, and/or whether or not the party is placing bids, would convey bids or bidding strategies and would be prohibited.

While 47 CFR 1.2105(c) does not prohibit business discussions and negotiations among auction applicants that are unrelated to the auction, each

applicant must remain vigilant not to communicate, directly or indirectly, information that affects, or could affect, bids or bidding strategies. Certain discussions, even if they do not directly address the licenses offered in Auction 113 or the AWS–1 and AWS–3 bands still might touch upon subject areas that relate to bids and bidding strategies or to post-auction market structure, which could convey price or geographic information related to bidding strategies. Such subject areas include, but are not limited to, management, sales, local marketing agreements, and other transactional agreements.

OEA and WTB caution applicants that bids or bidding strategies may be communicated outside situations that involve one party subject to the prohibition communicating privately and directly with another such party. For example, the Commission has warned that prohibited “communications concerning bids and bidding strategies may include communications regarding capital calls or requests for additional funds in support of bids or bidding strategies to the extent such communications convey information concerning the bids and bidding strategies directly or indirectly.” Moreover, the Commission found a violation of the rule against prohibited communications when an applicant used the Commission’s bidding system to disclose “its bidding strategy in a manner that explicitly invited other auction participants to cooperate and collaborate . . . in specific markets,” and it has placed auction participants on notice that the use of its bidding system “to disclose market information to competitors will not be tolerated and will subject bidders to sanctions.”

Likewise, when completing a short-form application, each applicant should avoid any statements or disclosures that may violate 47 CFR 1.2105(c), particularly in light of the limited information procedures in effect for Auction 113. Specifically, an applicant should avoid including any information in its short-form application that might convey information regarding its license selections, such as referring to markets or other geographic areas in describing agreements, including any information in application attachments that will be publicly available that may otherwise disclose the applicant’s license selections, or using applicant names or attachment file names in the application that refer to licenses being offered.

Applicants also should be mindful that communicating non-public application or bidding information publicly or privately to another

applicant may violate 47 CFR 1.2105(c) even though that information subsequently may be made public during later periods of the application or bidding processes.

4. Communicating With Third Parties

47 CFR 1.2105(c) does not prohibit an applicant from communicating bids or bidding strategies to a third party, such as a consultant or consulting firm, counsel, or lender. An applicant should take appropriate steps, however, to ensure that any third party it employs for advice pertaining to its bids or bidding strategies does not become a conduit for prohibited communications to other specified parties, as that would violate the rule. For example, an applicant might require a third party, such as a lender, to sign a non-disclosure agreement before the applicant communicates any information regarding bids or bidding strategy to the third party. Within third-party firms, separate individual employees, such as attorneys or auction consultants, may advise individual applicants on bids or bidding strategies, as long as such firms implement firewalls and other compliance procedures that prevent such individuals from communicating the bids or bidding strategies of one applicant to other individuals representing separate applicants. Although firewalls and/or other procedures should be used, their existence is not an absolute defense to liability if a violation of the rule has occurred.

As the Commission has noted in other spectrum auctions, in the case of an individual, the objective precautionary measure of a firewall is not available. As a result, an individual that is privy to bids or bidding information of more than one applicant presents a greater risk of becoming a conduit for a prohibited communication. OEA and WTB will take the same approach to interpreting the prohibited communications rule in Auction 113. OEA and WTB emphasize that whether a prohibited communication has taken place in a given case will depend on all the facts pertaining to the case, including who possessed what information, what information was conveyed to whom, and the course of bidding in the auction.

OEA and WTB remind potential applicants that they may discuss the short-form application or bids for specific licenses with the counsel, consultant, or expert of their choice *before* the short-form application deadline. Furthermore, the same third-party individual could continue to give

advice after the short-form deadline regarding the application, provided that no information pertaining to bids or bidding strategies, including licenses selected on the short-form application, is conveyed to that individual.

Applicants also should use caution in their dealings with other parties, such as members of the press, financial analysts, or others who might become conduits for the communication of prohibited bidding information. For example, even though communicating that it has applied to participate in the auction will not violate the rule, an applicant's statement to the press or a statement on social media that it intends to stop bidding in an auction could give rise to a finding of a 47 CFR 1.2105 violation. Similarly, an applicant's public statement of intent not to place bids during bidding in Auction 113 could also violate the rule.

5. 47 CFR 1.2105(c) Certifications

By electronically submitting its FCC Form 175, each applicant for Auction 113 certifies its compliance with 47 CFR 1.2105(c) of the rules. The mere filing of a certifying statement as part of an application, however, will not outweigh specific evidence that a prohibited communication has occurred, nor will it preclude the initiation of an investigation when warranted.

6. Duty To Report Prohibited Communications

47 CFR 1.2105(c)(4) requires that any applicant that makes or receives a communication that appears to violate 47 CFR 1.2105(c) must report such communication in writing to the Commission immediately, and in no case later than five business days after the communication occurs. Each applicant's obligation to report any such communication continues beyond the five-day period after the communication is made, even if the report is not made within the five-day period.

7. Procedures for Reporting Prohibited Communications

A party reporting any information or communication pursuant to 47 CFR 1.65(a), 1.2105(a)(2), or 1.2105(c)(4) must take care to ensure that any report of a prohibited communication does not itself give rise to a violation of 47 CFR 1.2105(c). For example, a party's report of a prohibited communication could violate the rule by communicating prohibited information to other parties specified under the rule through the use of Commission filing procedures that allow such materials to be made available for public inspection.

An applicant must file only a single report concerning a prohibited communication and must file that report with the Commission personnel expressly charged with administering the Commission's auctions. This rule is designed to minimize the risk of inadvertent dissemination of information in such reports. Any reports required by 47 CFR 1.2105(c) must be filed consistent with the instructions set forth in the *Auction 113 Procedures Public Notice*. For Auction 113, such reports must be filed with the Chief of the Auctions Division, Office of Economics and Analytics, by the most expeditious means available. Any such report should be submitted by email to the Auctions Division Chief and sent to auction113@fcc.gov. If you choose instead to submit a report in hard copy, contact Auctions Division staff at auction113@fcc.gov or (202) 418-0660 for guidance.

Given the potential competitive sensitivity of public disclosure of information in such a report, a party seeking to report such a prohibited communication should consider submitting its report with a request that the report or portions of the submission be withheld from public inspection by following the procedures specified in 47 CFR 0.459. OEA and WTB encourage such parties to coordinate with the Auctions Division staff about the procedures for submitting such reports.

8. Additional Information Concerning Prohibition on Certain Communications in Commission Auctions

A summary listing of documents issued by the Commission and OEA/WTB addressing the application of 47 CFR 1.2105(c) is available on the Commission's auction web page at www.fcc.gov/summary-listing-documents-addressing-application-rule-prohibiting-certain-communications.

9. Antitrust Laws

Regardless of compliance with the Commission's rules, applicants remain subject to the antitrust laws, which are designed to prevent anticompetitive behavior in the marketplace. Compliance with the disclosure requirements of 47 CFR 1.2105(c)(4) will not insulate a party from enforcement of the antitrust laws. For instance, a violation of the antitrust laws could arise out of actions taking place well before any party submits a short-form application. The Commission has cited a number of examples of potentially anticompetitive actions that would be prohibited under antitrust laws: for example, actual or potential competitors may not agree to divide territories in

order to minimize competition, regardless of whether they split a market in which they both do business, or whether they merely reserve one market for one and another market for the other.

To the extent OEA and WTB become aware of specific allegations that suggest that violations of the federal antitrust laws may have occurred, they may refer such allegations to the United States Department of Justice for investigation. If an applicant is found to have violated the antitrust laws or the Commission's rules in connection with its participation in the competitive bidding process, then it may be subject to a forfeiture and may be prohibited from participating further in Auction 113 and in future auctions, among other sanctions.

V. Bidding Procedures

OEA and WTB adopt their proposal to conduct Auction 113 using an ascending clock-1 auction format. The clock-1 auction format was used in Auction 108 and is similar to the clock phase of past Commission ascending clock auctions, but rather than offering multiple generic spectrum blocks in a category in a geographic area, each frequency-specific license in an EA or CMA will constitute its own category with a supply of 1. Therefore, in the clock-1 auction format adopted for Auction 113, bidders will bid on frequency-specific licenses in a clock phase. This proposal has ample support in the record.

While OEA and WTB set forth the key bidding procedures for the clock-1 auction in the *Auction 113 Procedures Public Notice*, OEA, in conjunction with WTB, released concurrently with the *Auction 113 Procedures Public Notice* an updated technical guide (Auction 113 Technical Guide) that provides further technical details about the adopted bidding procedures. The information in the Auction 113 Technical Guide, which is available in the Education section on the Auction 113 website (www.fcc.gov/auction/113), supplements the decisions made by OEA and WTB in the *Auction 113 Procedures Public Notice*.

A. Clock-1 Auction Structure

Under the clock-1 format that OEA and WTB adopt, each bidder will be able to bid for specific licenses in the clock bidding rounds, in license-by-license bidding. The auction will proceed in a series of rounds, with bidding conducted simultaneously for all licenses available in the auction. Consistent with prior Commission clock auctions, for each bidding round, the bidding system will announce a clock

price for each license, and a bidder will indicate its demand for licenses at the prices associated with the current round. Under the clock-1 auction format, a bidder's demand for a license can be zero or one.

The clock price for a license will increase from round to round if more than one bidder indicates demand for the license. The bidding rounds will continue until the number of bidders demanding each license does not exceed one. Once bidding rounds stop, the bidder with demand for a license will become the winning bidder.

B. Individual Licenses in Two Geographic Area Types

Auction 113 will offer 200 geographic area-based licenses in 199 markets in the 1695–1710 MHz, 1755–1780 MHz, and the 2155–2180 MHz bands. The Auction 113 inventory consists of licenses in EAs and CMAs. The 48 EA licenses include frequency blocks designated A1, B1, H, I, and/or J; the 152 CMA licenses are all for frequency block G. In Auction 113, only one geographic area (EA173) has more than one frequency block available, and it includes both the H and the I blocks.

C. Bidding Rounds

Auction 113 will consist of sequential bidding rounds, each followed by the release of round results. OEA and WTB will conduct bidding simultaneously for all licenses available in the auction. In the first bidding round of Auction 113, a bidder will indicate whether it demands the licenses at the minimum opening bid price. Before each subsequent bidding round, the bidding system will announce a start-of-round price and a clock price for each license, and during the round, qualified bidders will indicate the licenses for which they wish to bid at the prices associated with the current round. Bidding rounds will be open for predetermined periods of time. Bidders will be subject to activity and eligibility rules that govern the pace at which they participate in the auction.

For each license, the clock price will increase from round to round if more than one bidder indicates demand for that license. The bidding rounds will continue until, for every license, demand does not exceed one. At that point, the bidder still indicating demand for a license will be the winning bidder.

The initial bidding schedule will be announced in a public notice to be released at least one week before the start of bidding. Details on viewing round results, including the location and format of downloadable results files for each round, will be released

concurrent with or prior to that public notice.

A bidder will be able to submit bids via the internet through the bidding system user interface, the bidding system's upload function, or using the auction bidder line. The bidding system's upload function accepts bid files in a comma-separated values (CSV) text format. The bidding system will allow a bidder to submit bids only for licenses the bidder selected on its FCC Form 175 and for which the bidder has sufficient bidding eligibility.

During each open bidding round, a bidder will be able to modify its bids in the current bidding round. Bids can be modified either through the user interface, the bidding system's upload function, or through the auction bidder line. If a bidder modifies its bids by uploading a new file, then that file, including all of the file's bids and modifications, will replace all of the bidder's bids previously submitted in the round. The system will take the last bid file submission as that bidder's bids for the round. OEA and WTB urge bidders to verify their bids in each round. Information on how to do so will be made available in educational materials that OEA will provide, including a bidding system user guide and an online bidding procedures tutorial.

OEA will retain the discretion to change the bidding schedule in order to foster an auction pace that reasonably balances speed with the bidders' need to study round results and adjust their bidding strategies. Such adjustments may include changes to the amount of time for bidding rounds, the amount of time between rounds, or the number of rounds per day, depending upon bidding activity and other factors.

D. Stopping Rule

OEA and WTB adopt their proposal to employ a simultaneous stopping rule for Auction 113, which means all licenses simultaneously remain open for bidding until the first round in which, after bid processing, no license has excess demand, at which point the auction will close.

E. Activity Rule

For the reasons set forth in the *Auction 113 Comment Public Notice*, OEA and WTB adopt their proposal to employ an activity rule that requires bidders to bid actively throughout the auction, rather than wait until late in the auction before participating. For this clock auction, a bidder's activity in a round for purposes of the activity rule will be the sum of the bidding units associated with the bidder's demands as

applied by the bidding system during bid processing. Bidders are required to be active on a specific percentage (the *activity requirement percentage*) of their current bidding eligibility during each round of the auction. Failure to maintain the requisite activity level will result in a reduction in the bidder's eligibility, possibly curtailing or eliminating the bidder's ability to place bids in subsequent rounds of the auction.

OEA and WTB adopt their proposal to require that bidders maintain a fixed, high level of activity in each round of Auction 113 in order to maintain bidding eligibility. In order for posted prices and aggregate demand in the clock auction to reflect bidders' true demands reliably, the bidding system requires a high activity requirement percentage to incentivize bidders to start bidding early in the auction for the licenses that they want to acquire. Consistent with past practice, bidders will be required to be active on between 90% and 100% of their bidding eligibility in all clock rounds, with the specific percentage for each round to be set by OEA. OEA will set the activity requirement percentage initially at 95%.

If the activity requirement is met, then the bidder's eligibility will not change for the next round. If the activity requirement is not met in a round, the bidder's eligibility will be reduced to an amount that brings the bidder into compliance with the requirement. Bidding activity will be based on the bids that are applied by the bidding system. That is, if a bidder submits a bid to reduce its demand for a license, but the bidding system cannot apply the request because demand for that license will fall below one, then the bidder's activity will reflect its unreduced demand (*i.e.*, the license will still count toward the bidder's activity).

OEA retains the discretion to change the activity requirement percentage during the auction. The bidding system will announce any such changes in advance of the round in which they would take effect, giving bidders adequate notice to adjust their bidding strategies.

Most commenters did not object to the proposal to set the initial activity requirement percentage at 95%, which the Commission has successfully used in every clock auction since the format was introduced for the Broadcast Incentive Auction. However, one commenter proposes to reduce the activity requirement to 90% or to use a more complicated tiered eligibility system to reduce the activity requirement below 95%, arguing that "strict" activity requirements create

challenges for bidders, especially smaller entities, who are "navigating complex auction rules." This commenter claims that "unforeseen technical or financial constraints have limited bidder activity, leading to a loss of eligibility," but provides no examples of such instances. OEA and WTB are not persuaded by these unsupported arguments, and see no convincing evidence of a need to deviate from the proposed 95% initial activity requirement. Moreover, OEA and WTB agree that they should not depart from the "tried-and-true bidding framework" that has made Commission auctions successful, including changing features that are in place to protect the integrity of the auction or introducing features that would unnecessarily complicate bidding system development or bidding strategies. The 95% initial activity requirement has consistently demonstrated that it balances providing bidders with the flexibility to substitute across markets in response to learned price information with providing bidders incentives to bid in each round of the auction for the markets that they are sincerely interested in. Lowering the initial activity requirement could extend the duration of the auction if bidders delay placing their bids until the activity requirement is increased. OEA and WTB therefore decline to reduce the initial activity requirement below 95% because doing so could create more uncertainty regarding the exact level of bidder demand, provide less helpful information to bidders about aggregate demand, and likely prolong the auction as bidders could delay their bidding until later in the auction.

In the *Auction 113 Comment Public Notice*, OEA and WTB sought comment on procedures for a contingent bidding limit that would allow a bidder's submitted bids to have bidding activity that is greater than the bidder's eligibility. In particular, OEA and WTB sought comment on whether the contingent bidding limit would be useful with the limited inventory in Auction 113 or whether it would add unnecessary complexity. The only two commenters that addressed this both object to allowing contingent bidding in Auction 113, arguing that the contingent bidding limit would introduce complexity and uncertainty into the bidding without adding any appreciable benefits to the bidders or the Commission, and that the contingent bidding limit was scarcely utilized by bidders based on their analysis of bidding data from the Commission's four most recent clock auctions. OEA and WTB agree that including a

contingent bidding limit in Auction 113 would introduce added complexity. Given that Auction 113 has a more limited inventory than recent auctions, OEA and WTB expect fewer bidders to attempt to switch between licenses, lowering the likelihood that bidders see submitted bids go unapplied during bid processing. As such, OEA and WTB find a contingent bidding limit to be unnecessary, and will not include it in Auction 113.

For Auction 113, OEA and WTB will not provide for activity rule waivers to preserve a bidder's eligibility. This approach has been followed in every ascending clock auction since the Commission introduced the format. The clock auction relies on precisely identifying the point at which demand decreases to equal supply to determine winning bidders and final prices. Allowing waivers would create uncertainty with respect to the exact level of bidder demand, would reduce the incentives to bid sincerely, and would interfere with the basic clock price-setting and winner determination mechanism. Moreover, uncertainty about the level of demand would affect the way bidders' requests to reduce demand are processed by the bidding system. Submitting proxy instructions can address some of the circumstances under which a bidder inadvertently risks losing bidding eligibility.

F. Acceptable Bids

1. Reserve Prices

In the *Auction 113 Comment Public Notice*, OEA and WTB proposed not to establish reserve prices other than minimum opening bid amounts for the licenses being offered in Auction 113, reasoning that, unlike Auction 97, the public interest did not provide any specific basis for doing so in Auction 113. However, OEA and WTB invited commenters that consider a reserve price to be in the public interest to describe what specific factors lead them to that conclusion.

Three commenters argue that adopting an aggregate reserve price is necessary to achieve Congress' goal of fully funding the Commission's Supply Chain Reimbursement Program in a single auction, to ensure that AWS-3 spectrum is not sold for less than it is worth, and to avoid subjecting Auction 97 defaulting bidders to disproportionately large liabilities—with one commenter specifically advocating for the adoption of a \$3.3 billion aggregate reserve. Two other commenters, however, ask OEA and WTB to reject calls for an aggregate reserve price in Auction 113, arguing

that it is not necessary where the Commission is already proposing robust minimum opening bids that will prevent licenses from being assigned at nominal amounts. Those commenters further observe that an aggregate reserve price that is set too high could ultimately cause the auction to fail, which would in turn deprive the Treasury of all revenue and result in valuable spectrum remaining unlicensed and unused.

OEA and WTB agree, and adopt their proposal not to establish reserve prices for Auction 113 licenses, other than minimum opening bid amounts. As the Commission has previously explained, while the primary purpose of a minimum opening bid is to speed up the course of an auction, a minimum opening bid also can serve a revenue-enhancing function like a reserve price, because if bids are not accepted below a certain level, they will also not be sold below that level. That is, a minimum opening bid effectively functions as a reserve price. OEA and WTB therefore conclude that adopting an aggregate reserve price is not necessary for an auction in which they are adopting minimum opening bids that are sufficiently high so as to prevent licenses from being assigned at nominal amounts and in which OEA and WTB have no statutory obligation to do so.

Contrary to one commenter's arguments, the Commission is not required to adopt a reserve price to ensure that the maximum funding earmarked by Congress for the Commission's Supply Chain Reimbursement Program is fully funded from a single auction. OEA and WTB agree that Congress's directive that proceeds raised in Auction 113 be used to support the Commission's Supply Chain Reimbursement Program does not require that the Commission risk a failed auction by setting a \$3.3 billion reserve price. If a reserve was established but not met, the auction would provide no funds at all. It is unreasonable to believe that Congress intended such a result. Moreover, in the *Part 1 Third Report and Order*, 63 FR 2315 (January 15, 1998), 63 FR 12658 (March 16, 1998), 63 FR 29958 (June 2, 1998), the Commission concluded that 47 U.S.C. 309(j)(4)(F) does not require it to use reserve prices or minimum opening bids to maximize the revenue earned in all future spectrum auctions because the other auction goals in 47 U.S.C. 309(j)(3)—such as ensuring the deployment and rapid deployment of new technologies and services and promoting economic opportunity and competition—have not been eliminated,

and the Commission must continue to balance and pursue all of its objectives.

OEA and WTB find unavailing commenters' arguments that the lack of a reserve price would be detrimental to defaulting bidders from Auction 97 and that setting a reserve price would help these defaulting bidders avoid facing disproportionately large liabilities in Auction 113. The Commission is not obligated to establish an aggregate reserve price equal to the sum of all bids on which bidders defaulted in Auction 97—*i.e.*, \$3.3 billion—in order to shield past defaulting bidders from the consequences of their own actions and to protect them from any risk that they would be required to pay a deficiency payment following Auction 113. Indeed, bidders in a Commission auction are on notice that they bear any risk that may be associated with their winning bids, because the Commission's default payment rules make clear that “[a] bidder assumes a binding obligation to pay its full bid amount upon acceptance of the winning bid at the close of an auction.” See 47 CFR 1.2104(g)(2). Those rules also make clear that if a bidder defaults on its winning bid, it will be subject to a default payment consisting of a deficiency payment equal to the difference between the amount of the defaulted bid amount and the amount of the winning bid in a subsequent auction, plus an additional default payment percentage amount. Setting a reserve price that would render the deficiency payment provision of the default payment meaningless would distort auction incentives and likely encourage more defaults in the future.

The Commission has previously explained that the reserve price and minimum opening bid provision in 47 U.S.C. 309(j)(4)(F) is intended to prevent licenses from being assigned via auction at nominal amounts, which could result, for example, from insufficient competition in the auction that might in turn be due to the inability of potential bidders to assess the market adequately or develop business plans. Moreover, the Commission has discretion regarding whether to employ a minimum opening bid and/or reserve price in an auction, after considering, among other factors, the amount of spectrum being auctioned, levels of incumbency, the availability of technology to provide service, the size of the geographic service areas, issues of interference with other spectrum bands, and any other relevant factors that could reasonably have an impact on valuation of the spectrum being auctioned. Given the circumstances in Auction 113—*i.e.*, that it is an auction of licenses in

spectrum bands that are already in use for 5G services, that this is the first auction the Commission will be conducting in almost four years, and that the licenses being offered in Auction 113 have been lying fallow for ten years during the pendency of litigation—OEA and WTB conclude these factors should be sufficient to ensure that there will be sufficient competition in the auction and that these licenses will not be assigned at nominal amounts. This will in turn benefit the public more than establishing a reserve price in the absence of a statutory directive to do so.

2. Minimum Opening Bids

As is typical for spectrum license auctions, OEA and WTB sought comment on the use of a minimum opening bid and/or reserve price, as mandated by 47 U.S.C. 309(j) of the Communications Act. OEA and WTB will establish minimum opening bids for every license in Auction 113. The bidding system will not accept bids at prices less than the minimum opening bid specified for each license. Based on the Commission's experience in past auctions, setting appropriate minimum opening bids is an effective tool to prevent an excessive number of bidding rounds at very low prices.

OEA and WTB adopt their proposed minimum opening bid amounts. OEA and WTB calculate minimum opening bids on a license-by-license basis based on \$0.01 per MHz-pop for the paired licenses in areas with a population of less than 300,000, \$0.02 per MHz-pop for the paired licenses in areas with a population of at least 300,000 and less than 1,000,000, \$0.05 per MHz-pop for the paired licenses in areas with a population of at least 1,000,000, and \$0.01 per MHz-pop for the unpaired licenses. For all licenses, minimum opening bids will be subject to a minimum of \$1,000 per license.

Two commenters argue the proposed minimum opening bids are too low and propose that the minimum opening bids for the licenses in Auction 113 not be lower than the minimum opening bids of the corresponding licenses in Auction 97. They both argue that lower minimum opening bids in Auction 113 on some licenses, relative to the corresponding minimum opening bids in Auction 97, may result in lower winning bids on those licenses and lower auction revenue.

OEA and WTB are unconvinced by these arguments. As the Commission has recognized in past auctions, minimum opening bids are not intended to be a reflection of final license prices, but instead a starting point for bidding.

The minimum opening bid on a license has less bearing on the final price of the license than it does on the number of rounds required to reach the final price. OEA and WTB also disagree that lower minimum opening bids on some licenses in Auction 113 (relative to Auction 97) will reduce auction revenue, even though other minimum opening bids in Auction 113 are higher (relative to Auction 97). In past auctions, the Commission has recognized that a critical factor in setting minimum opening bids is to not set them above the market clearing price, which is unknown prior to the auction and, if set too high, could result in lower participation and unsold licenses. Another commenter supports this principle, agreeing that the minimum opening bids OEA and WTB adopt will facilitate robust price discovery and participation. OEA and WTB find that the amounts they adopt for Auction 113 balance the competing objectives for minimum opening bids because (1) they are sufficiently low so as not to deter participation or interfere with the price-setting and winner determination mechanisms of the auction, and (2) they are sufficiently high so as not to result in an excessive number of rounds at prices very distant from the final prices and to not permit the licenses to be sold for nominal amounts.

The minimum opening bids that OEA and WTB adopt for the midband AWS-3 spectrum licenses available in Auction 113 are in line with the minimum opening bids that have been set for every recent auction of mid-band spectrum. In Auction 110 for licenses in the 3.45–3.55 GHz band, the minimum opening bids were calculated based on \$0.02 or \$0.06 per MHz-pop, according to the population tiers of the geographic area. In Auction 108 for licenses in the 2.5 GHz band, the minimum opening bids were calculated based on \$0.006 per MHz-pop for all licenses. In Auction 107 for licenses in the 3.7–3.98 GHz band, the minimum opening bids were calculated based on \$0.003, \$0.006 or \$0.03 per MHz-pop, according to the population tiers of the geographic area. In Auction 105 for licenses in the 3.55–3.65 GHz band, the minimum opening bids were calculated based on \$0.02 per MHz-pop for all licenses. Commenters have not presented any evidence that there have been changes to the market conditions for 5G-suitable spectrum that could justify increasing the minimum opening bids for Auction 113 above the range of minimum opening bids found in these four auctions of midband spectrum. OEA and WTB find that this

range of minimum opening bids better reflects current market conditions than the minimum opening bids that were used in Auction 97.

One commenter suggests implementing the use of “adaptive pricing mechanisms” that would decrease minimum opening bids during the auction for licenses that do not receive any bids at the current minimum opening bids. OEA and WTB do not believe that this approach would be helpful to bidders in Auction 113. No commenters submitted evidence demonstrating that the specific minimum opening bids OEA and WTB proposed for Auction 113 are too high. The minimum opening bids OEA and WTB adopt in Auction 113 use a lower dollar-per-MHz-pop basis in areas with lower populations than in areas with higher populations, reducing the risk of licenses in rural areas going unsold. The number of licenses unsold in recent auctions has been relatively small, suggesting that minimum opening bids have not been set inappropriately high. In Auction 110, 0.5% of licenses were not sold; in Auction 108, 1.8% of licenses were not sold; in Auction 107, there were no unsold licenses; and in Auction 105, 8.9% of licenses were not sold. Furthermore, OEA and WTB have concerns that introducing a feature into the bidding system to reduce certain minimum opening bids “for licenses that receive no bids after a defined number of rounds” could introduce additional complexity into bidding strategies and could run counter to the objective of not permitting licenses to be sold for nominal amounts. Therefore, OEA and WTB decline to implement this suggestion.

The minimum opening bids for all licenses offered in Auction 113 are set forth in the Attachment A file on the Auction 113 website at www.fcc.gov/auction/113.

3. Clock Price Increments

OEA and WTB adopt the procedures regarding clock price increments as described in the *Auction 113 Comment Public Notice*. Therefore, after bidding in the first round and before each subsequent round, for each license, the bidding system will announce the start-of-round price and the clock price for the upcoming round—that is, the lowest price and the highest price at which bidders can submit bids during the round. As long as aggregate demand for the license at the clock price exceeds one, the start-of-round price for the upcoming round will be equal to the clock price from the prior round. If aggregate demand equaled one at a price in the previous round, then the start-of-

round price for the next round will be equal to the price at which demand equaled one. If aggregate demand was zero in the previous round, then the start-of-round price for the next round will remain the same.

OEA and WTB will set the clock price for a license for a round by adding a percentage increment to the start-of-round price. OEA and WTB will set the initial increment percentage at 10%, and OEA may adjust this increment percentage within a range of 5% to 30%, inclusive, in later rounds. To ensure that an increase in the percentage increment does not result in an unduly large increase for a license, the total dollar amount of the increment (the difference between the clock price and the start-of-round price) will be capped at a certain amount. OEA and WTB will set this cap on the increment initially at \$50 million, and OEA may adjust the cap in later rounds. The 5% to 30% increment range and cap will allow us to manage the auction pace and take into account bidders’ needs to reevaluate their bidding strategies while also moving the auction along quickly.

4. Bid Types

Under the clock-1 auction format adopted for Auction 113, a bidder will indicate in each round the licenses it demands at the prices associated with the round. A “simple” bid indicates a desired quantity (in this auction, one or zero) at a price. In the first round, a bidder indicates the licenses it demands at the minimum opening bids by indicating a quantity of one for each of those licenses. After the first round, a bidder that wants to maintain the same processed demand for a license at the new clock price would submit a bid for the license at the clock price, indicating that it is willing to pay up to that price, if need be, for the license. A bid to maintain the same processed demand cannot be at a price less than the clock price.

OEA and WTB will not permit a “switch” bid to reduce demand for one license in a market and increase demand for another license in the same market in Auction 113. OEA and WTB did not receive any comments on this issue. The inventory of licenses for Auction 113 contains only one market in which there are multiple licenses that may be considered similar, thus the additional bidding and system complexity necessary to permit switch bidding in this market is not worthwhile. A bidder that wants to bid on both licenses within the market that has two licenses could bid on these two licenses separately.

5. Intra-Round Bids

After the first round, bids to change demand can be made at prices between the start-of-round price and the clock price. These are known as intra-round bids. A bidder will be permitted to make intra-round bids by indicating the quantity it demands for the license (in this auction, one or zero) and a price between the start-of-round price and the clock price at which it wants to change its demand. For example, if a bidder has processed demand for a license at the start-of-round price of \$200, but no longer wants the license if the price increases by more than \$10, the bidder would indicate a bid quantity of zero at a price of \$210. Similarly, if the bidder wishes to reduce its demand to zero if the price increases at all above \$200, the bidder would indicate a bid quantity of zero at the start-of-round price of \$200.

Permitting intra-round bids allows the bidding system to use relatively large clock price increments, because bidders can submit bids at prices lower than the clock prices. This may reduce the number of rounds in the auction without increasing the risk that a large clock price increment will prevent the auction from accurately determining the market clearing price, at which only one bidder demands the license.

Intra-round bid amounts will be limited to multiples of \$10 for prices below \$10,000; to multiples of \$100 for prices between \$10,000 and \$100,000, inclusive; and to multiples of \$1,000 for prices above \$100,000. OEA and WTB limit intra-round bids to these multiples to deter anti-competitive strategic bidding.

6. Proxy Bids

OEA and WTB adopt their proposal, which is supported by the record, to make proxy bidding an option available to bidders in Auction 113. In the first round, a bidder may submit a proxy instruction to the bidding system for any license for which it submits a bid in the first round. After the first round, a bidder may submit a proxy instruction to the bidding system for any license for which it has processed demand. A proxy instruction for a license must indicate a reduction in demand for the license to zero at a price higher than the current round's clock price. Proxy instructions to increase a bidder's demand for a license at a given price will not be permitted.

Under the procedures OEA and WTB adopt here, if a proxy instruction has been submitted, the bidding system will automatically submit a proxy bid to maintain the bidder's demand for the license in every subsequent round as

long as the clock price for the round is less than the proxy instruction price. In the first round in which the clock price is greater than or equal to the proxy instruction price, the bidding system will submit a proxy bid on behalf of the bidder to reduce the bidder's demand for that license to zero at the proxy instruction price. For example, if a bidder has processed demand for a license with a clock price of \$1,000, and the bidder is willing to purchase the license for a price up to \$1,800, the bidder could submit a proxy instruction to reduce its demand for the license to 0 at \$1,800. In that case, the bidding system will submit proxy bids to maintain the bidder's demand for the license in each subsequent round as long as the clock price is less than \$1,800. In a round in which the clock price is above \$1,800, the bidding system will submit a proxy bid to reduce the bidder's demand for the license to zero at the price of \$1,800.

In the case that a bid to reduce demand, whether placed according to proxy instructions or submitted by the bidder in the round, is not applied during bid processing, the bidding system will automatically generate a proxy instruction at the bid price and, in the following rounds, submit proxy bids on behalf of the bidder according to that proxy instruction. For example, suppose that the start-of-round price for a license is \$10,000, the clock price is \$12,000, and a bidder with processed demand for the license submits a bid to reduce its demand to 0 at price \$11,500. If the bid is not applied during bid processing (e.g., because there were no other bids for the license in the round), in the following round the bidding system will submit a proxy bid on behalf of the bidder to reduce demand for the license to 0 at price \$11,500. The proxy instruction preserves in the bidding system the bidder's interest in retaining demand for the license only if the price is no higher than \$11,500, which may help avoid having the license sold later in the auction to another bidder at a price less than what the initial bidder would be willing to pay.

In any round, a bidder can remove or modify any existing proxy instructions or proxy bids for the round by submitting new bids through the user interface or file upload. The system will take the last bid submission as that bidder's bids and proxy instructions. Bidders are reminded that any bids submitted through an upload will replace all bids and proxy instructions previously submitted.

As is the case for intra-round bid amounts, proxy instruction prices will

be limited to multiples of \$10 for prices below \$10,000; to multiples of \$100 for prices between \$10,000 and \$100,000, inclusive; and to multiples of \$1,000 for prices above \$100,000. Proxy instructions will not be publicly released either during or after the auction.

Commenters agree that proxy bidding as proposed in the *Auction 113 Comment Public Notice* alleviates the burden and resources required to monitor a multiple-round auction. One commenter states that proxy bidding will also promote more efficient auction outcomes by reducing the risk of erroneous bids and allowing for more efficient use of bidder resources. Another commenter supports allowing proxy bidding, but suggests that OEA and WTB consider introducing conditional proxy bid increases in demand to allow a bidder to instruct the bidding system to bid on an additional license if its price falls below a certain level, claiming this approach would help bidders navigate the complexities of managing multiple licenses.

OEA and WTB conclude that adopting this commenter's proposal is unnecessary in an ascending clock auction because the posted prices and start-of-round prices never decrease from one round to the next. In the ascending clock auction managing substitutions between multiple licenses is already possible, for instance, by placing a bid to decrease demand on one license, and, if the bid to reduce demand is processed, placing a bid to increase demand for another license that has the same or fewer bidding units as the former license. This type of substitution does not require a proxy bid to increase demand. Proxy bids are not intended to relieve bidders of their responsibility to manage their bidding eligibility or to actively follow round-to-round changes in prices and aggregate demand. Furthermore, in the ascending clock auction, once a bidder has processed demand for a license, the bidder cannot ensure or guarantee that it will not win the license when the auction closes. Similarly, a bidder cannot ensure or guarantee that the price of a license will not continue to rise in future rounds, or that the relative price of a license compared to another license will not change in future rounds.

7. Missing Bids

Under the clock-1 auction format, if a bidder does not submit bids in the current round for all of the licenses for which it had processed demand in the previous round and does not have proxy instructions in place, the bidding system will consider those licenses to

have missing bids. Missing bids are treated by the bidding system as requests to reduce demand to zero at the start-of-round prices for the licenses with missing bids. If these requests are applied, then a bidder's bidding activity, and its bidding eligibility for the next round, may be reduced. A bidder can avoid having missing bids by either indicating its demand in every round or by entering appropriate proxy instructions.

G. Bid Processing

OEA and WTB adopt bid processing procedures that the bidding system will use after each round of bidding to process bids to change demand, to determine the *processed demand* of each bidder for each license, and to determine the *posted price* for each license that will serve as the start-of-round price for the next round. Bids to maintain demand will always be applied by the bidding system during bid processing.

1. No Excess Supply Rule for Bids To Reduce Demand

Under the clock-1 auction format, the bidding system will not allow a bidder to reduce its demand for a license if the reduction would cause aggregate demand to fall below one (the "no excess supply" rule). Therefore, if a bidder submits a bid to reduce its demand from one to zero for a license if the price should increase above the price in its bid, the bidding system will treat the bid as a request to reduce demand that will be applied only if the no excess supply rule would be satisfied.

OEA and WTB adopt the no excess supply rule for Auction 113. The no excess supply rule has been integral to the success of the clock auction since the clock auction was introduced at the Commission in the Broadcast Incentive Auction. One commenter proposes to introduce exceptions to the no excess supply rule, claiming it has created barriers for bidders in past auctions, but provides no examples to support this claim, which is counterintuitive on its face. The purpose of not allowing the use of withdrawals and proactive waivers in a clock auction is to reduce complexity and uncertainty about bidder demand for spectrum. The clock auction relies on identifying the point at which demand decreases to equal supply to determine prices. Allowing withdrawals, proactive waivers, or exceptions to the no excess supply rule would create uncertainty with respect to the exact level of bidder demand and would interfere with the basic clock price-setting and winner determination

mechanism. The no excess supply rule ensures that once there is demand for a license that the license will not then go unsold. The no excess supply rule makes it risky or costly for a bidder to engage in gamesmanship by increasing its demand for a license in one round, potentially causing the price of the license to increase for another bidder, and then reducing its demand for the license in a subsequent round. OEA and WTB agree that they should not introduce exceptions that are contrary to the underlying purpose of the rules, which is to protect the integrity of the auction.

2. Eligibility Rule for Bids To Increase Demand

The bidding system will not allow a bidder to increase its demand for a license if the total number of bidding units associated with all of the bidder's license demands exceeds the bidder's eligibility for the round. Therefore, if a bidder submits a bid to add a license for which it did not have processed demand in the previous round, the bidding system will treat the bid as a request to increase demand that will be applied only if it would not cause the bidder's processed activity to exceed its eligibility.

3. Processed Demand

OEA and WTB adopt the procedures described in the *Auction 113 Comment Public Notice* to determine the order in which the bidding system will process bids after a round ends. After a round ends, the bidding system will first consider and apply all bids to maintain demand at the clock price, and then it will process bids to change demand in order of price point, where the price point represents the percentage of the distance between the bid price and the start-of-round price, relative to the distance between the clock price and the start-of-round price. The bidding system will process bids to change demand in ascending order of price point across all licenses and all bidders, first by considering intra-round bids in order of price point and then, finally, bids at the clock price (*i.e.*, bids with a price point equal to 100%). As it considers each submitted bid during bid processing, the bidding system will determine whether there is excess demand for a license at that point in the processing in order to determine whether a bidder's request to reduce demand for that license can be applied. Likewise, the bidding system will evaluate the activity associated with the bidder's most recently determined demands at that point in the processing

to determine whether a request to increase demand can be applied.

If a bid can be applied, the licenses that the bidder holds at that point in the processing would be adjusted, and aggregate demand for the license would be recalculated accordingly. If the bid cannot be applied, the unfulfilled bid will be held in a queue, to be considered later during the current round's bid processing. The bidding system will then consider the bid submitted at the next lowest price point, and given the most recently determined demands of bidders, see if the bid can be applied. Note that the price point at which a bid is considered by the bidding system can affect whether the bid is applied, because at any given price point some bidders may request to increase demand for licenses while others may request reductions.

Every time a bid is applied, the unfulfilled bids held in the queue will be reconsidered, in the order of their price points. Bids that were not applied because demand would fall below one or because the bidder's processed activity would exceed its eligibility will be considered, again in price point order, if there should be excess demand or if the bidder's processed activity is reduced sufficiently later in the processing after other bids are processed.

This step of bid processing will conclude when all bids from the round have been processed and no unfulfilled bids held in the queue can be applied. The bidding system will then automatically generate a proxy instruction for each bid to reduce demand that was not applied. However, the bidding system will not carry over to the next round unfulfilled bid requests to increase demand. The bidding system will advise bidders about whether their bids were applied when round results are released.

4. Price Determination

As described in the *Auction 113 Comment Public Notice*, the bidding system further will determine, based on aggregate demand, the posted price for each license for the round, with a license's posted price serving as its start-of-round price for the next round. The price for a license will increase from round to round as long as there is excess demand for the license, but will not increase if either no bidder demands the license or if only a single bidder demands the license.

If, at the end of a round, aggregate demand for a license exceeds the supply of one, the posted price will equal the clock price for the round. If a reduction in demand was applied during the

round and caused demand for a license to fall to one, the posted price will be the highest price at which a reduction was applied for that license. If aggregate demand is zero, or if aggregate demand is one and no bid to reduce demand was applied for the license, then the posted price will equal the start-of-round price for the round. The range of acceptable bid amounts for the next round will be set by adding the percentage increment to the posted price.

Under the clock-1 auction format, if a bid to reduce demand is not applied, it is because there is no excess demand for the license and, therefore, the posted price will not increase. Hence, the posted price for a license will not be higher than the bid price of a bidder that makes a bid to reduce demand that cannot be applied.

After the bids of the round have been processed, if the stopping rule has not been met, the bidding system will announce clock prices to indicate a range of acceptable bids for the next round. Each bidder will be informed of the licenses for which it has processed demand and of the aggregate demand for each license.

5. Caps on Bidding Credits

Eligible applicants claiming either a small business or rural service provider bidding credit will be subject to specified caps on the total bidding credit discount that they may receive. For Auction 113, OEA and WTB adopt the bidding credit caps at the amounts proposed for the reasons discussed in the *Auction 113 Comment Public Notice*. Specifically, OEA and WTB adopt a \$25 million cap on the total bidding credit discount that may be awarded to an eligible small business, and a \$10 million cap on the total bidding credit discount that may be awarded to an eligible rural service provider in Auction 113. Additionally, to create parity among eligible small businesses and rural service providers competing against each other in smaller markets, no winning designated entity bidder may receive more than \$10 million in bidding credit discounts in total for licenses won in markets with a population of 500,000 or fewer.

Two commenters argue against adopting bidding credit caps in Auction 113. The Commission's part 1 rules, however, require a cap on a winning bid discount that will be offered to small businesses and rural service providers. See 47 CFR 1.2110(f)(2)(ii), (4)(ii). Amendments to those rules require a rulemaking proceeding and cannot be done in the context of establishing the procedures for Auction 113 because

such action is outside the scope of OEA's and WTB's delegated authority.

The record supports adopting the small business bidding credit cap and rural service bidding credit cap for Auction 113 at the amounts proposed, and OEA and WTB find this consistent with the Commission's decisions in recent spectrum auctions. In the 2015 *Updating Part 1 Report and Order*, the Commission adopted small business and rural service provider bidding credit caps and established the parameters for implementing such bidding credit caps in a given auction based on an evaluation of the expected capital requirements presented by the specific service and the inventory of licenses to be auctioned. The Commission's rules provide for a small business bidding credit cap of not less than \$25 million and a rural service provider bidding credit of not less than \$10 million, to be determined on an auction-by-auction basis.

Under the parameters established in the 2015 *Updating Part 1 Report Order*, OEA and WTB find that a \$25 million small business bidding credit cap for Auction 113 is appropriate because this is an auction of a limited number of AWS-3 licenses and the expected capital requirements associated with these AWS-3 licenses are not likely to be any higher than those for bands where OEA and WTB adopted the same \$25 million cap, given that many providers have already cleared, standardized, deployed, and offer service using other licenses in the same bands.

Some commenters disagree with this approach. One commenter, for example, proposes that the Commission increase the bidding credit caps to account for inflation, noting that a decade has passed since Auction 97 and, "according to the Bureau of Labor Statistics, \$25 million in November 2014 dollars would be worth more than \$33 million today." However, recent auction data demonstrate that a \$25 million cap on small business bidding credits has allowed a substantial majority of eligible small businesses to take advantage of the bidding credit program and be unaffected by the cap. Whatever the impact of inflation generally, OEA and WTB see no persuasive evidence that a \$25 million cap would impair the meaningful opportunity that the bidding credit provides for small businesses to participate in Auction 113.

One commenter argues that, in proposing to apply a \$25 million small business bidding credit cap, the "lens through which [OEA and WTB view] small business participation in Auction

113" is "out of focus" and OEA and WTB should instead draw on the results of Auction 97 to assess the capital requirements for Auction 113. This commenter reasons that the Auction 97 results demonstrate that a \$25 million small business bidding credit cap is "untenable," because Northstar Wireless, LLC (Northstar) and SNR Wireless LicenseCo, LLC (SNR) placed \$3.4 billion in winning bids for 197 of the licenses available in Auction 113, with the expectation that they would be eligible for \$859 million in bidding credits. OEA and WTB find this argument meritless inasmuch as the Commission's very purpose in requiring the implementation of a minimum small business bidding credit cap in all auctions that offer such a credit is to safeguard against the use of bidding credits by entities that are not *bona fide* small businesses, such as the applicants that were denied bidding credits in Auction 97. The fact that a bidder claiming eligibility for bidding credits in Auction 97 could have bid with an expectation of receiving close to \$1 billion in bidding discounts, as Northstar and SNR did, illustrates why the Commission established a cap on bidding credits that is reasonably proportional to the capital expenditures for spectrum licenses likely needed by *bona fide* small businesses, as well as the appropriateness of the caps set in the Commission's most recent auctions. Moreover, applying a reasonable bidding credit cap in Auction 97 such as the one OEA and WTB adopt for Auction 113 would have substantially lessened the financial impact of SNR's and Northstar's being found ineligible for the bidding credits that they claimed, and perhaps they would not have had the incentive to bid, in aggregate, so much more than they were ultimately willing to pay. As the Commission concluded in the 2015 *Updating Part 1 Report Order*, a \$25 million bidding credit cap provides a significant benefit to the vast majority of *bona fide* small businesses that may participate in Auction 113, particularly since applying the cap would allow a bidder eligible for a 25% discount to receive that discount on gross bids of up to \$100 million.

Nor are OEA and WTB persuaded by a commenter's proposal to introduce more complex bidding credit caps such as regional bidding credit caps that are a function of regional spectrum values, population density, median income, or broadband access disparities. Because the \$25 million bidding credit cap in recent auctions allowed the substantial majority of small business to realize the

full value of their bidding credit based on their gross winning bid amounts, OEA and WTB find it unnecessary to introduce other bidding credit caps in some regions that would increase complexity, make it more likely that a small business would be limited by some regional cap, and could create issues for bidders and the bidding system as a result of regional borders.

Based on the Commission's experience in its spectrum auctions, OEA and WTB also find a \$10 million rural service provider bidding credit cap is appropriate because, as the Commission explained in the 2015 *Updating Part 1 Report and Order*, a rural service provider's approach to bidding is generally more targeted and usually focuses on competing for a few select license areas that align with its existing service territory or adjacent areas.

Lastly, OEA and WTB find that a \$10 million cap on the overall bidding credit amount that any winning small business bidder may apply to licenses won in small markets is appropriate based on the Commission's conclusions in the 2015 *Updating Part 1 Report and Order*. This is consistent with the approach adopted in all of the Commission's spectrum actions beginning with the Broadcast Incentive Auction and strikes a measured and reasonable balance to protect against abuse of the designated entity program while also allowing large designated entities a higher cap in large service areas. One commenter proposes that rather than capping the bidding credits used by a designated entity for particular small markets based on population, OEA and WTB cap the bidding credits for rural service providers at the same level as that for small businesses. After considering the purpose and benefits of a rural service provider bidding credit, the Commission concluded in the 2015 *Updating Part 1 Report and Order* that rural service providers did not warrant as high a bidding credit as other designated entities. Given the different nature of their business plans and financial resources, it concluded that different bidding credit caps, and the methodology for implementing them in the Broadcast Incentive Auction, were warranted for small businesses and rural service providers. These different caps have been maintained for auctions subsequent to the Broadcast Incentive Auction. This commenter provides no evidence to support a finding that a different conclusion would be appropriate with respect to the AWS-3 licenses remaining in the Commission's spectrum inventory.

OEA and WTB conclude that the adoption of these caps on the overall amount of bidding credits offered in Auction 113 serves the Commission's statutory goals by awarding meaningful opportunities to *bona fide* small businesses and eligible rural service providers, while preventing unjust enrichment and ensuring efficient and intensive use of spectrum. Notably, by adopting these caps for Auction 113, OEA and WTB will provide an important additional safeguard, as the Commission intended, to prevent ineligible entities from undercutting the Commission's rules in a manner similar to circumstances of Auction 97. This approach is simple and straightforward to implement and will not impose an artificial restriction on the amount eligible small businesses and rural service providers are likely to bid.

6. Winning Bids

Under the clock-1 auction format, a bidder with processed demand for a license at the time the stopping rule is met will become the winning bidder for the license. The final price for a license will be the posted price for the final round.

VI. Post-Auction Procedures

The public notice announcing the close of the bidding and auction results will be released within several days after bidding has ended in Auction 113. This public notice will also establish the deadlines for submitting down payments, final payments, and the long-form applications (FCC Form 601) for the auction.

A. Down Payments

The Commission's rules provide that, unless otherwise specified by public notice, within 10 business days after the release of the auction closing public notice for Auction 113, each winning bidder must submit sufficient funds (in addition to its upfront payment) to bring its total amount of money on deposit with the Commission to 20% of the net amount of its winning bids (less any bidding credits, if applicable).

B. Final Payments

The Commission's rules provide that each winning bidder must submit the balance of the net amount for each of its winning bids within 10 business days after the deadline for submitting down payments.

C. Long-Form Application (FCC Form 601)

The Commission's rules provide that, within 10 business days after release of the auction closing public notice,

winning bidders must electronically submit a properly completed post-auction long-form application (FCC Form 601), including the applicable filing fee prescribed in 47 CFR 1.1102, for the license(s) they won through the auction.

A winning bidder claiming eligibility for a small business bidding credit or a rural service provider bidding credit must demonstrate its eligibility for the bidding credit sought in its FCC Form 601. Further instructions on these and other filing requirements will be provided to winning bidders in the auction closing public notice for Auction 113.

A winning bidder will also be required to provide as part of its long-form application any agreement or arrangement it has entered into and a summary of the specific terms, conditions, and parties involved in any agreement it has entered into. This applies to any bidding consortia, joint venture, partnership, or agreement, understanding, or other arrangement entered into relating to the competitive bidding process, including any agreement relating to the post-auction market structure. Failure to comply with the Commission's rules can result in enforcement action.

A winning bidder organized as bidding consortium must comply with the long-form application procedures set forth in 47 CFR 1.2107(g). Specifically, license(s) won by a consortium must be applied for as follows: (a) an individual member of the consortium or a new legal entity comprising two or more individual consortium members must file for licenses covered by the winning bids; (b) each member or group of members of a winning consortium seeking separate licenses will be required to file a separate FCC Form 601 for its/their respective license(s) in their legal business name; (c) in the case of a license to be partitioned or disaggregated, the member or group filing the applicable FCC Form 601 shall include the parties' partitioning or disaggregation agreement with the FCC Form 601; and (d) if a designated entity credit is sought (either small business or rural service provider), the applicant must meet the applicable eligibility requirements in the Commission's rules for the credit.

D. Ownership Disclosure Information Report (FCC Form 602)

Within 10 business days after the release of the *Auction 113 Closing Public Notice*, each winning bidder must also comply with the ownership reporting requirements in 47 CFR 1.913, 1.919, and 1.2112 by submitting an

ownership disclosure information report for wireless telecommunications services (FCC Form 602) with its FCC Form 601.

If a winning bidder already has a complete and accurate FCC Form 602 on file in the FCC's Universal Licensing System (ULS), then it is not necessary to file a new report, but the winning bidder must certify in its FCC Form 601 that the information on file with the Commission is complete and accurate. If the winning bidder does not have an FCC Form 602 on file, or if the form on file is not complete and accurate, then the winning bidder must submit a new one.

When a winning bidder submits an FCC Form 175, ULS automatically creates an ownership record. This record is not an FCC Form 602, but it may be used to pre-fill the FCC Form 602 with the ownership information submitted on the winning bidder's FCC Form 175 application. A winning bidder must review the pre-filled information and confirm that it is complete and accurate as of the filing date of the FCC Form 601 before certifying and submitting the FCC Form 602. Further instructions will be provided to winning bidders in the *Auction 113 Closing Public Notice*.

E. Tribal Lands Bidding Credit

A winning bidder that intends to use its license(s) to deploy facilities and provide services to qualifying Tribal lands that have a wireline penetration rate equal to or below 85% may be eligible to receive a Tribal lands bidding credit as set forth in 47 CFR 1.2107 and 1.2110(f). A Tribal lands bidding credit is in addition to, and separate from, any other bidding credit for which a winning bidder may qualify.

Unlike other bidding credits that are requested prior to an auction, a winning bidder applies for a Tribal lands bidding credit after the auction when it files its FCC Form 601. When initially filing its FCC Form 601, the winning bidder will be required to advise the Commission whether it intends to seek a Tribal lands bidding credit, for each license won in a particular auction, by checking the designated box(es). After stating its intent to seek a Tribal lands bidding credit, the winning bidder will have 180 days from the close of the applicable long-form application filing deadline within which to amend its application to select the specific qualifying Tribal lands to be served and provide the required Tribal government certifications. A licensee receiving a Tribal lands bidding credit is subject to performance criteria as set forth in 47 CFR 1.2110(f)(3)(vii). For additional

information on the Tribal lands bidding credit, including how the amount of the credit is calculated, applicants should review the Commission's rulemaking proceeding regarding Tribal lands bidding credits and related public notices.

F. Default and Disqualification

Any winning bidder that defaults or is disqualified after the close of an auction (*i.e.*, fails to remit the required down payment by the specified deadline, fails to submit a timely long-form application, fails to make a full and timely final payment, or is otherwise disqualified) is liable for default payments as described in 47 CFR 1.2104(g)(2). A default payment consists of a deficiency payment, equal to the difference between the amount of the bidder's winning bid and the amount of the winning bid the next time a license covering the same spectrum is won in an auction, plus an additional payment equal to a percentage of the defaulter's bid or of the subsequent winning bid, whichever is less.

The Commission's rules provide that, in advance of each auction, it will establish a percentage between 3% and 20% of the applicable winning bid to be assessed as an additional default payment. As the Commission has indicated, the level of this additional payment in each auction will be based on the nature of the service and the licenses being offered. In the *Auction 113 Comment Public Notice*, OEA and WTB proposed to set the additional default payment for Auction 113 at 15% of the applicable bid for winning bids. One commenter, however, opposes the proposed 15% additional default payment percentage, arguing instead that OEA and WTB should implement the maximum default payment percentage of 20% to ensure that defaults that occurred in Auction 97 are not repeated. Another commenter opposes this request, claiming that it is designed to discourage competitor participation in Auction 113.

As the Commission has previously emphasized, defaults weaken the integrity of the auction process and may impede the deployment of service to the public. Due to prior defaults, the AWS-3 spectrum being offered in Auction 113 has been in the Commission's inventory for a full decade after it was first offered in Auction 97. OEA and WTB therefore agree that it is important to take steps to minimize the chance of defaults on winning bids in this auction. OEA and WTB disagree with the assertion that implementing a 20% additional default payment would serve only to discourage participation in the auction. This

commenter does not explain how adopting a higher additional default payment to discourage insincere bidding and defaults by bidders who are unable to pay their full bid amount would discourage bidding by sincere bidders who have adequate financing to pay their full bids. And in any case, whatever deterrent effect the higher default payment amount may or may not have would be outweighed by the public interest in encouraging only sincere bidding. OEA and WTB conclude that a higher additional default payment will be more effective in deterring defaults in Auction 113 and therefore adopt the maximum additional default payment percentage of 20% for this auction.

Finally, in the event of a default, the Commission has the discretion to re-auction the license or offer it to the next highest bidder (in descending order) at its final bid amount. In addition, if a default or disqualification involves gross misconduct, misrepresentation, or bad faith by an applicant, then the Commission may declare the applicant and its principals ineligible to bid in future auctions and may take any other action that it deems necessary, including institution of proceedings to revoke any existing authorizations held by the applicant.

G. Refund of Remaining Upfront Payment Balance

If a bidder is due a refund, the bidder must request a refund in writing with the information listed below. All refunds of upfront payment balances will be returned to the payer of record as identified on the FCC Form 159, or on the wire transfer, unless the payer submits written authorization instructing otherwise. Bidders are encouraged to use the Refund icon found in the *Review or Modify Existing Applications* table on the *FRN Selection* screen or the Refund Form link available on the *Auction Application Submit Confirmation* page in the AAP to access the form. After the required information is completed on the blank form, the form should be printed and signed, and submitted to the Commission by fax or email.

If you have elected not to access the Refund Form, the Commission is requesting that all of the following information be supplied in writing:

Name, address, contact and phone number of Bank
ABA Number (capable to accept ACH payments)
Account Number to Credit
Name of Account Holder
FCC Registration Number (FRN)

All refund requests must be submitted by fax to the Revenue & Receivables Operations Group/Auctions at (202) 418–2843, or by email to RROGWireFaxes@fcc.gov.

Note: Refund processing generally takes up to two weeks to complete. Bidders with questions about refunds should contact Scott Radcliffe at (202) 418–7518 or Theresa Meeks at (202) 418–2945.

VII. Procedural Matters

A. Paperwork Reduction Act Analysis

The Office of Management and Budget (OMB) has approved the information collections in the Application to Participate in an FCC Auction, FCC Form 175. The *Auction 113 Procedures Public Notice* does not contain new or substantively modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. Therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198. The Commission will be submitting a non-substantive change request to OMB concerning OMB 3060–0600 related to the certification requirement and the acknowledgment statement for Auction 113 applicants adopted in the *Auction 113 Procedures Public Notice*, and the Commission will not require Auction 113 applicants to make this certification or submit the acknowledgement statement in FCC Form 175 until OMB has approved the non-substantive change request.

B. Congressional Review Act

The Commission has determined, and Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, concurs, that this rule is “non-major” under the Congressional Review Act, 5 U.S.C. 804(2). The Commission will send a copy of the *Auction 113 Procedures Public Notice* to Congress and the Government Accountability Office pursuant to 5 U.S.C. 801(a)(1)(A).

C. Final Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act of 1980, as amended (RFA), OEA and WTB incorporated a Supplemental Initial Regulatory Flexibility Analysis (Supplemental IRFA) in the *Auction 113 Comment Public Notice* released in March 2025. OEA and WTB sought written public comment on the proposals in the *Auction 113 Comment Public Notice*, including comments on the

Supplemental IRFA. The comments received on the Supplemental IRFA are addressed below. The *Auction 113 Procedures Public Notice* establishes the procedures to be used for Auction 113. This Final Regulatory Flexibility Analysis (FRFA) reflects actions taken in the *Auction 113 Procedures Public Notice*, and supplements the Final Regulatory Flexibility Analyses completed by the Commission in the 2014 AWS–3 Report and Order, the 2025 AWS–3 Report and Order, and other Commission orders pursuant to which Auction 113 will be conducted. This FRFA conforms to the RFA, and it (or summaries thereof) will be published in the **Federal Register**.

Need for, and Objectives of, the Rules. The *Auction 113 Procedures Public Notice* resolves all open issues, and addresses comments filed in response to the *Auction 113 Comment Public Notice*. The licenses in Auction 113 are being offered pursuant to the Spectrum and Secure Technology and Innovations Act, which directs the Commission to initiate a system of competitive bidding to grant licenses for spectrum in its inventory in the AWS–3 spectrum bands. The *Auction 113 Procedures Public Notice* implements auction procedures for those entities that seek to bid in Auction 113 to acquire geographic-based licenses in the 1695–1710 MHz, 1755–1780 MHz, and 2155–2180 MHz bands (collectively, the AWS–3 bands). The *Auction 113 Procedures Public Notice* adopts procedural rules and terms and conditions governing Auction 113, and the post-auction application and payment processes, as well as sets the minimum opening bid amounts for licenses in the AWS–3 bands that will be offered in Auction 113.

To promote the efficient and fair administration of the competitive bidding process for all Auction 113 participants, including small entities, OEA and WTB adopt the following procedures for Auction 113:

- A requirement that any applicant seeking to participate in Auction 113 certify in its short-form application, under penalty of perjury, that it has read the public notice adopting procedures for Auction 113 and that it has familiarized itself with those procedures and the requirements for a license and operating facilities in the AWS–3 bands;
- A requirement that any applicant seeking to bid in the 1755–1780 MHz submit a signed statement with its short-form application acknowledging that the applicant’s operations in the 1755–1780 MHz band may be subject to interference from Federal systems in certain geographic zones, that the

applicant must accept interference from such Federal systems in those zones, and that the applicant has considered these risks before submitting any bids for applicable licenses in Auction 113;

- Identification of AT&T, T-Mobile, and Verizon as nationwide providers for the purpose of implementing the competitive bidding rules in Auction 113, including 47 CFR 1.2105(c), the rule prohibiting certain communications;

- Use of anonymous bidding/limited information procedures, under which OEA and WTB will not make the following information public until after bidding has closed: (1) the licenses that an applicant selects for bidding in its short-form application (FCC Form 175); (2) the amount of any upfront payment made by or on behalf of an applicant for Auction 113; (3) any applicant’s bidding eligibility; and (4) any other bidding-related information that might reveal the identity of the bidder placing a bid;

- Establishment of bidding credit caps for eligible small businesses in Auction 113;

- Establishment of bidding credit caps for eligible rural service providers in Auction 113;

- Use of a clock auction format (clock-1) with a supply of one for Auction 113 under which each qualified bidder will indicate in successive clock bidding rounds its demand for licenses at the prices associated with the current round;

- Use of a simultaneous stopping rule for Auction 113, under which all licenses remain available for bidding until no license has excess demand;

- Establishment of a specific minimum opening bid for each license available in Auction 113 based on \$0.01 per MHz-pop for the paired licenses in areas with a population of less than 300,000, \$0.02 per MHz-pop for the paired licenses in areas with a population of at least 300,000 and less than 1,000,000, \$0.05 per MHz-pop for the paired licenses in areas with a population of at least 1,000,000, and \$0.01 per MHz-pop for the unpaired licenses, with a minimum opening bid of \$1,000 per license;

- A specific upfront payment amount for each license available in Auction 113;

- Establishment of a bidder’s initial bidding eligibility in bidding units based on that bidder’s upfront payment through assignment of a specific number of bidding units for each license;

- Provision of delegated authority to OEA, in conjunction with WTB, to exercise its discretion to delay, suspend, or cancel bidding in Auction 113 for any reason that affects the ability of the

competitive bidding process to be conducted fairly and efficiently;

- Retention by OEA of discretion to adjust the bidding schedule in order to manage the pace of Auction 113;
- Use of information procedures which would make public after each round of Auction 113, for each license, the aggregate demand, the posted price of the last completed round, and the clock price for the next round;
- Use of an activity rule that would require bidders to be active on between 90% and 100% of their bidding eligibility in all clock rounds, with the initial activity requirement percentage set at 95%, and with OEA retaining discretion to change the activity requirement percentage during the auction;
- Establishment of acceptable bid amounts, including clock price increments and intra-round bids, along with a proposed methodology for calculating such amounts;
- An option to permit a bidder to submit a proxy instruction to reduce its demand for a license to zero at a price higher than the current round's clock price and a requirement that bidders indicate their demand in every round or submit appropriate proxy instructions;
- Establishment of a methodology for processing bids and requests to reduce and increase demand subject to the no excess supply rule for bids to reduce demand and the eligibility rule for bids to increase demand; and
- Establishment of an additional default payment of 20% under 47 CFR 1.2104(g)(2) of the rules in the event that a winning bidder defaults or is disqualified after the auction.

The procedures for the conduct of Auction 113 constitute the more specific implementation of the competitive bidding rules contemplated by 47 CFR parts 1 and 27, and the underlying rulemaking orders, including the 2014 AWS-3 Report and Order, the 2025 AWS-3 Report and Order, and relevant competitive bidding orders, and are fully consistent therewith.

Response to Comments by the Chief Counsel for Advocacy of the Small Business Administration. Pursuant to the Small Business Jobs Act of 2010, which amended the RFA, the Commission is required to respond to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA) and provide a detailed statement of any changes made to the proposed procedures as a result of those comments. The Chief Counsel did not file any comments in response to the procedures that were proposed in the *Auction 113 Comment Public Notice*.

Summary of Significant Issues Raised by Public Comments in Response to the IRFA. The only party that filed comments directly in response to the Supplemental IRFA contends that the Commission's definition of "small entities" used in the Supplemental IRFA "may unintentionally exclude businesses in high-cost urban markets" because "while these businesses fall outside the thresholds for 'small entities,' they often face challenges similar to those in rural areas, such as high operational costs and limited resources." That commenter suggests that the Commission "reevaluate its small entity criteria by considering factors like regional cost variations and market-specific metrics (e.g., population density, median income, broadband access) . . . [to] better align with [47 U.S.C.] 309(j)(3)(B)'s goal of promoting diverse participation and equitable access to spectrum," and notes that the Supplemental IRFA highlights the compliance burdens that Auction 113 could impose and suggests that a more detailed analysis of these costs—broken down by market type or industry—would help uncover the unique challenges small businesses in underserved markets face. That commenter submits that providing tools such as reporting templates, compliance checklists, and cost estimation guides would further support small entities, reduce administrative burdens, and enable broader participation in Auction 113.

Other parties filed comments relating to small entities in response to the proposals in the *Auction 113 Comment Public Notice*. Two parties advocate that licenses for AWS-3 spectrum should be offered in smaller licensing areas in Auction 113, with one of these parties specifically asserting that small businesses would benefit from changing the geographic area of Block G to offering licenses at a county level rather than the CMA level. Several parties opposed the request to change the geographic area size of Block G from CMAs to counties. Some commenters oppose any amendments to small business bidding credits in effect for Auction 97 for Auction 113. In these comments, there were two prevailing themes of discussion: (1) the application of the 47 CFR part 1, subpart Q small business bidding rules in effect for Auction 97, and (2) the proposal for a \$25 million bidding credit cap for Auction 113. Regarding the application of 47 CFR part 1, subpart Q small business bidding rules, two parties specifically advocate for applying the 47 CFR part 1, subpart Q designated entity

rules in effect for Auction 97 in Auction 113 because they contend that any rule changes will be to the detriment of small businesses, amongst other concerns unrelated to small businesses. Regarding the proposal to apply a \$25 million small business bidding credit cap in Auction 113, all parties commenting on the proposal oppose it. All of these parties oppose any bidding credit cap, however, one of these parties advocates for an increase of the bidding credit cap to \$33 million in order to adjust the bidding credit cap to account for inflation if bidding credit caps are adopted for Auction 113. Additionally, one party opposes the proposed 95% activity level to retain full eligibility, because although it encourages active participation, it may unintentionally exclude less experienced bidders and small entities that lack the resources to engage dynamically in every round.

Description and Estimate of the Number of Small Entities to Which the Rules Will Apply. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "Small organization, and "small governmental jurisdiction." In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act (SBA). A "small business concern" is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA. The SBA establishes small business size standards that agencies are required to use when promulgating regulations relating to small businesses; agencies may establish alternative size standards for use in such programs, but must consult and obtain approval from SBA before doing so.

The Commission's actions, over time, may affect small entities that are not easily categorized at present. The Commission therefore describes three broad groups of small entities that could be directly affected by its actions. In general, a small business is an independent business having fewer than 500 employees. These types of small businesses represent 99.9% of all businesses in the United States, which translates to 34.75 million businesses. Next, "small organizations" are not-for-profit enterprises that are independently owned and operated and not dominant in their field. While the Commission does not have data regarding the number of non-profits that meet that

criteria, over 99 percent of nonprofits have fewer than 500 employees. Finally, “small governmental jurisdictions” are defined as cities, counties, towns, townships, villages, school districts, or special districts with populations of less than fifty thousand. Based on the 2022 U.S. Census of Governments data, the Commission estimates that at least 48,724 out of 90,835 local government jurisdictions have a population of less than 50,000.

The procedures adopted in the *Auction 113 Procedures Public Notice*

will apply to small entities in the industries identified in the chart below by their six-digit North American Industry Classification System (NAICS) codes and corresponding SBA size standard. The NAICS is the standard used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy. See www.census.gov/NAICS for further details regarding the NAICS codes. The

size standards in Table 1 are set forth in 13 CFR 121.201, by six digit NAICS code. Based on currently available U.S. Census data regarding the estimated number of small firms in each identified industry, OEA and WTB conclude that the adopted procedures will impact a substantial number of small entities. Where available, OEA and WTB also provide additional information regarding the number of potentially affected entities in the industries identified in Tables 1 and 2.

TABLE 1—2022 U.S. CENSUS BUREAU DATA BY NAICS CODE

Regulated industry (NAICS classification)	NAICS code	SBA size standard	Total firms	Small firms	% Small firms in industry
Satellite Telecommunications	517410	\$47 million	275	242	88.00
Wireless Telecommunications Carriers (except Satellite)	517112	1,500 employees	2,893	2,837	98.06

TABLE 2—TELECOMMUNICATIONS SERVICE PROVIDER DATA

2024 Universal Service Monitoring Report Telecommunications Service provider data (data as of December 2023)	SBA size standard (1,500 employees)		
	Total number FCC Form 499A filers	Small firms	% Small entities
Affected entity			
Wireless Telecommunications Carriers (except Satellite)	585	498	85.13

Description of Economic Impact and Projected Reporting, Recordkeeping and Other Compliance Requirements for Small Entities. The RFA directs agencies to describe the economic impact of proposed rules on small entities, as well as projected reporting, recordkeeping and other compliance requirements, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record. The Commission designed the auction application process to minimize reporting and compliance requirements for small entities and other applicants, and the *Auction 113 Procedures Public Notice* reflects its efforts to remain consistent with this approach. In the first part of the Commission’s two-phased auction application process, parties desiring to participate in an auction file streamlined, short-form applications in which they certify under penalty of perjury as to their qualifications, and to having reviewed the *Auction 113 Procedures Public Notice*. Eligibility to participate in bidding is based on an applicant’s short-form application and certifications, as well as remittance of a timely and sufficient upfront payment. In the second phase of the process, winning bidders file a more comprehensive long-

form application. Thus, an applicant that fails to become a winning bidder does not need to file a long-form application or provide the additional showings and more detailed demonstrations required of a winning bidder, thereby saving small entities and other applicants the time and expense associated with unnecessary filings.

Applicants that wish to participate in Auction 113 are required to certify that they have read the *Auction 113 Procedures Public Notice* and the procedures adopted herein, and are also familiar with the procedures and requirements for obtaining a license and operating facilities in the AWS–3 bands. The certification requirement allows applicants to educate themselves about the procedures for participation in Auction 113, as well as their obligation to stay abreast of relevant information before bidding in Auction 113 begins, and throughout the entire Auction 113 process. Adoption of this requirement may help small entities and other applicants avoid, among other things, rule violations or technical errors that could prevent them from becoming a qualified bidder or obtaining a license after placing a winning bid. Moreover, as discussed below, the Commission makes available to potential and actual participants, at no cost, a variety of information, resources, and guidance,

including interactive, online tutorials and technical guides. The requirement that applicants certify that they have read the *Auction 113 Procedures Public Notice* and are familiar with the procedures and requirements for the auction will help ensure that small entity applicants are aware that these detailed educational materials, which are designed to enhance their understanding of the pre-bidding and bidding processes, are available for their use.

OEA and WTB do not expect that the processes and procedures adopted in the *Auction 113 Procedures Public Notice* will require small entities to hire attorneys, engineers, consultants, or other professionals to participate in Auction 113 and comply with the procedures they adopt. Moreover, OEA and WTB do not believe that the cost of compliance will unduly burden small entities that choose to participate in the auction. The processes and procedures adopted in the *Auction 113 Procedures Public Notice* are consistent with existing Commission policies and procedures used in prior auctions. Thus, some small entities may already be familiar with such procedures and have the processes and procedures in place to facilitate compliance and minimize their costs to comply. Even for those small entities that may be new to the

Commission's auction process, the various resources that will be made available, including, but not limited to, the mock auction, remote electronic bidding, and access to hotlines for both technical and auction assistance, should help facilitate participation without the need to hire professionals. These resources are in addition to the resources discussed in the *Auction 113 Procedures Public Notice* that small entities and other applicants will be able to access. By providing these resources as well as the resources discussed below, OEA and WTB expect small entities that use the available resources to experience lower participation and compliance costs.

Discussion of Steps Taken to Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered. The RFA requires an agency to provide "a description of the steps the agency has taken to minimize the significant economic impact on small entities . . . including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected."

In the *Auction 113 Procedures Public Notice*, OEA and WTB have taken steps to minimize any economic impact of the Commission's auction procedures on small businesses through, among other things, the many resources provided to potential auction participants. Consistent with the past practices in prior auctions, small entities that are potential participants will have access to detailed educational information and Commission personnel to help guide their participation in Auction 113, which should alleviate any need to hire professionals. Only one party filed comments in response to the *Auction 113 Comment Public Notice* regarding the Commission's provision of these materials. In reaching their conclusions in the *Auction 113 Procedures Public Notice*, OEA and WTB considered the alternatives presented in this party's comments. For example, this party advocates for additional educational support in the form of personalized and interactive tools claiming that the available educational materials are often too generalized for bidders, particularly small entities, to apply to their particular circumstances, also suggests that the Commission provide a more detailed analysis, including additional educational resources, of the costs of compliance with the Supplemental IRFA to further support small

businesses in underserved markets. By this party's own acknowledgement, however, the Commission's educational resources are "valuable components" to a "demonstra[ble] commitment to equipping participants with the tools they need for Auction 113."

To assist small entities with the AAS and the bidding system in Auction 113, the Commission currently offers a wide variety of free educational materials, demonstrations, educational opportunities, and other information and resources. For example, small entities and other would-be participants will also be provided with various materials on the pre-bidding process in advance of the short-form application filing window, which includes step-by-step instructions on how to complete FCC Form 175. The Commission has taken steps to ensure that the AAS is simple to use, and that FCC Form 175 is easy to complete. For example, if an applicant for Auction 113 previously filed an FCC Form 602 ownership disclosure information report or filed an application to participate in a previous auction in which ownership information was disclosed and the applicant uses the same FRN used to make that filing to create its FCC Form 175 for Auction 113, the AAS will give the applicant the option to pre-fill the most current ownership information contained in any such filing into certain ownership sections on the applicant's FCC Form 175. Accordingly, in light of all the educational resources the Commission already provides to bidders in an auction, OEA and WTB conclude that the added benefit, if any, of developing alternative personalized and interactive educational tools in time for Auction 113 is outweighed by the time and expense that the Commission would incur to customize such resources.

In addition, small entities will have access to the web-based, interactive online tutorials produced by Commission staff to familiarize themselves with auction procedures, filing requirements, bidding procedures, and other matters related to an auction.

Prior to the start of bidding, eligible bidders will be given an opportunity to become familiar with auction procedures and the bidding system by participating in a mock auction. Eligible bidders will have access to a user guide for the bidding system, bidding file formats, and an online bidding procedures tutorial in advance of the mock auction. Further, OEA and WTB will conduct Auction 113 electronically over the internet using a web-based bidding system that eliminates the need for small entities and other bidders to be

physically present in a specific location. These mechanisms are made available to facilitate participation in Auction 113 by all eligible bidders and may result in significant cost savings for small entities that use them. Moreover, the adoption of bidding procedures in advance of the auction, consistent with statutory directive, is designed to ensure that the auction will be administered predictably and fairly for all participants, including small businesses. These steps provide measures to prepare and support the ability of a small business to comprehend the Commission's bidding rules, including the rules relating to the proposal for a 95% activity level to retain full eligibility in auction rounds. Given the steps they have taken, OEA and WTB decline to adopt the alternative proposal offered by a commenter to lower the activity rule threshold.

Small entities and other auction participants may seek clarification of, or guidance on, complying with competitive bidding rules and procedures, reporting requirements, and using the bidding system at any stage of the auction process. Additionally, the FCC Auctions Hotline will provide small entities one-on-one access to Commission staff for information about the auction process and procedures. Further, the FCC Auctions Technical Support Hotline is another resource that provides technical assistance to applicants, including small entities, on issues such as access to or navigation within the electronic FCC Form 175 and use of the bidding system.

The Commission also makes various databases and other sources of information, including the Auctions program websites and copies of Commission decisions, available to the public without charge, providing a low-cost mechanism for small entities to conduct research prior to and throughout the auction. Prior to the start of bidding, and at the close of Auction 113, OEA and WTB will post public notices on the Commission's Auctions website that articulate the procedures and deadlines for the auction. The Commission makes this information easily accessible and without charge to benefit small entities and other Auction 113 applicants, including small entities, thereby lowering their administrative costs to comply with the Commission's competitive bidding rules.

After the initial application stage, auction participants whose applications have been deemed incomplete have the opportunity to correct certain errors. An applicant whose application is deemed incomplete will receive a letter from the

Commission identifying the specific errors in their application and providing the contact information for a specific Commission staff member who has been assigned to provide assistance. Additionally, after the application process is complete and the Commission has identified the applicants who will be qualified to bid in Auction 113, all qualified bidders for Auction 113 will automatically be registered for the auction, and registration materials will be distributed prior to the auction by overnight delivery. Applicants are not required to take any further steps until bidding commences.

Another step taken to minimize the economic impact for small entities participating in Auction 113 is the Commission's adoption of bidding credits for small businesses and rural service providers. OEA and WTB received comments discussing the adoption of bidding credits for small businesses and rural service providers and the application of the 47 CFR part 1, subpart Q bidding credit rules as in effect for Auction 97 in Auction 113. These discussions of eligibility for small business bidding credits were resolved in the *2025 AWS-3 Report and Order*. In accordance with the service rules applicable to the AWS-3 band licenses to be offered in Auction 113, bidding credit discounts will be available to eligible small businesses and small business consortia on the following basis: (1) a bidder with attributed average annual gross revenues that do not exceed \$55 million for the preceding five years is eligible to receive a 15% discount on its overall payment; or (2) a bidder with attributed average annual gross revenues that do not exceed \$20 million for the preceding five years is eligible to receive a 25% discount on its overall payment. Eligible applicants can receive only one of the available small business bidding credits—not both.

An eligible rural service provider may request a 15% discount on its overall payment using a rural service provider bidding credit. To be eligible for a rural service provider bidding credit, an applicant must: (1) be a service provider that is in the business of providing commercial communications services and, together with its controlling interests, affiliates, and the affiliates of its controlling interests, has fewer than 250,000 combined wireless, wireline, broadband, and cable subscribers; and (2) serve predominantly rural areas. Rural areas are defined as counties with a population density of 100 or fewer persons per square mile. Eligible applicants can request either a small business bidding credit or a rural

service provider bidding credit, but not both.

The total bidding credit discount that may be awarded to an eligible small business is capped at \$25 million and there is a \$10 million cap that may be awarded to a rural service provider. In addition, to create parity among eligible small businesses and rural service providers competing against each other in smaller markets, OEA and WTB adopt a \$10 million cap on the overall amount of bidding credits that any winning designated entity bidder may apply to winning licenses in markets with a population of 500,000 or less. Based on the technical characteristics of AWS-3 licenses and their analysis of past auction data, OEA and WTB anticipate that the caps adopted in the *Auction 113 Procedures Public Notice* will allow the majority of small businesses to take full advantage of the bidding credit program, thereby lowering the relative costs of participation for small businesses. While eligible entities will have the opportunity to compete at auction without being unduly constrained, the caps are reasonable enough to ensure that ineligible entities are not encouraged to undercut the Commission's rules, thereby achieving the Commission's dual statutory goals of benefiting designated entities and at the same time preventing unjust enrichment. In Auction 113, bidding credit caps were adopted not only because OEA and WTB are required to do so by 47 CFR part 1, subpart Q, but also because bidding credit caps provide safeguards for both the Commission and small entities and other Auction 113 bidders. Therefore, OEA and WTB rejected the alternatives received in comments opposing the bidding credit cap as proposed, including those opposing any form of a bidding credit cap as well as those opposing proposals for an increase. Likewise, OEA and WTB are unable to consider any changes to the geographic size of licenses offered in Auction 113, as proposed by a commenter and supported by another commenter, because the Commission adopted the use of CMAs for AWS-3 spectrum licenses in the context of a rulemaking and amending that decision is outside the scope of OEA's and WTB's delegated authority to establish auction procedures.

A Tribal lands bidding credit will also be available to winning bidders that intend to deploy facilities and provide services to qualifying Tribal lands that have a wireline penetration rate equal or below 85%. The Tribal lands bidding credit is in addition to, and separate from, any other bidding credit winning

bidders may qualify to claim. Therefore, small entities that are eligible for the small or rural bidding credit can also claim the Tribal lands bidding credit, provided they meet the requirements of 47 CFR 1.2107 and 1.2110(f).

The procedures for the conduct of Auction 113 constitute the more specific implementation of the competitive bidding rules contemplated by 47 CFR parts 1 and 27 and the underlying rulemaking orders, including the *2014 AWS-3 Report and Order*, the *2025 AWS-3 Report and Order*, and relevant competitive bidding orders, and are fully consistent therewith.

Report to Congress. The Commission will send a copy of the *Auction 113 Procedures Public Notice*, including this FRFA, in a report to Congress pursuant to the Congressional Review Act. In addition, the Commission will send a copy of the *Auction 113 Procedures Public Notice*, including this FRFA to the Chief Counsel for Advocacy of the SBA and will publish a copy of the *Auction 113 Procedures Public Notice* and the FRFA (or summaries thereof) in the **Federal Register**.

Federal Communications Commission.

Gary Michaels,

Deputy Chief, Auctions Division, Office of Economics and Analytics.

[FR Doc. 2025-23785 Filed 12-22-25; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 25-1062; FR ID 323503]

Radio Broadcasting Services; Various Locations

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document amends the Table of FM Allotments, of the Federal Communications Commission's (Commission) rules, by reinstating certain channels as a vacant FM allotment in various communities. The FM allotments were previously removed from the FM Table because a construction permit and/or license was granted. These FM allotments are now considered vacant because of the cancellation of the associated FM authorizations or the dismissal of long-form auction FM applications. A staff engineering analysis confirms that all of the vacant FM allotments complies with the minimum distance separation requirements and principle community coverage requirements of the

Commission's rules. The window period for filing applications for these vacant FM allotments will not be opened at this time. Instead, the issue of opening these allotments for filing will be addressed by the Commission in subsequent order.

DATES: Effective December 23, 2025.

FOR FURTHER INFORMATION CONTACT:

Rolanda F. Smith, Media Bureau, (202) 418-2054, Rolanda-Faye.Smith@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Order*, adopted December 16, 2025, and released December 17, 2025. The full text of this Commission decision is available online at <https://apps.fcc.gov/ecfs/>. The full text of this document can also be downloaded in Word or Portable Document Format (PDF) at <https://www.fcc.gov/edocs>. This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104-13. The Commission will not send a copy of the *Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A), because these allotments were previously reported.

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

Federal Communications Commission.

Nazifa Sawez,

Assistant Chief, Audio Division, Media Bureau.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

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

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

■ 2. In § 73.202(b), amend table 1 (Table of FM Allotments) by:

- a. Adding the entry for “Eufaula” in alphabetical order under Alabama;
- b. Revising the entry for “Coalinga” in alphabetical order under California;
- c. Adding the entry for “Port St. Joe” in alphabetical order under Florida;
- d. Adding the entry for “Warrenton” in alphabetical order under Georgia;
- e. Revising the entry for “Grand Marais” in alphabetical order under Minnesota;
- f. Adding the entry for “Vardaman” in alphabetical order under Mississippi;

■ g. Adding the entry for “Jefferson City” in alphabetical order under Missouri;

■ h. Adding the entry for “Conrad” in alphabetical order under Montana;

■ i. Adding the entry for “Hatteras” in alphabetical order under North Carolina;

■ j. Adding the entry for “Meyersdale” in alphabetical order under Pennsylvania;

■ k. Adding the entry for “New Ellenton” in alphabetical order under South Carolina;

■ l. Under Texas:

■ i. Revising the entry for “Big Lake” in alphabetical order;

■ ii. Adding the entry for “Farwell” in alphabetical order; and

■ iii. Revising the entries for “Junction” and “Lockney” in alphabetical order.

The additions and revisions read as follows:

§ 73.202 Table of Allotments.

* * * * *

(b) * * *

TABLE 1 TO PARAGRAPH (b)

[U.S. States]

Channel No.				
Alabama				
* * * * *				
Eufaula	250A.			
* * * * *				
California				
* * * * *				
Coalinga	247A, 261B.			
* * * * *				
Florida				
* * * * *				
Port St. Joe	229C2.			
* * * * *				
Georgia				
* * * * *				
Warrenton	226A.			
* * * * *				
Minnesota				
Grand Marais	237C1, 245C2.			

TABLE 1 TO PARAGRAPH (b)—
Continued
[U.S. States]

Channel No.				
* * * * *				
Mississippi				
* * * * *				
Vardaman	258A.			
* * * * *				
Missouri				
* * * * *				
Jefferson City	281A.			
* * * * *				
Montana				
Conrad	229C1.			
* * * * *				
North Carolina				
Hatteras	233C1.			
* * * * *				
Pennsylvania				
* * * * *				
Meyersdale	227A.			
* * * * *				
South Carolina				
New Ellenton	274A.			
* * * * *				
Texas				
* * * * *				
Big Lake	246A, 252C1, 281C1, 296C3.			
* * * * *				
Farwell	252C1.			
* * * * *				
Junction	263A, 290A, 297C3.			
* * * * *				
Lockney	271A.			
* * * * *				

[FR Doc. 2025-23750 Filed 12-22-25; 8:45 am]

BILLING CODE 6712-01-P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 622**

[Docket No. 200124–0029]

RTID 0648–XF398

Reef Fish Fishery of the Gulf of America; 2026 Red Snapper Private Angling Component Closure in Federal Waters Off Texas

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS announces a closure for the 2026 fishing season for the red snapper recreational private angling component in the exclusive economic zone (EEZ) off Texas in the Gulf of America (Gulf) through this temporary rule. The red snapper recreational private angling component in the Gulf EEZ off Texas will close at 12:01 a.m., local time, on January 1, 2026, until 12:01 a.m., local time, on May 22, 2026. This closure is necessary to prevent the private angling component from exceeding the Texas regional management area annual catch limit (ACL) and to prevent overfishing of the Gulf red snapper resource.

DATES: This closure is effective at 12:01 a.m., local time, on January 1, 2026, until 12:01 a.m., local time, on May 22, 2026.

FOR FURTHER INFORMATION CONTACT: Frank Helies, NMFS Southeast Regional Office, telephone: 727–824–5305, email: Frank.Helies@noaa.gov.

SUPPLEMENTARY INFORMATION: The Gulf reef fish fishery, which includes red snapper, is managed under the Fishery Management Plan for the Reef Fish Resources of the Gulf (FMP). The FMP was prepared by the Gulf Fishery Management Council, approved by the Secretary of Commerce, and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

The final rule implementing Amendment 40 to the FMP established two components within the recreational sector fishing for Gulf red snapper: the private angling component, and the

Federal for-hire component (80 FR 22422, April 22, 2015). Amendment 40 also allocated the red snapper recreational ACL (recreational quota) between the components and established separate seasonal closures for the two components. On February 6, 2020, NMFS implemented Amendments 50 A–F to the FMP, which delegated authority to the Gulf states (Louisiana, Mississippi, Alabama, Florida, and Texas) to establish specific management measures for the harvest of red snapper in Federal waters of the Gulf by the private angling component of the recreational sector (85 FR 6819, February 6, 2020). These amendments allocated a portion of the private angling ACL to each state, and each state is required to constrain landings to its allocation.

As described at 50 CFR 622.23(c), a Gulf state with an active delegation may request that NMFS close all, or an area of, Federal waters off that state to the harvest and possession of red snapper by private anglers. The state is required to request the closure by letter to NMFS, providing dates and geographic coordinates for the closure. If the request is within the scope of the analysis in Amendment 50A, NMFS publishes a notice in the **Federal Register** implementing the closure for the fishing year. Based on the analysis in Amendment 50A, Texas may request a closure of all Federal waters off the state to allow a year-round fishing season in state waters. As described at 50 CFR 622.2, “off Texas” is defined as the waters in the Gulf west of a rhumb line from 29°32.1′ N lat., 93°47.7′ W long. to 26°11.4′ N lat., 92°53′ W long., which line is an extension of the boundary between Louisiana and Texas.

On December 9, 2025, NMFS received a request from the Texas Parks and Wildlife Department (TPWD) to close the EEZ off Texas to the red snapper recreational private angling component during the 2026 fishing year. Texas requested that the closure be effective from January 1 through May 21, 2026. NMFS has determined that this request is within the scope of the analysis contained within Amendment 50A, which analyzed the potential impacts of a closure of all Federal waters off Texas, consistent with Texas’s intent to maintain a year-round fishing season in state waters during which a part of Texas’ ACL could be caught.

Therefore, the red snapper recreational private angling component

in the Gulf EEZ off Texas will close at 12:01 a.m., local time, on January 1, 2026, until 12:01 a.m., local time, on May 22, 2026. This closure applies to all private-anglers (those on board vessels that have not been issued a valid Federal charter vessel/headboat permit for Gulf reef fish) regardless of which state they are from or where they intend to land. Once the EEZ off Texas opens on May 22, 2026, TPWD will continue to monitor private recreational landings, and if necessary, will request that NMFS again close the EEZ in 2026 to ensure the Texas regional management area ACL is not exceeded.

On and after the effective date of this closure in the EEZ off Texas, the harvest and possession of red snapper in the EEZ off Texas by the private angling component is prohibited and the bag and possession limits for the red snapper private angling component in the closed area is zero.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 622.23(c), which was issued pursuant to 304(b), and is exempt from review under Executive Order 12866, and other applicable laws.

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 and contrary to the public interest. Such procedures are unnecessary because the rule implementing the area closure authority and the state-specific private angling ACLs has already been subject to notice and comment, and all that remains is to notify the public of the closure. Such procedures are contrary to the public interest because a failure to implement the closure by January 1, 2026, would be inconsistent with Texas’s state management plan and may result in less access to red snapper in state waters.

For the aforementioned reasons, there is also good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

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

Dated: December 19, 2025.

Kelly Denit,

*Director, Office of Sustainable Fisheries,
National Marine Fisheries Service.*

[FR Doc. 2025–23742 Filed 12–19–25; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 622****[Docket No. 230427–0115]****RTID 0648–XF377****Reef Fish Fishery of the Gulf of America; Partial Holdback of Commercial Quota for the Deep-Water Grouper Complex**

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

ACTION: Temporary rule; commercial quota holdback.

SUMMARY: NMFS issues this temporary rule to withhold a portion of the commercial allocation of deep-water grouper (DWG) for the 2026 fishing year in anticipation of the upcoming rulemaking for Amendment 58B to the Fishery Management Plan for the Reef Fish Resources of the Gulf (FMP). If approved and implemented, Amendment 58B would, in part, end overfishing of yellowedge grouper and reduce the DWG commercial annual catch limit (ACL) and commercial quota. This temporary rule will withhold a portion of the distribution of DWG individual fishing quota (IFQ) allocation on January 1, 2026, to shareholders in the Groupers and Tilefishes IFQ (GT–IFQ) program in the amount equal to the anticipated reduction in the commercial quota.

DATES: This temporary rule is effective from January 1, 2026, until June 1, 2026.

FOR FURTHER INFORMATION CONTACT: Dan Luers, NMFS Southeast Regional Office, telephone: 727–824–5305, email: daniel.luers@noaa.gov.

SUPPLEMENTARY INFORMATION: The reef fish fishery in the Gulf of America (Gulf) includes DWG and is managed under the FMP. The FMP was prepared by the Gulf Fishery Management Council (Council), approved by the Secretary of Commerce, and is implemented by NMFS through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

All catch limits in this temporary rule are in pounds (lb) gutted weight.

In the Gulf, the DWG complex consists of yellowedge grouper, warsaw grouper, snowy grouper, and speckled hind. Commercial harvest of the DWG species occurs under the GT–IFQ program and landings are managed to

the commercial quota, which is reduced from the commercial ACL. The current DWG commercial ACL is 1,070,000 lb (485,000 kg) and the commercial quota is 1,024,000 lb (464,000 kg), which is 4 percent below the commercial ACL. The buffer between the commercial ACL and the commercial quota is in place to account for scientific uncertainty with the level of discards and to allow for the IFQ flexibility measures under which some species in the shallow-water grouper complex can be landed under the DWG quota.

In 2023, the Southeast Data, Assessment, and Review 85 (SEDAR 85) assessed Gulf yellowedge grouper and indicated that while the stock was not overfished, it was experiencing overfishing and therefore harvest must be reduced. The Council's Scientific and Statistical Committee (SSC) accepted SEDAR 85 as consistent with the best scientific information available and recommended updated status determination criteria and catch levels for yellowedge grouper. The Council's SSC then evaluated the catch limits for the remaining species in the DWG complex and recommended that their catch levels also be reduced. As a result of the SSC recommendations, the Council initiated work on Amendment 58B to, among other measures, end overfishing of yellowedge grouper and reduce the harvest of the other species in the DWG complex. The Council approved Amendment 58B at its August 2025 meeting and is preparing to submit the amendment to NMFS for review. If approved, NMFS expects any final rule implementing Amendment 58B to be effective no later than June 1, 2026. Consistent with the SSC's recommendations, Amendment 58B would reduce the total allowable harvest of DWG. For the commercial sector, Amendment 58B would reduce the commercial ACL from 1,070,000 lb (485,000 kg) to 498,358 lb (226,051 kg) and the commercial quota from 1,024,000 lb (464,000 kg) to 478,424 lb (217,009 kg).

Under the GT–IFQ program, annual quota is distributed to IFQ shareholders as allocation (including multi-use allocation) on January 1, and most IFQ program participants begin to use or transfer their allocation early in each year. After shareholders begin transferring or landing allocation, NMFS is not able to retroactively withdraw allocation from shareholder accounts if a commercial quota decrease becomes effective after the beginning of the fishing year. Regulations at 50 CFR 622.22(a)(4), require NMFS to withhold distribution of IFQ allocation on January 1 in the amount equal to an expected

reduction in the commercial quota. Accordingly, through this temporary rule NMFS withholds distribution of a portion of the 2026 commercial quota of DWG equal to the anticipated reduction recommended by the Council in Amendment 58B.

NMFS will distribute the available DWG allocation of 478,424 lb (217,009 kg), on January 1, 2026. If NMFS does not implement Amendment 58B, including the revised commercial quota, by June 1, 2026, then NMFS will distribute the withheld allocation back to the current shareholders, as determined by the shares held on the same date that NMFS distributes the withheld IFQ quota.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is taken under 50 CFR 622.22(a)(4), which was issued pursuant to section 304(b) of the Magnuson-Stevens Act, and is exempt from review under Executive Order 12866, and other applicable laws.

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 is unnecessary and contrary to the public interest. Such procedures are unnecessary because the regulation at 50 CFR 622.22(a)(4) has already been subject to notice and public comment, and the public is aware of the expected quota reduction included in Amendment 58B. Therefore, all that remains is to notify the public that a portion of the commercial DWG allocation in 2026 will be withheld to allow for the implementation of the Amendment 58B in 2026, if approved. Such procedures are contrary to the public interest because notice and comment would require delaying the reduction in DWG harvest as specified in Amendment 58B until 2027. If NMFS does not withhold the necessary DWG allocation, shareholders can begin transferring or landing allocation on January 1, 2026, and NMFS would not be able to retroactively withdraw allocation from shareholder accounts. Delaying implementation of Amendment 58B until 2027 could allow for continued overfishing of yellowedge grouper and harvest of other DWG species in excess of the level supported by the best scientific information available and recommended by the Council's SSC.

For the aforementioned reasons, the NMFS Assistant Administrator also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 1801 *et seq.*

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

Dated: December 19, 2025.

Kelly Denit,

*Director, Office of Sustainable Fisheries,
National Marine Fisheries Service.*

[FR Doc. 2025-23747 Filed 12-22-25; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 230427-0115]

RTID 0648-XF378

Reef Fish Fishery of the Gulf of America; Partial Holdback of Commercial Quota for the Other Shallow-Water Grouper Complex

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

ACTION: Temporary rule; commercial quota holdback.

SUMMARY: NMFS issues this temporary rule to withhold a portion of the commercial allocation of the Other Shallow-Water Grouper (SWG) complex for the 2026 fishing year in anticipation of the upcoming rulemaking to implement a framework action under the Fishery Management Plan for the Reef Fish Resources of the Gulf (FMP). If implemented by NMFS, the framework action would, in part, reduce the commercial annual catch limit (ACL) and commercial quota for the Other SWG complex. This temporary rule will withhold the distribution of a portion of the Other SWG individual fishing quota (IFQ) allocation on January 1, 2026, to shareholders in the Groupers and Tilefishes IFQ (GT-IFQ) program in the amount equal to the anticipated reduction in the commercial quota.

DATES: This temporary rule is effective from January 1, 2026, until June 1, 2026.

FOR FURTHER INFORMATION CONTACT: Frank Helies, NMFS Southeast Regional Office, telephone: 727-824-5305, email: frank.helies@noaa.gov.

SUPPLEMENTARY INFORMATION: The reef fish fishery in the Gulf of America (Gulf) includes Other SWG and is managed under the FMP. The FMP was prepared by the Gulf Fishery Management Council (Council), approved by the Secretary of Commerce, and is implemented by NMFS through regulations at 50 CFR part 622 under the

authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

All catch limits in this temporary rule are in pounds (lb) gutted weight.

In the Gulf, the Other SWG complex consists of scamp, yellowmouth grouper, black grouper, and yellowfin grouper. Commercial harvest of Other SWG species occurs under the GT-IFQ program and landings are managed to the commercial quota, which is reduced from the commercial ACL. The current commercial ACL is 547,000 lb (248,115 kg) and the commercial annual catch target (ACT, or quota) is 526,000 lb (238,590 kg), which is 4 percent below the commercial ACL. The buffer between the commercial ACL and the commercial quota is in place to account for scientific uncertainty with the level of discards and to allow for the IFQ flexibility measures under which some species in the deep-water grouper complex can be landed under the Other SWG quota.

In 2022, the Southeast Data, Assessment, and Review 68 (SEDAR 68) assessed scamp and yellowmouth grouper together and indicated that harvest must be reduced. The Council's Scientific and Statistical Committee (SSC) accepted SEDAR 68 as consistent with the best scientific information available and recommended updated status determination criteria and catch levels for these two stocks. The remaining Other SWG species, black grouper and yellowfin grouper, could not be assessed due to a lack of the data necessary to accurately assess population metrics of these species in the Gulf.

As a result of the SSC recommendations for scamp and yellowmouth grouper, the Council initiated work on Amendment 58A to the FMP, which considers dissolving the Other SWG complex and creating two new complexes, one for scamp and yellowmouth grouper and another for black grouper and yellowfin grouper, and setting catch limits for these new complexes. Amendment 58A also considers changes to the commercial IFQ program to reflect the two new complexes as well as other management measures. In recognition of the complexity of Amendment 58A and the additional time required for its development and implementation, the Council developed a framework action to reduce harvest of scamp and yellowmouth, consistent with the SSC recommendations, until Amendment 58A can be completed. The Council approved the framework action at its June 2025 meeting. If NMFS determines that the proposed regulations to

implement the framework action are consistent with the FMP and other applicable law, NMFS expects to publish a proposed rule in early 2026 and intends for any final rule to be effective by June 1, 2026. The framework action would reduce the total allowable harvest of Other SWG and reduce the commercial ACL from 547,000 lb (248,115 kg) to 255,636 lb (115,955 kg), and the commercial quota from 525,000 lb (238,136 kg) to 245,410 lb (111,316 kg). Commercial landings have never exceeded this proposed commercial quota.

Under the GT-IFQ program, annual quota is distributed to IFQ shareholders as allocation (including multi-use allocation) on January 1, and most IFQ program participants begin to use or transfer their allocation early in each year. After shareholders begin transferring or landing allocation, NMFS is not able to retroactively withdraw allocation from shareholder accounts if a commercial quota decrease becomes effective after the beginning of the fishing year. Regulations at 50 CFR 622.22(a)(4), require NMFS to withhold distribution of IFQ allocation on January 1 in the amount equal to an expected reduction in the commercial quota. Accordingly, through this temporary rule NMFS withholds distribution of the portion of the 2026 commercial quota of Other SWG equal to the anticipated reduction recommended by the Council in the framework action.

NMFS will distribute the available Other SWG allocation of 245,410 lb (111,316 kg), on January 1, 2026. If NMFS does not implement the framework action, including the revised commercial quota, by June 1, 2026, then NMFS will distribute the withheld allocation back to the current shareholders, as determined by the shares held on the same date that NMFS distributes the withheld IFQ quota.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is taken under 50 CFR 622.22(a)(4), which was issued pursuant to section 304(b) of the Magnuson-Stevens Act, and is exempt from review under Executive Order 12866, and other applicable laws.

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 is unnecessary and contrary to the public interest. Such procedures are unnecessary because the regulation at 50 CFR 622.22(a)(4) has already been subject to notice and public comment, and the public is aware of the expected

quota reduction included in the framework action. Therefore, all that remains is to notify the public that a portion of the commercial Other SWG allocation in 2026 will be withheld to allow for the implementation of the framework action in 2026 if a final rule is effective before June 1. Such procedures are contrary to the public interest because notice and comment would not allow NMFS to implement the framework action to reduce Other SWG complex catch levels until 2027. If NMFS does not withhold the necessary commercial Other SWG allocation, shareholders can begin transferring or landing allocation on January 1, 2026, and NMFS would not be able to retroactively withdraw allocation from shareholder accounts. Delaying implementation of the framework action until 2027 could allow for harvest of scamp and yellowmouth grouper in excess of the level supported by the most recent stock assessment.

For the aforementioned reasons, the NMFS Assistant Administrator also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 1801 *et seq.*

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

Dated: December 19, 2025.

Kelly Denit,

*Director, Office of Sustainable Fisheries,
National Marine Fisheries Service.*

[FR Doc. 2025–23755 Filed 12–22–25; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 240916–0238; RTID 0648–XF352]

Atlantic Highly Migratory Species; Adjustments to the 2025 North Atlantic Albacore Tuna, North and South Atlantic Swordfish, and Atlantic Bluefin Tuna Category Quotas

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

ACTION: Temporary rule; quota adjustment.

SUMMARY: NMFS adjusts the 2025 baseline quotas for U.S. North Atlantic albacore tuna (northern albacore) and North and South Atlantic swordfish quotas based on 2024 underharvest and applicable international quota transfers. NMFS also adjusts the 2025 Atlantic

bluefin tuna category subquotas based on 2024 overharvest. These temporary adjustments apply throughout the 2025 fishing year and are effective through December 31, 2025 (for portions of the 2025 fishing year that are already completed, they are considered to apply retrospectively). These actions are necessary to implement the 2025 quotas consistent with the recommendations of the International Commission for the Conservation of Atlantic Tunas (ICCAT) as required by the Atlantic Tunas Convention Act (ATCA), and to achieve domestic management objectives under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Full annual baseline allocations will be available to U.S. harvesters starting January 1, 2026. Note that NMFS intends to take separate action as soon as possible in 2026 to modify the baseline Atlantic bluefin tuna quota consistent with the quota agreed to at the 2025 ICCAT annual meeting.

DATES: Effective December 23, 2025, through December 31, 2025.

FOR FURTHER INFORMATION CONTACT:

Steve Durkee (steve.durkee@noaa.gov) or Carrie Soltanoff (carrie.soltanoff@noaa.gov) by email or phone at 301–427–8503.

SUPPLEMENTARY INFORMATION: U.S. northern albacore, swordfish, and bluefin tuna fisheries, are managed under the authority of ATCA (16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Act (16 U.S.C. 1801 *et seq.*). The Highly Migratory Species Fishery Management Plan (HMS FMP) and its amendments are implemented by regulations at 50 CFR part 635. Section 635.27(a) implements the ICCAT-recommended quota and describes the annual quota adjustment process for bluefin tuna, including in the event of an overharvest. Section 635.27(c) implements the ICCAT-recommended quotas and describes the quota adjustment process for both North and South Atlantic swordfish. Section 635.27(e) implements the northern albacore annual quota recommended by ICCAT and describes the annual northern albacore quota adjustment process. NMFS is required under the Magnuson-Stevens Act to provide U.S. fishing vessels with a reasonable opportunity to harvest quotas under relevant international fishery agreements such as the International Convention for the Conservation of Atlantic Tunas, which is implemented domestically pursuant to ATCA.

Consistent with the relevant binding ICCAT Recommendations and the requirements under the Magnuson-

Stevens Act, this action adjusts the 2025 baseline quotas for U.S. North Atlantic albacore tuna (northern albacore) and North and South Atlantic swordfish quotas based on 2024 underharvest and applicable international quota transfer. This action also adjusts the 2025 Atlantic bluefin tuna category subquotas based on 2024 overharvest. These temporary adjustments apply throughout the 2025 fishing year and are effective through December 31, 2025 (for portions of the 2025 fishing year that are already completed, they are considered to apply retrospectively). Furthermore, these temporary adjustments are consistent with the quota levels that NMFS considered throughout 2025 when taking actions during the fishing year to adjust the bluefin tuna retention limits and close bluefin tuna quota categories (e.g., 90 FR 25158, June 16, 2025; 90 FR 45152, September 19, 2025). Full annual baseline allocations will be available to U.S. harvesters starting January 1, 2026. Once complete catch information for fishing year 2025 is available, NMFS will determine whether any resulting adjustments to 2026 quotas are necessitated based on ICCAT overharvest requirements or underharvest carryover allowances. Additionally, NMFS plans to take action as soon as possible in 2026 to modify the baseline bluefin tuna quota consistent with the quota that was agreed to at the 2025 ICCAT annual meeting.

Note that, consistent with how the quotas are established, weight information for northern albacore and bluefin tuna below is shown in metric tons (mt) whole weight (ww), and weight information for swordfish is shown in both dressed weight (dw) and ww.

Northern Albacore Annual Quota and Adjustment Process

Consistent with the northern albacore quota regulations at § 635.27(e), NMFS adjusts the U.S. annual northern albacore quota for allowable underharvest in the previous year. NMFS makes such adjustments consistent with ICCAT carryover limits, and when complete catch information for the prior year is available and finalized. The baseline quota is 889.4 mt. The maximum underharvest that may be carried forward from one year to the next is 25 percent of its baseline quota, thus 222.4 mt.

For 2024, the adjusted quota was 1,067.3 mt (89 FR 77029, September 20, 2024). In 2024, the United States landed 228.4 mt of northern albacore which is 838.9 mt less than the 2024 adjusted quota. This underharvest exceeds the

222.4-mt underharvest carryover limit allowed under Recommendation 23–05; therefore, only 222.4 mt may be carried

forward to the 2025 fishing year. Thus, the adjusted 2025 northern albacore quota will be 1,111.8 mt (889.4-mt

baseline quota + 222.4-mt carryover = 1,111.8 mt) (table 1).

TABLE 1—2024 NORTHERN ALBACORE QUOTA

Northern albacore quota (mt ww)	2024	2025
Baseline Quota	889.4	889.4
Underharvest from Previous Year	708.9	838.9
Underharvest Carryover from Previous Year †	(+) 177.9	(+) 222.4
Adjusted Quota (Baseline + Underharvest)	1,067.3	1,111.8

† Allowable underharvest carryover is capped at 25 percent of the baseline quota allocation (222.4 mt ww).

North and South Atlantic Swordfish Annual Quota and Adjustment Process

North Atlantic Swordfish

Consistent with the North Atlantic swordfish quota regulations at § 635.27(c), in this action, NMFS adjusts the 2025 U.S. annual North Atlantic swordfish quota for allowable underharvest from 2024. NMFS makes such adjustments consistent with ICCAT carryover limits and when complete catch information for the prior year is available and finalized. The U.S. North Atlantic swordfish baseline annual quota is 2,937.6 mt dw (3,907 mt ww).

As codified at § 635.27(c)(3), the maximum North Atlantic swordfish underharvest that may be carried

forward from one year to the next is 15 percent of the baseline quota, which equates to 440.6 mt dw (586 mt ww). For 2024, the adjusted North Atlantic swordfish quota was 3,227.8 mt dw (89 FR 77029, September 20, 2024). In 2024, U.S. landings of North Atlantic swordfish, which includes landings and dead discards, was 669.5 mt dw, which is 2,558.3 mt dw less than the 2024 adjusted quota. This underharvest exceeds the 440.6-mt dw underharvest carryover limit allowed; therefore, only 440.6 mt dw may be carried forward to the 2025 fishing year. Additionally, specific to only 2025, ICCAT Recommendation 24–10 provides for a transfer of quota from the United States to Costa Rica of 225.6 mt dw (300 mt ww).

Thus, the adjusted 2025 North Atlantic swordfish quota will be 3,152.6 mt dw (2,937.6-mt dw baseline quota + 440.6-mt dw underharvest – 225.6-mt dw quota transfer to Costa Rica = 3,152.6 mt dw). From the adjusted quota and consistent with § 635.27(c)(1)(i), 50 mt dw would be allocated to the Reserve category for inseason adjustments and research; 300 mt dw would be allocated to the incidental category, which covers recreational landings and landings by incidental swordfish permit holders; and the remainder of the adjusted quota (2,802.6 mt dw) would be allocated to the directed category, which will be split equally between two seasons in 2025 (January through June, and July through December) (table 2).

TABLE 2—2025 NORTH ATLANTIC SWORDFISH QUOTAS

North Atlantic swordfish quota (mt dw)	2024	2025
Baseline Quota	2,937.6	2,937.6
International Quota Transfers *	(–) 150.4	(–) 225.6
Underharvest from Previous Year	2,369.9	2,558.3
Underharvest Carryover from Previous Year †	(+) 440.6	(+) 440.6
Adjusted Quota (Baseline + Carryover + Transfer)	3,227.8	3,152.6
Quota Allocation:		
Directed Category	3,028.2	2,802.6
Incidental Category	300	300
Reserve Category	50	50

* Under ICCAT Recommendation 23–04, the United States transferred 150.4 mt dw (200 mt ww) to Morocco in 2024. Under ICCAT Recommendation 24–10, the United States would transfer 225.6 mt dw (300 mt ww) to Costa Rica in 2025.

† Allowable underharvest carryover is capped at 15 percent of the baseline quota (440.6 mt dw).

South Atlantic Swordfish

Consistent with the South Atlantic swordfish quota regulations at § 635.27(c), NMFS adjusts the U.S. annual South Atlantic swordfish quota for allowable underharvest, if any, in the previous year. NMFS makes such adjustments, if needed, consistent with ICCAT carryover limits and when complete catch information for the prior year is available and finalized. Consistent with ICCAT Recommendation 17–03 as amended by

Recommendation 22–04, the U.S. South Atlantic swordfish baseline annual quota is 75.2 mt dw (100 mt ww), and the amount of underharvest that the United States can carry forward from one year to the next is 75.2 mt dw (100 mt ww) (table 3). In 2024, there were no landings of South Atlantic swordfish by U.S. fishermen, which is an underharvest of 75.2 mt dw of the 2024 adjusted quota. Of that underharvest, 75.2 mt dw may be carried forward to the 2025 fishing year. Under

Recommendations 17–03 and 22–04, the United States continues to transfer a total of 75.2 mt dw (100 mt ww) to other countries. These transfers are 37.6 mt dw (50 mt ww) to Namibia, 18.8 mt dw (25 mt ww) to Côte d'Ivoire, and 18.8 mt dw (25 mt ww) to Belize. Thus, the adjusted 2025 South Atlantic swordfish quota will be 75.2 mt dw (table 3).

TABLE 3—2025 SOUTH ATLANTIC SWORDFISH QUOTAS

South Atlantic swordfish quota (mt dw)	2024	2025
Baseline Quota	75.2	75.2
International Quota Transfers *	(–) 75.2	(–) 75.2
Underharvest from Previous Year	75.2	75.2
Underharvest Carryover from Previous Year †	75.2	75.2
Adjusted quota (Baseline + Carryover + Transfers)	75.2	75.2

* Under ICCAT Recommendation 22–04, the United States transfers 75.2 mt dw (100 mt ww) annually as follows: Namibia (37.6 mt dw, 50 mt ww), Côte d'Ivoire (18.8 mt dw, 25 mt ww), and Belize (18.8 mt dw, 25 mt ww).

† Allowable underharvest carryover is capped at 75.2 dw (100 mt ww) for the South Atlantic.

Bluefin Tuna Annual Quota, Subquotas, and Adjustment Process

Consistent with the bluefin tuna quota regulations at § 635.27(a), in this action, NMFS adjusts the 2025 U.S. annual bluefin tuna quota and subquotas due to an overharvest in 2024. NMFS makes such temporary adjustments consistent with ICCAT overharvest requirements and when complete catch information for the prior year is available and finalized. The 2025 U.S. bluefin tuna baseline annual quota is 1,316.14 mt, not including an additional annual 25-mt allocation allocated for incidental catch by pelagic longline vessels fishing in the Northeast Distant gear restricted area (NED). As described above, these temporary adjustments apply throughout the 2025 fishing year and are effective through December 31, 2025 (for portions of the 2025 fishing year that are already completed, they are considered to apply retrospectively). Furthermore, these temporary adjustments are consistent with the quota levels that NMFS considered throughout 2025 when taking actions during the fishing year to adjust bluefin tuna retention limits and close bluefin tuna quota categories (e.g., 90 FR 25158, June 16, 2025; 90 FR 45152, September 19, 2025).

Per the regulatory formula established at 50 CFR 635.27(a), the baseline bluefin tuna quota is divided among domestic quota categories according to the

following percentages: General—54 percent (710.7 mt); Angling—22.6 percent (297.4 mt); Longline—15.9 percent (209.3 mt) (i.e., total not including the 25-mt allocation for the NED); Harpoon—4.5 percent (59.2 mt); Trap—0.1 percent (1.3 mt); and Reserve—2.9 percent (38.2 mt). Note that any fishing under exempted fishing permits, scientific research permits, and display permits per the regulations at § 635.32 is accounted against the school reserve or Reserve quota (§ 635.27(a)(6)) depending on the size of the fish.

Under ICCAT Recommendation 22–10, if, in a given year, any ICCAT Party has an overharvest of its total quota, its initial quota for the next year will be reduced by 100 percent of the excess of such total quota, and ICCAT may authorize other appropriate actions. Further, if an ICCAT Party has an overharvest of its total quota during any two consecutive years, ICCAT will recommend appropriate measures, which may include, but are not limited to, reduction in the ICCAT Party's total quota equal to a minimum of 125 percent of the overharvest amount and, if necessary, trade restrictive measures. Additionally, under the regulations at § 635.27(a)(9), on an annual basis, based on landing, catch statistics, and other available information, if NMFS determines that catches from the previous year indicates that a bluefin tuna quota for any category or, as appropriate, subcategory has been

exceeded (overharvest), NMFS may subtract all or a portion of the overharvest from that quota category or subcategory for the following fishing year.

The 2024 adjusted bluefin tuna quota was 1,475.2 mt (89 FR 77029, September 20, 2024). The total U.S. bluefin tuna catch (which includes landings and pelagic longline dead discards) in 2024 was 1,616.4 mt. Thus, the U.S. catch exceeded the 2024 adjusted quota by 141.2 mt. As such, consistent with the ICCAT Recommendation 22–10 and the regulations, NMFS is reducing the overall 2025 quota by 141.2 mt. Subtracting the total overharvest amount of 141.2 mt from the 2025 U.S. baseline quota of 1,341.14 mt (including the 25-mt set-aside for the NED) results in a total adjusted quota of 1,199.94 mt for 2025.

Also, consistent with § 635.27(a)(9), NMFS is adjusting the subquotas of the categories that exceeded their quota. Catches by the following three bluefin tuna quota categories contributed to the 2024 overharvest: 78 percent by the Angling category, 19 percent by the General category, and 3 percent by the Harpoon category. Applying those percentages to the total overharvest amount of 141.2 mt results in the pro rata reductions shown in table 4. The resulting 2025 adjusted quota and subquota allocations can be found in table 4.

TABLE 4—BASELINE BLUEFIN TUNA QUOTAS AND SUBQUOTAS AND 2025 ADJUSTED QUOTAS AND SUBQUOTAS

	Baseline quota and subquotas (mt)	Pro rata reductions to categories for 2025 (mt)	2025 adjusted quota and subquotas (mt)
Subquotas:			
General category	710.7	– 26.8	683.9
Harpoon category	59.2	– 4.3	54.9
Longline category	209.3		209.3
Trap category	1.3		1.3
Angling category	297.4	– 110.1	187.3
Reserve category	38.2		38.2
NED set-aside (for use by the Longline category)	25		25
Annual Total U.S. quota	1,341.14	– 141.2	1,199.94

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act (16 U.S.C. 1855(d)) and regulations at 50 CFR part 635 and this action is exempt from review under Executive Order 12866.

The AA finds that pursuant to 5 U.S.C. 553(b)(B), it is unnecessary to provide prior notice of, and an opportunity for public comment on, this action for the following reasons. The rulemaking processes for Amendment 13 to the 2006 Consolidated HMS FMP (87 FR 59966, October 3, 2022), the 2022 Atlantic bluefin tuna and northern albacore quota rule (87 FR 33049, June 1, 2022), and the 2016 North and South Atlantic Swordfish Quota Adjustment Rule (81 FR 48719, July 26, 2016) specifically provided prior notice of, and accepted public comment on, the formulaic quota adjustment processes for the northern albacore, Atlantic bluefin tuna, and swordfish fisheries and the manner in which they occur. These processes have not changed, and the application of these formulas to adjust the relevant quotas is a routine action that does not have discretionary aspects requiring additional agency consideration. Additionally, similar actions to adjust the quotas based on finalized information regarding the previous year's landings occur annually, and the regulated community expects such adjustments in 2025. NMFS has also informed fishery participants through various management actions throughout the 2025 fishing season of the pending quota adjustments. The delay that would result from unnecessarily soliciting public comments would interfere with management of the fisheries at issue. These fisheries are currently open and permit holders are actively fishing, and delay thus raises the risk that the quotas could be exceeded. For all of these reasons, it is unnecessary to provide prior notice and an additional opportunity for public comment on this action.

There is good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in the date of effectiveness and to make the rule effective upon the date of publication in the **Federal Register**. As described above, this is a routine action that applies existing quota adjustment formulas, and that the regulated community anticipates annually. The 2025 fisheries for northern albacore, North and South Atlantic swordfish, and bluefin tuna opened on January 1, 2025, and end on December 31, 2025. As noted above, these fisheries are currently open, permit holders are

actively fishing, and the adjusted quotas automatically revert back to the baseline quotas on January 1, 2026. As such, there is no need to delay the effective date of this rule's quota adjustments. Any further delay would be contrary to the Magnuson-Stevens Act requirement to allow U.S. vessels reasonable opportunity to harvest highly migratory species allocations and quotas under relevant international fishery agreements such as ICCAT.

Because prior notice and opportunity for public comment are not required for this rule by 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.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: December 19, 2025.

Kelly Denit,

*Director, Office of Sustainable Fisheries,
National Marine Fisheries Service.*

[FR Doc. 2025–23749 Filed 12–22–25; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 241203–0308; RTID 0648–XF390]

Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; Quota Transfer From New York to North Carolina

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

ACTION: Temporary rule; quota transfer.

SUMMARY: NMFS announces that the State of New York is transferring a portion of their 2025 commercial bluefish quota to the State of North Carolina. This quota adjustment is necessary to comply with the Atlantic Bluefish Fishery Management Plan (FMP) quota transfer provisions. This announcement informs the public of the revised 2025 commercial bluefish quotas for New York and North Carolina.

DATES: Effective December 22, 2025, through December 31, 2025.

FOR FURTHER INFORMATION CONTACT: Matthew Rigdon, Fishery Management Specialist, (978) 281–9336.

SUPPLEMENTARY INFORMATION: Regulations governing the Atlantic bluefish fishery are found in 50 CFR

648.160 through 648.167. These regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through Florida. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.162, and the final 2025 allocations were published on December 10, 2024 (89 FR 99138).

The final rule implementing amendment 1 to the FMP, as published in the **Federal Register** on July 26, 2000 (65 FR 45844), provided a mechanism for transferring bluefish commercial quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can request approval to transfer or combine bluefish commercial quota under § 648.162(e). The Regional Administrator is required to consider three criteria in the evaluation of requests for quota transfers or combinations: (1) the transfers would not preclude the overall annual quota from being fully harvested; (2) the transfers address an unforeseen variation or contingency in the fishery; and (3) the transfers are consistent with the objectives of the FMP and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The Regional Administrator has determined these criteria have been met for the transfers approved in this notification.

New York is transferring 100,000 pounds (lb) (45,359 kilograms (kg)) to North Carolina through mutual agreement of the states. This transfer was requested to ensure North Carolina would not exceed its 2025 state quota. The revised bluefish quotas for 2025 are: New York, 377,518 lb (171,239 kg); and North Carolina, 1,422,012 lb (645,014 kg).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 648.162(e)(1)(i) through (iii), which was issued pursuant to section 304(b), and is exempted from review under Executive Order 12866.

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

Dated: December 19, 2025.

Kelly Denit,

*Director, Office of Sustainable Fisheries,
National Marine Fisheries Service.*

[FR Doc. 2025–23758 Filed 12–22–25; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 648**

[Docket No. 241203–0308; RTID 0648–XF391]

Fisheries of the Northeastern United States; Summer Flounder Fishery; Quota Transfer From North Carolina to New York

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

ACTION: Temporary rule; quota transfer.

SUMMARY: NMFS announces that the State of North Carolina is transferring a portion of its 2025 commercial summer flounder quota to the State of New York. This adjustment to the 2025 fishing year quota is necessary to comply with the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan (FMP) quota transfer provisions. This announcement informs the public of the revised 2025 commercial quotas for North Carolina and New York.

DATES: Effective December 22, 2025, through December 31, 2025.

FOR FURTHER INFORMATION CONTACT: Matthew Rigdon, Fishery Management Specialist, (978) 281–9336.

SUPPLEMENTARY INFORMATION: Regulations governing the summer flounder fishery are found in 50 CFR 648.100 through 648.111. These regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through North Carolina. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.102, and the final 2025 allocations were published on December 10, 2024 (89 FR 99138).

The final rule implementing amendment 5 to the FMP, as published in the **Federal Register** on December 17, 1993 (58 FR 65936), provided a mechanism for transferring summer flounder commercial quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can transfer or combine summer flounder commercial quota under § 648.102(c)(2). The Regional Administrator is required to consider three criteria in the evaluation of requests for quota transfers or combinations: (1) the transfers or combinations would not preclude the overall annual quota from being fully

harvested; (2) the transfers address an unforeseen variation or contingency in the fishery; and (3) the transfers are consistent with the objectives of the FMP and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The Regional Administrator has determined these three criteria have been met for the transfer approved in this notification.

North Carolina is transferring 100,000 pounds (lb; 45,359 kilograms (kg)) of summer flounder to New York through a mutual agreement between the states. This transfer was requested to ensure that New York would not exceed its 2025 state quota. The revised summer flounder quotas for 2025 are: North Carolina, 2,232,603 lb (1,012,692 kg); and New York, 822,157 lb (372,924 kg).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 648.102(c)(2)(i) through (iv), which was issued pursuant to section 304(b) of the Magnuson-Stevens Act, and is exempted from review under Executive Order 12866.

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

Dated: December 19, 2025.

Kelly Denit,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2025–23754 Filed 12–22–25; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 648**

[Docket No. 251208–0181; RTID 0648–XF413]

Fisheries of the Northeastern United States; 2026 Atlantic Herring Fishery Specifications

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

ACTION: Temporary rule; inseason.

SUMMARY: NMFS is finalizing the 2026 Atlantic herring specifications and river herring and shad catch caps for the Atlantic herring fishery. This action is necessary to implement previously projected 2026 Atlantic herring specifications, including the river herring and shad catch caps. This action is intended to achieve the objectives of the Atlantic Herring Fishery

Management Plan, including preventing overfishing, helping rebuild an overfished stock, and achieving optimum yield on a continuing basis.

DATES: The 2026 specifications for the Atlantic herring fishery are effective from January 1 through December 31, 2026.

FOR FURTHER INFORMATION CONTACT:

Carrie Nordeen, Fishery Policy Analyst, 978–281–9272.

SUPPLEMENTARY INFORMATION: NMFS and the New England Fishery Management Council (Council) manage the Atlantic herring fishery pursuant to the Atlantic Herring Fishery Management Plan. Regulations at 50 CFR 648.200 require the Council to recommend herring specifications for NMFS's approval and provide the Council with the discretion to recommend river herring and shad catch caps as part of the specifications. Prior to the start of 2026, the Council recommended herring specifications and river herring and shad catch caps for 2026. On December 11, 2025, NMFS published a final rule (90 FR 57376) setting the Council-recommended 2025 herring specifications and projecting the 2026–2027 herring specifications.

At the end of each fishing year, NMFS evaluates catch information to determine if there were catch overages or unharvested catch compared to the annual catch limit (ACL) or the sub-ACLs for the herring management areas. If catch exceeds a sub-ACL or the ACL, regulations at § 648.201(a)(3) may require a sub-ACL or ACL deduction in a subsequent year. Additionally, regulations at § 648.201(g)(2) prohibit the carryover of unharvested catch to 2026.

NMFS reviewed 2024 fishery information against the projected 2026 herring specifications. There were no catch overages, nor is there any new biological information that would require altering the projected 2026 specifications published in December 2025. Based on this information, NMFS is finalizing the 2026 herring specifications, including the river herring and shad catch caps, as projected in the December 2025 final rule and outlined below in tables 1 and 2. These 2026 herring fishery specifications are expected to prevent overfishing, help rebuild an overfished stock, and achieve optimum yield on a continuing basis. NMFS will provide notice of the final 2027 herring fishery specifications, and any necessary adjustments, prior to the start of 2027.

TABLE 1—2026 ATLANTIC HERRING SPECIFICATIONS

Specifications	Amount in metric tons (mt)
Overfishing Limit	23,491
Acceptable Biological Catch	13,165
Management Uncertainty	4,031
Annual Catch Limit/Optimum Yield	9,134
Domestic Annual Harvest	9,134
Border Transfer	0
Domestic Annual Processing	9,134
US At-Sea Processing	0
Area 1A Sub-ACL (28.9%)	2,640
Area 1B Sub-ACL (4.3%)	393
Area 2 Sub-ACL (27.8%)	2,539
Area 3 Sub-ACL (39%)	3,562
Fixed Gear Set-Aside	30
Research Set-Aside	0%

If New Brunswick weir landings are less than 2,600 mt through October 1, then 1,000 mt will be subtracted from the management uncertainty and reallocated to the Area 1A sub-ACL and the ACL.

TABLE 2—2026 RIVER HERRING AND SHAD CATCH CAPS

Catch cap	Amount in metric tons (mt)
Gulf of Maine Midwater Trawl	76.7
Cape Cod Midwater Trawl	32.4
Southern New England Midwater Trawl	129.6
Southern New England Bottom Trawl	122.3

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 648, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866. The Assistant Administrator for Fisheries, NOAA, finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment on this notice because it would be unnecessary and contrary to the public interest. The proposed rule for the 2025–2027 herring specifications (90 FR 26955; June 25, 2025), pursuant to the process described in the herring regulations (§ 648.200), provided the public with the opportunity to comment on the specifications, including the projected 2026 specifications and river herring and shad catch caps. None of the comments on the proposed 2025–2027 herring specifications resulted in any substantive changes in the final rule setting the 2025 specifications and projecting the 2026–2027 specifications. This action simply finalizes the projected 2026 specifications, as described in both the proposed and final rules, without changes as the proposed and final rules for the 2025–2027 herring specifications provided a full opportunity for the public to comment on the projected 2026 specifications and the substance and process of this action. Additionally, the 2026 ACL (9,134 mt)

is 64 percent higher than the current, adjusted 2025 ACL (5,556 mt), providing additional economic opportunity for the vessels participating in the herring fishery. If implementation of this action is delayed beyond the start of the fishing year on January 1, 2026, to solicit public comment, it may result in a negative economic impact on the herring fishing industry. Based on these considerations, NMFS further finds, pursuant to 5 U.S.C 553(d)(3), good cause to waive the 30-day delayed effectiveness period for the reasons stated above.

Authority: 16 U.S.C. 1801 *et seq.*
Dated: December 19, 2025.
Kelly Denit,
Director, Office of Sustainable Fisheries,
National Marine Fisheries Service.
[FR Doc. 2025–23796 Filed 12–22–25; 8:45 am]
BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 250312–0037; RTID 0648–XF395]

Fisheries of the Exclusive Economic Zone Off Alaska; Inseason Adjustment to the 2026 Gulf of Alaska Pacific Cod Total Allowable Catch

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.
ACTION: Temporary rule; inseason adjustment; request for comments.

SUMMARY: NMFS is adjusting the 2026 total allowable catch (TAC) amounts for the Gulf of Alaska (GOA) Pacific cod fisheries. This action is necessary because NMFS has determined that these TACs are incorrectly specified and that the adjustments are necessary to ensure that harvest of Pacific cod does not exceed biological limits for the stock, as established by the best scientific information available for Pacific cod in the GOA. This action is consistent with the goals and objectives of the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP).
DATES: Effective 0001 hours, Alaska local time (A.l.t.), January 1, 2026,

through March 17, 2026, unless otherwise modified or superseded through publication of the final 2026 and 2027 harvest specifications for GOA groundfish in the **Federal Register**.

Comments must be received at the following **ADDRESSES** no later than January 7, 2026.

ADDRESSES: You may submit comments on this document, identified by docket number NOAA–NMFS–2024–0124 by any of the following methods:

Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to <https://www.regulations.gov> and enter NOAA–NMFS–2024–0124 in the Search box. Click on the “Comment” icon, complete the required fields, and enter or attach your comments.

Mail: Submit written comments to Gretchen Harrington, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on <https://www.regulations.gov> without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter “N/A” in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Abby Jahn, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the FMP prepared and recommended by the North Pacific Fishery Management Council (Council) under authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Regulations governing fishing by U.S. vessels in accordance with the FMP

appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The final 2025 and 2026 harvest specifications for groundfish in the GOA set the 2026 Pacific cod TAC at 22,235 metric tons (mt) in the GOA (90 FR 12468, March 18, 2025). In December 2025, the Council recommended a 2026 Pacific cod TAC of 21,826 mt for the GOA, which is less than the 22,235 mt established by the final 2025 and 2026 harvest specifications for groundfish in the GOA. The Council’s recommended 2026 Pacific cod TAC for the GOA is based on the Scientific and Statistical Committee’s (SSC’s) overfishing limit (OFL) and acceptable biological catch (ABC) recommendations and is adjusted to account for the State of Alaska’s guideline harvest level (GHL). The GHL increased from 30 to 35 percent for the Western GOA regulatory area by the Alaska Board of Fisheries (BOF) in October 2025. There were no GHL changes by the BOF for the Central GOA or Eastern GOA regulatory areas, which remain at 25 percent for both areas. However, because the GHL increased for the Western GOA regulatory area, the Western GOA TAC and GOA wide TAC must be adjusted to account for that increase to ensure that the sum of all Pacific cod removals from State waters and Federal waters in the GOA not exceed the Pacific cod ABC.

Steller sea lions occur in the same location as Pacific cod fisheries and are listed as endangered under the Endangered Species Act. Pacific cod are one of the predominant prey species for Steller sea lions in the GOA. Regulations implementing Steller sea lion protection measures include regulations at § 679.20(a)(12)(i) that specify, for each sector, the seasonal apportionment of Pacific cod TAC in the Western GOA and Central GOA regulatory areas.

Stock assessments were not completed in 2025 due to the lapse in appropriations and resulting government shutdown from October 1, 2025 through November 12, 2025. The SSC recommendations are informed by the Groundfish Plan Team’s recommended OFLs and ABCs from their November 2024 meeting as well as

a review of the most recent Stock Assessment and Fishery Evaluation (SAFE) report dated November 2024. The Council’s TAC recommendations are based on those of its Advisory Panel, consistent with the SSC’s OFL and ABC recommendations, and reflect the most recent information on the State GHL and Pacific cod.

In accordance with § 679.25(a)(1)(iii), (a)(2)(i)(A), and (a)(2)(iv), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2026 Pacific cod TACs and subsequent sector allocations and seasonal apportionments are incorrectly specified and that adjustments are necessary to ensure that harvest of Pacific cod does not exceed biological limits for the stock. Without these adjustments, harvests of Pacific cod in State waters and Federal waters in the GOA could exceed the ABC which is equal to the annual catch limit and could increase the risk of overfishing. This determination is based on the November 2024 SAFE report and SSC recommendations for OFL and ABC, which is the best available scientific information on biological stock status. This determination is also based on TAC recommendations by the Council at the December 2025 meeting, and in consideration of the increase in the State GHL for the State waters fishery in the Western GOA regulatory area. The adjustments are also necessary to ensure that the Pacific cod TACs are seasonally apportioned among sectors consistent with Steller sea lion protection measures set forth in regulation (§ 679.20(a)(12)(i)(A) & (B)).

Pursuant to § 679.25(a)(1)(iii), the Regional Administrator is adjusting the 2026 GOA Pacific cod TAC to 21,826 mt. Therefore, table 2 of the final 2025 and 2026 harvest specifications for groundfish in the GOA (90 FR 12468, March 18, 2025) is revised consistent with this adjustment.

Pursuant to § 679.20(a)(6)(ii) and (a)(12)(i), table 6 of the final 2025 and 2026 harvest specifications for groundfish in the GOA (90 FR 12468, March 18, 2025) is revised for the 2026 TACs of Pacific cod in the GOA.

TABLE 1—FINAL 2026 SEASONAL APPORTIONMENTS AND ALLOCATION OF PACIFIC COD TOTAL ALLOWABLE CATCH AMOUNTS IN THE GOA; ALLOCATIONS IN THE WESTERN GOA AND CENTRAL GOA SECTORS, AND THE EASTERN GOA INSHORE AND OFFSHORE PROCESSING COMPONENTS

[Values are rounded to the nearest metric ton]

Regulatory area and sector	Annual allocation (mt)	A Season		B Season	
		Sector percentage of annual non-jig TAC	Seasonal allowances (mt)	Sector percentage of annual non-jig TAC	Seasonal allowances (mt)
Western GOA					
Jig (2.5% of TAC)	133	n/a	80	n/a	53
Hook-and-line CV	72	0.70	36	0.70	36
Hook-and-line CP	1,026	10.90	565	8.90	461
Trawl CV	1,991	31.54	1,635	6.86	356
Trawl CP	125	0.90	47	1.50	78
All Pot CV and Pot CP	1,971	19.80	1,027	18.20	944
Total	5,318	63.84	3,390	36.16	1,928
Central GOA					
Jig (4 of TAC)	578	n/a	347	n/a	231
Hook-and-line <50 CV	2,025	9.32	1,292	5.29	733
Hook-and-line ≥50 CV	930	5.61	778	1.10	152
Hook-and-line CP	708	4.11	570	1.00	138
Trawl CV ¹	5,767	25.29	3,508	16.29	2,259
Trawl CP	582	2.00	278	2.19	304
All Pot CV and Pot CP	3,857	17.83	2,473	9.98	1,384
Total	14,447	64.16	9,246	35.84	5,201
Eastern GOA		Inshore (90 of Annual TAC)		Offshore (10 of Annual TAC)	
Total	2,061	1,855		206	

¹ Trawl catcher vessels participating in Rockfish Program cooperatives receive 3.81 percent, or 550 mt, of the annual Central GOA TAC (see table 28c to 50 CFR part 679), which is deducted from the Trawl CV B season allowance. This inseason adjustment also updates the apportionment found in table 13 of the final 2025 and 2026 harvest specifications for groundfish in the GOA (*i.e.*, Final 2026 Apportionments of Rockfish Secondary Species in the Central GOA to Catcher Vessel and Catcher/Processor Cooperatives) (90 FR 12468, March 18, 2025).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b) of the Magnuson-Stevens Act, and is exempt from review under Executive Order 12866.

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 would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data and information in a timely fashion and would allow for harvests that exceed the appropriate allocation for Pacific cod based on the most recent information available. Without an immediate adjustment decreasing Pacific cod TACs, harvests of Pacific cod in State waters and Federal waters in the GOA could exceed the ABC, and therefore the annual catch limit for Pacific cod and increase the risk of overfishing. NMFS was unable to publish a notice providing time for

public comment because the most recent, relevant data and information only became available as of December 19, 2025. This action must be effective by January 1, 2026, to ensure harvests of Pacific cod are consistent with seasonal apportionments for Pacific cod that are based on regulations implementing Steller sea lion protection measures.

Without this inseason adjustment, NMFS could not allow the fishery for Pacific cod in the GOA to be harvested in an expedient manner. Under § 679.25(c)(2), interested persons are invited to submit written comments on this action to the above ADDRESSES until January 7, 2026.

There is good cause under 5 U.S.C. 553(d)(3) to establish an effective date less than 30 days after date of publication. This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

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

Dated: December 19, 2025.

Kelly Denit,

*Director, Office of Sustainable Fisheries,
National Marine Fisheries Service.*

[FR Doc. 2025–23786 Filed 12–22–25; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 250312–0036; RTID 0648–XF374]

Fisheries of the Exclusive Economic Zone Off Alaska; Several Groundfish Species in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; apportionment of reserves; request for comments.

SUMMARY: NMFS apportions amounts of the nonspecified reserves to the total allowable catch (TAC) of “other flatfish” and octopuses. This action is necessary to allow the fisheries to continue operating. It is intended to promote the goals and objectives of the fishery management plan for the Bering Sea and Aleutian Islands Management (BSAI) management area.

DATES: Effective December 22, 2025, through 2400 hours, Alaska local time, December 31, 2025. Comments must be received at the following address no later than 4:30 p.m., Alaska local time, January 6, 2026.

ADDRESSES: You may submit comments on this document, identified by docket number NOAA–NMFS–2024–0116, by any of the following methods:

Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal. Visit <https://www.regulations.gov> and type NOAA–NMFS–2024–0116 in the Search box. Click on the “Comment” icon, complete the required fields, and enter or attach your comments.

Mail: Submit written comments to Gretchen Harrington, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on <https://www.regulations.gov> without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter “N/A” in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Andrew Olson, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the BSAI Management Area (FMP) prepared and recommended by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Regulations governing fishing by U.S. vessels in accordance with the FMP appear at 50 CFR part 679 and subpart H of 50 CFR part 600.

The 2025 TAC for “other flatfish” was established as 5,225 metric tons (mt) by the final 2025 and 2026 harvest specifications for groundfish in the BSAI (90 FR 12640, March 18, 2025) and reapportionment of groundfish reserves (90 FR 27483, June 27, 2025).

The 2025 TAC and ITAC for octopuses was established as 400 mt and 340 mt, respectively, by the final 2025 and 2026 harvest specifications for groundfish in the BSAI (90 FR 12640, March 18, 2025).

In accordance with § 679.20(a)(3), the Regional Administrator, Alaska Region, NMFS, has reviewed the most current available data and finds that the TAC for “other flatfish” and octopuses needs to be supplemented from the nonspecified reserves to promote efficiency in the utilization of fishery resources in the BSAI and allow fishing operations to continue.

Therefore, in accordance with § 679.20(b)(3), NMFS apportions 600 mt from the nonspecified reserves of groundfish in the BSAI management area as follows: 500 mt to “other flatfish” and 100 mt to octopuses. This apportionment is authorized by § 679.20(b)(1)(i) and consistent with § 679.20(a)(3) and does not result in overfishing of any target species because the revised TACs are equal to or less than the specifications of the acceptable biological catch for “other flatfish” and octopuses in the final 2025 and 2026 harvest specifications for groundfish in the BSAI (90 FR 12640, March 18, 2025).

The harvest specifications for the 2025 TACs included in the final 2025 and 2026 harvest specifications for groundfish in the BSAI is revised as follows: 5,725 mt for “other flatfish” and 440 mt for octopuses.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b) of the Magnuson-Stevens Act, and is exempt from review under Executive Order 12866.

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 would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the apportionment of the nonspecified reserves of groundfish to “other flatfish” and octopuses. This action is necessary for the efficient utilization of fishery resources in the BSAI and to allow the fisheries

harvesting these groundfish to continue operating. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data on catch of “other flatfish” and octopuses only became available as of December 19, 2025. Finally, NMFS provided notice and an opportunity for public comment on the proposed 2025 and 2026 harvest specifications for groundfish in the BSAI that included the amount of proposed nonspecified reserves from which NMFS can apportion to any target species that contributed to that reserve (89 FR 96186, December 4, 2024). The final 2025 and 2026 harvest specifications for groundfish in the BSAI explained that, during the fishing year, any amount of the nonspecified reserve may be apportioned by NMFS to a target species that contributed to the nonspecified reserves consistent with § 679.20(b)(1)(i) (90 FR 12640, March 18, 2025).

There is good cause under 5 U.S.C. 553(d)(3) to make this action effective immediately upon filing with the Office of the Federal Register. This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Under § 679.20(b)(3)(iii), interested persons are invited to submit written comments on this action (see **ADDRESSES** section) until January 6, 2026.

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

Dated: December 19, 2025.

Kelly Denit,

*Director, Office of Sustainable Fisheries,
National Marine Fisheries Service.*

[FR Doc. 2025–23776 Filed 12–22–25; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 250312–0036; RTID 0648–XF403]

Fisheries of the Exclusive Economic Zone Off Alaska; Inseason Adjustment to the 2026 Aleutian Islands Pacific Cod Total Allowable Catch Amount and Bering Sea and Aleutian Islands Pacific Cod Allocations

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

ACTION: Temporary rule; inseason adjustment; request for comments.

SUMMARY: NMFS is adjusting the 2026 total allowable catch (TAC) amount for

Aleutian Islands (AI) Pacific cod and the Bering Sea and Aleutian Islands (BSAI) Pacific cod sector allocations and seasonal apportionments. NMFS has determined the AI Pacific cod TAC is incorrectly specified and these adjustments will address the underharvest of BSAI Pacific cod TACs that would result if the TACs were not adjusted. This action is consistent with the goals and objectives of the Fishery Management Plan for Groundfish of the BSAI Management Area (FMP).

DATES: Effective 0001 hours, Alaska local time (A.l.t.), January 1, 2026, through March 18, 2026, unless otherwise modified or superseded through publication of the final 2026 and 2027 harvest specifications for BSAI groundfish.

Comments must be received at the following **ADDRESSES** no later than 4:30 p.m., A.l.t., January 7, 2026.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2024–0116, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Visit <https://www.regulations.gov> and type NOAA–NMFS–2024–0116 in the Search box. Click on the “Comment” icon, complete the required fields, and enter or attach your comments.

- *Mail:* Submit written comments to Gretchen Harrington, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on <https://www.regulations.gov> without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter “N/A” in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Andrew Olson, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the FMP prepared and recommended by the North Pacific Fishery Management Council (Council) under authority of the Magnuson-

Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR 600 and 50 CFR part 679.

The final 2025 and 2026 harvest specifications for groundfish in the BSAI (90 FR 12640, March 18, 2025) set the 2026 AI Pacific cod TAC at 8,432 mt. In December 2025, the Council recommended a 2026 AI Pacific cod TAC of 8,951 mt, which is more than the AI Pacific cod TAC of 8,432 mt established for 2026 by the final 2025 and 2026 harvest specifications for groundfish in the BSAI. This increase in TAC accounts for a reduction in the guideline harvest level (GHL) set for the State of Alaska (State) waters Pacific cod fishery in the AI. The AI Pacific cod TAC accounts for the State GHL for Pacific cod to ensure that the sum of all State and Federal Pacific cod removals do not exceed the acceptable biological catch (ABC) set for AI Islands Pacific cod.

Steller sea lions occur in the same location as the Pacific cod fisheries and are listed as endangered under the Endangered Species Act. Pacific cod is a principal prey species for Steller sea lions in the BSAI. NMFS published regulations and the revised harvest limit amount for Pacific cod fisheries to implement Steller sea lion protection measures to ensure that groundfish fisheries of the BSAI are not likely to jeopardize the continued existence of the western distinct population segment of Steller sea lions or destroy or adversely modify their designated critical habitat (79 FR 70286, November 25, 2014). These measures include regulations requiring the seasonal apportionment of Pacific cod harvest and the specification of an Area 543 Pacific cod harvest limit. To calculate the Area 543 Pacific cod harvest limit, NMFS first subtracts the State GHL Pacific cod amount from the AI Pacific cod ABC. Then NMFS determines the harvest limit in Area 543 by multiplying the percentage of Pacific cod estimated in Area 543 by the remaining ABC for AI Pacific cod.

Stock assessments were not completed in 2025 due to the lapse in appropriations and resulting government shutdown from October 1, 2025 through November 12, 2025. The Scientific and Statistical Committee (SSC) recommendations are informed by the Groundfish Plan Team’s recommended overfishing limits (OFLs) and ABCs from their November 2024 meeting as well as a review of the most recent Stock Assessment and Fishery

Evaluation (SAFE) report dated November 2024. The Council’s TAC recommendations are based on those of its Advisory Panel, consistent with the SSC’s OFL and ABC recommendations, and reflect the most recent information on the State GHL and Pacific cod.

In accordance with § 679.25(a)(1)(iii), (a)(2)(i)(C), and (a)(2)(iv), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2026 AI Pacific cod TAC and subsequent BSAI Pacific cod sector allocations and seasonal apportionments are incorrectly specified and that adjustments are necessary to address the underharvest of BSAI Pacific cod that could occur if the AI Pacific cod TAC and BSAI Pacific cod sector allocations are not increased consistent with the TAC recommendations by the Council at the December 2025 meeting. This determination is based on the November 2024 SAFE report and the TAC recommendations by the Council at the December 2025 meeting, and in consideration of the change in the State GHL for the State waters fishery in the AI and the regulations implementing the Steller sea lion protection measures. The adjustment to the AI Pacific cod TAC is also necessary to ensure that the BSAI Pacific cod TACs are seasonally apportioned among sectors consistent with the Steller sea lion protection measures and that the Area 543 Pacific cod harvest limit, which is based on Pacific cod abundance in Area 543, is correctly specified. These adjustments are based upon the best available scientific information concerning the biological stock status of AI Pacific cod.

Pursuant to § 679.25(a)(1)(iii), the Regional Administrator is adjusting the 2026 AI Pacific cod TAC to 8,951 mt. Therefore, table 2 of the final 2025 and 2026 harvest specifications for groundfish in the BSAI (90 FR 12640, March 18, 2025) is revised consistent with this adjustment.

Pursuant to § 679.20(a)(7), table 10 of the final 2025 and 2026 harvest specifications for groundfish in the BSAI (90 FR 12640, March 18, 2025) is revised for the 2026 sector allocations and seasonal allowances of the BSAI Pacific cod TAC, Community Development Quota (CDQ) Program directed fishing allowances (DFAs), and Pacific Cod Trawl Cooperative (PCTC) Program DFAs consistent with this adjustment.

TABLE 10—FINAL 2026 SECTOR ALLOCATIONS AND SEASONAL ALLOWANCES OF THE BSAI PACIFIC COD TAC
[Values are rounded to the nearest metric ton]

Sector	Percent	2026 share of area, gear, and sector total	Season	Season amounts
Total Bering Sea TAC	n/a	123,077	n/a	n/a
Bering Sea CDQ	n/a	13,169	See § 679.20(a)(7)(i)(B)	n/a
Bering Sea non-CDQ TAC	n/a	109,908	n/a	n/a
Total Aleutian Islands TAC	n/a	8,951	n/a	n/a
Aleutian Islands CDQ	n/a	958	See § 679.20(a)(7)(i)(B)	n/a
Aleutian Islands non-CDQ TAC	n/a	7,993	n/a	n/a
Western Aleutian Islands Limit	n/a	2,864	n/a	n/a
Total BSAI non-CDQ TAC ¹	100	117,901	n/a	n/a
Total hook-and-line/pot gear	60.8	71,684	n/a	n/a
Hook-and-line/pot ICA ²	n/a	500	n/a	n/a
Hook-and-line/pot sub-total	n/a	71,184	n/a	n/a
Hook-and-line catcher/processors	48.7	57,017	n/a	n/a
A-season	n/a	n/a	Jan 1–Jun 10	29,079
B-season	n/a	n/a	June 10–Dec 31	27,938
Hook-and-line catcher vessels ≥60 ft LOA	0.2	234	n/a	n/a
A-season	n/a	n/a	Jan 1–Jun 10	119
B-season	n/a	n/a	June 10–Dec 31	115
Pot catcher/processors	1.5	1,756	n/a	n/a
A-season	n/a	n/a	Jan 1–Jun 10	896
B-season	n/a	n/a	Sept 1–Dec 31	861
Pot catcher vessels ≥60 ft LOA	8.4	9,835	n/a	n/a
A-season	n/a	n/a	Jan 1–Jun 10	5,016
B-season	n/a	n/a	Sept 1–Dec 31	4,819
Catcher vessels <60 ft LOA using hook-and-line or pot ...	2	2,342	n/a	n/a
Trawl catcher vessels ³	22.1	26,056	n/a	n/a
A-season ICA	n/a	n/a	Jan 20–Apr 1	1,500
A-season PCTC	n/a	n/a	Jan 20–Apr 1	17,782
B-season ICA	n/a	n/a	Apr 1–Jun 10	600
B-season PCTC	n/a	n/a	Apr 1–Jun 10	2,166
C-season trawl catcher vessels	n/a	n/a	Jun 10–Nov 1	3,908
AFA trawl catcher/processors	2.3	2,712	n/a	n/a
A-season	n/a	n/a	Jan 20–Apr 1	2,034
B-season	n/a	n/a	Apr 1–Jun 10	678
C-season	n/a	n/a	Jun 10–Nov 1	0
Amendment 80	13.4	15,799	n/a	n/a
A-season	n/a	n/a	Jan 20–Apr 1	11,849
B-season	n/a	n/a	Apr 1–Jun 10	3,950
C-season	n/a	n/a	Jun 10–Dec 31	0
Jig	1.4	1,651	n/a	n/a
A-season	n/a	n/a	Jan 1–Apr 30	990
B-season	n/a	n/a	Apr 30–Aug 31	330
C-season	n/a	n/a	Aug 31–Dec 31	330

¹ The sector allocations and seasonal allowances for BSAI Pacific cod TAC are based on the sum of the BS and AI Pacific cod TACs, after subtraction of the reserves for the CDQ Program. If the TAC for Pacific cod in either the BS or AI is or will be reached, then directed fishing will be prohibited for non-CDQ Pacific cod in that subarea, even if a BSAI allowance remains (§ 679.20(d)(1)(iii)).

² The incidental catch allowance (ICA) for the hook-and-line and pot sectors will be deducted from the aggregate portion of Pacific cod TAC allocated to the hook-and-line and pot sectors. The Regional Administrator sets an ICA of 500 mt based on anticipated incidental catch by these sectors in other fisheries.

³ The A and B season trawl CV Pacific cod allocation will be allocated to the PCTC Program after subtraction of the A and B season ICAs (§ 679.131(b)(1)). Section 679.131(b)(1)(i) requires NMFS to establish an ICA for incidental catch of Pacific cod by trawl CVs engaged in directed fishing for groundfish other than PCTC Program Pacific cod. The Regional Administrator sets for the A and B seasons, ICAs of 1,500 mt and 600 mt, respectively, to account for projected incidental catch of Pacific cod by trawl catcher vessels engaged in directed fishing for groundfish other than PCTC Program Pacific cod.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b) of the Magnuson-Stevens Act, and is exempt from review under Executive Order 12866.

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 would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data and information in a timely fashion and would result in the underharvest of Pacific cod in the BSAI if the AI Pacific cod TAC and BSAI Pacific cod sector allocations are not increased consistent with the TAC recommendations by the Council at

their December 2025 meeting. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data and information only became available as of December 19, 2025. This action must be effective by January 1, 2026, to ensure harvests of Pacific cod are consistent with seasonal apportionments and harvest limits for Pacific cod that are based on regulations

implementing Steller sea lion protection measures.

Without this inseason adjustment, NMFS could not allow the fishery for Pacific cod in the BSAI to be harvested in an expedient manner. Under § 679.25(c)(2), interested persons are invited to submit written comments on

this action to the above **ADDRESSES** until January 7, 2026.

There is good cause under 5 U.S.C. 553(d)(3) to establish an effective date less than 30 days after date of publication. This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Authority: 16 U.S.C. 1801 *et seq.*
Dated: December 19, 2025.
Kelly Denit,
Director, Office of Sustainable Fisheries,
National Marine Fisheries Service.
[FR Doc. 2025–23775 Filed 12–22–25; 8:45 am]
BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 90, No. 244

Tuesday, December 23, 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.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2025–0485; Project Identifier AD–2024–00670–A]

RIN 2120–AA64

Airworthiness Directives; Honda Aircraft Company LLC Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM).

SUMMARY: The FAA is revising a notice of proposed rulemaking (NPRM) that would have applied to certain Honda Aircraft Company LLC (Honda) Model HA–420 airplanes. This action revises the NPRM by updating the referenced service material to a new revision that includes redesigned replacement flap control pushrod assemblies that have been modified to prevent interference with adjacent parts. The FAA is proposing this airworthiness directive (AD) to address the unsafe condition on these products. Since these actions would impose an additional burden over those in the NPRM, the agency is requesting comments on this SNPRM.

DATES: The FAA must receive comments on this SNPRM by February 6, 2026.

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–2025–0485; 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 SNPRM, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For Honda Aircraft Company material identified in this proposed AD, contact Honda, 6430 Ballinger Road, Greensboro, NC 27410; phone: (336) 662–0246; website: *hondajet.com*.

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

FOR FURTHER INFORMATION CONTACT:

Kelly Fichter, Aviation Safety Engineer, FAA, 1701 Columbia Avenue, College Park, GA 30337; (404) 474–5544; email: *ecb-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 using a method listed under the **ADDRESSES** section. Include “Docket No. FAA–2025–0485; Project Identifier AD–2024–00670–A” 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 again revise 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 SNPRM.

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 SNPRM 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 SNPRM, 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 SNPRM. Submissions containing CBI should be sent to Kelly Fichter, Aviation Safety Engineer, FAA, 701 Columbia Avenue, College Park, GA 30337. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2021–22–12, Amendment 39–21785 (86 FR 60753, November 4, 2021) (AD 2021–22–12), for certain Honda Model HA–420 airplanes. AD 2021–22–12 requires removing and cleaning the inner diameter of the flap control pushrod assembly and repetitively applying corrosion inhibiting compound (CIC) to this area. The FAA issued AD 2021–22–12 to prevent failure of the flap control pushrod assembly, which, if not addressed, could result in uncontrolled and un-announced flap asymmetry with consequent loss of control of the airplane.

The FAA issued an NPRM to amend 14 CFR part 39 by adding an AD to supersede AD 2021–22–12 that would have applied to certain serial-numbered Honda Model HA–420 airplanes. The NPRM was published in the **Federal Register** on April 11, 2025 (90 FR 15426). The NPRM was prompted by a report that the flap pushrod assemblies are susceptible to corrosion, and the subsequent development of updated flap control pushrod assemblies that are more corrosion resistant and do not require repetitive CIC applications. In the NPRM, the FAA proposed to continue to require removing and cleaning the inner diameter of the flap control pushrod assembly and repetitively applying CIC to this area.

The NPRM also proposed to expand the applicability to include additional airplanes and require replacing the flap control pushrod assemblies with new corrosion-resistant flap control pushrod assemblies.

Actions Since the NPRM Was Issued

Since the FAA issued the NPRM, it was discovered that the updated outboard corrosion resistant pushrods could interfere with the mid flap drive arms when fully deployed. As a result of this finding, the manufacturer published updated service material that includes a modified design of the flap control pushrod assembly to prevent interference with adjacent parts. The FAA is proposing this AD to address the unsafe condition on these products.

Comments

The FAA received one comment on the NPRM from an individual. The commenter supported the NPRM without change.

FAA’s Determination

The FAA is proposing this AD after determining the unsafe condition described previously is likely to exist or develop in other products of the same type design. Certain changes described above expand the scope of the NPRM. As a result, it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this SNPRM.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Honda Aircraft Company Alert Service Bulletin No. SB–420–27–009, Revision B, dated August 5, 2025. This material specifies procedures for replacing the flap control pushrod assemblies with improved design flap control pushrod assemblies. This proposed AD would also require Honda Aircraft Company Alert Service Bulletin No. SB–420–27–008, dated August 31, 2021, which the Director of the Federal Register approved for incorporation by reference as of

November 19, 2021 (86 FR 60753, November 4, 2021). 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.

Proposed AD Requirements in This SNPRM

This proposed AD would retain all of the requirements of AD 2021–22–12. This proposed AD would also expand the applicability to include additional airplanes and require replacing the flap control pushrod assemblies with new corrosion-resistant flap control pushrod assemblies as terminating action for the repetitive CIC applications required by AD 2021–22–12.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 107 airplanes 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
Remove, clean, and apply CIC to the flap control pushrod assembly (retained from AD 2021–22–12).	22 work-hours × \$85 per hour = \$1,870.	\$70	\$1,940	\$85,360 (44 airplanes).
Reapply CIC every 90 days (cost for each time) (retained from AD 2021–22–12).	1 work-hour × \$85 per hour = \$85.	70	155	\$6,820 (44 airplanes).
Replace the left and right inboard flap control pushrod assemblies.	22 work-hours × \$85 per hour = \$1,870.	5,168	7,038	\$753,066 (107 airplanes).

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]
- a. Removing Airworthiness Directive 2021–22–12, Amendment 39–21785 (86 FR 60753, November 4, 2021); and
- b. Adding the following new airworthiness directive:
Honda Aircraft Company LLC: Docket No. FAA–2025–0485; Project Identifier AD–2024–00670–A.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by February 6, 2026.

(b) Affected ADs

This AD replaces AD 2021–22–12, Amendment 39–21785 (86 FR 60753, November 4, 2021) (AD 2021–22–12).

(c) Applicability

This AD applies to the following Honda Aircraft Company LLC Model HA–420 airplanes, certificated in any category:

(1) Group 1 airplanes: serial numbers 42000153 through 42000158 and 42000160 through 42000206; and

(2) Group 2 airplanes: serial numbers 42000211, 42000212, and 42000215 through 42000287.

(d) Subject

Joint Aircraft System Component (JASC) Code 2752, Trailing Edge Flap Actuator.

(e) Unsafe Condition

This AD was prompted by a report that the flap pushrod assemblies are susceptible to corrosion. The FAA is issuing this AD to prevent failure of the flap control pushrod assembly. The unsafe condition, if not addressed, could result in uncontrolled and un-annunciated flap asymmetry with consequent loss of control of the airplane.

(f) Compliance

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

(g) Retained Actions From AD 2021–22–12 for Group 1 Airplanes

(1) Within 90 days after November 19, 2021 (the effective date of AD 2021–22–12), or 18 months after issuance of the first standard certificate of airworthiness, whichever occurs later: Remove, clean, apply corrosion inhibiting compound (CIC) to, and reinstall the left and right inboard and outboard flap control pushrod assemblies by following steps (3) through (6) of the Accomplishment Instructions in Honda Aircraft Company Alert Service Bulletin No. SB–420–27–008, dated August 31, 2021.

(2) Within 90 days or 300 hours time-in-service (TIS), whichever occurs first after accomplishing the actions required by paragraph (g)(1) of this AD, and thereafter at intervals not to exceed 90 days or 300 hours TIS, whichever occurs first: Reapply CIC by following step (5)(a) through (c) of the Accomplishment Instructions in Honda Aircraft Company Alert Service Bulletin No. SB–420–27–008, dated August 31, 2021.

(h) New Required Actions for Group 1 and Group 2 Airplanes

(1) Within 2 years after the effective date of this AD, replace the flap control pushrod assemblies with redesigned (zero hours TIS) flap control pushrod assemblies in accordance with steps (3) through (5) of the Accomplishment Instructions in Honda Aircraft Company Alert Service Bulletin No. SB–420–27–009 Revision B, dated August 5, 2025.

(2) For Group 1 airplanes, accomplishing the replacement required by paragraph (h)(1) of this AD terminates the requirements of paragraphs (g)(1) and (2) of this AD.

(i) Installation Prohibition

As of the effective date of this AD, do not install on any airplane, an inboard or outboard flap control pushrod assembly part number that is identified in the Effectivity section of Honda Aircraft Company Alert Service Bulletin No. SB–420–27–009 Revision B, dated August 5, 2025.

(j) No Reporting Requirement

Although Honda Aircraft Company Alert Service Bulletin No. SB–420–27–008, dated August 31, 2021, and Alert Service Bulletin No. SB–420–27–009, Revision B, dated August 5, 2025, specify to submit certain information to the manufacturer, this AD does not include those requirements.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, East Certification 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 East Certification 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.

(3) For material that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (k)(3)(i) and (ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition

(l) Additional Information

For more information about this AD, contact Kelly Fichter, Aviation Safety Engineer, FAA, 1701 Columbia Avenue, College Park, GA 30337; phone: (404) 474–5544; email: ecb-cos@faa.gov.

(m) 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.

(3) The following material was approved for IBR on [DATE 35 DAYS AFTER PUBLICATION OF THE FINAL RULE].

(i) Honda Aircraft Company Alert Service Bulletin No. SB–420–27–009, Revision B, dated August 5, 2025.

(ii) [Reserved]

(4) The following material was approved for IBR on November 19, 2021 (86 FR 60753, November 4, 2021).

(i) Honda Aircraft Company Alert Service Bulletin No. SB–420–27–008, dated August 31, 2021.

(ii) [Reserved]

(5) For Honda Aircraft Company material identified in this AD, contact Honda Aircraft Company LLC, 6430 Ballinger Road, Greensboro, NC 27410; phone: (336) 662–0246; website: hondajet.com.

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

(7) 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 December 17, 2025.

Steven W. Thompson,

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

[FR Doc. 2025–23719 Filed 12–22–25; 8:45 am]

BILLING CODE 4910–13–P

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

[Docket No. **FAA–2025–5397**; Project Identifier **MCAI–2025–00972–A**]

RIN 2120–AA64

Airworthiness Directives; Diamond Aircraft Industries Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2020–14–06, which applies to all Diamond Aircraft Industries Inc. (DAI) Model DA 40, DA 40 F, and DA 40 NG airplanes. AD 2020–14–06 requires replacing affected parts, inspecting the fuel tank chambers, and removing rubber material that has detached from the fuel tank connection hoses. AD 2020–14–06 also prohibits installing an affected part on any airplane. Since the FAA issued AD 2020–14–06, additional affected parts installed during production on Model DA 40 NG

airplanes have been reported. As a result, the manufacturer has published updated service material for the Model DA 40 NG.

This proposed AD would require the same actions as AD 2020–14–06 and would require updated service material to be used for the Model DA 40 NG airplanes. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this NPRM by February 6, 2026.

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–2025–5397; 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 Diamond Aircraft Industries material identified in this proposed AD, contact DAI, 1560 Crumlin Sideroad, London, Ontario, Canada, N5V 1S2; phone: (519) 457–4041, fax: (519) 457–4045; email: *support-canada@diamondaircraft.com*.

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

FOR FURTHER INFORMATION CONTACT: Joseph Catanzaro, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (516) 228–7366; email: *joseph.catanzaro@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 **ADDRESSES**. Include “Docket No. FAA–2025–5397; Project Identifier MCAI–2025–00972–A” 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 Joseph Catanzaro, 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

The FAA issued AD 2020–14–06, Amendment 39–21160 (85 FR 42687, July 15, 2020) (AD 2020–14–06), for DAI Model DA 40, DA 40 F, and DA 40 NG airplanes (including Model DA 40 NG airplanes that have been converted from the Model DA 40 D), all serial numbers, certificated in any category. AD 2020–14–06 was prompted by AD CF–2019–39, dated October 31, 2019 (Transport Canada AD CF–2019–39) issued by Transport Canada, which is the aviation authority for Canada. Transport Canada issued Transport Canada AD CF–2019–39 to correct an unsafe condition

identified as fuel tank connection hose deterioration.

AD 2020–14–06 requires replacing affected parts, inspecting the fuel tank chambers, and removing rubber material that has detached from the fuel tank connection hoses. AD 2020–14–06 also prohibits installing an affected part on any airplane. The FAA issued AD 2020–14–06 to detect deterioration of fuel tank connection hoses, which, if not corrected, could result in contamination of the fuel system and restriction of fuel flow, and could lead to fuel starvation and reduced control of the airplane.

Actions Since AD 2020–14–06 Was Issued

Since the FAA issued AD 2020–14–06, Transport Canada superseded Transport Canada AD CF–2019–39 and issued Transport Canada AD CF–2019–39R1, dated May 21, 2025 (also referred to as the MCAI). The MCAI states that since the issuance of Transport Canada AD CF–2019–39, Transport Canada has received reports of affected parts installed during production on DAI Model DA 40 NG airplanes. As a result, the manufacturer published updated service material for the Model DA 40 NG. The MCAI also continues to require replacing affected fuel tank connection hoses, inspecting the fuel tank chambers, and removing rubber material that has detached from the fuel tank connection hoses.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2025–5397.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Diamond Aircraft Industries Mandatory Service Bulletin No. MSB 40NG–064 Rev. 3, dated January 23, 2025, which specifies procedures for replacing affected parts, inspecting the fuel tank chambers, and removing rubber material that has detached from the hoses. This material also specifies the service centers from which the affected parts could have been obtained, and the serial numbers for additional DAI Model DA 40 NG airplanes that are affected by the unsafe condition and were not in the previous version of the material.

This proposed AD would also require the following Diamond Aircraft Industries Mandatory Service Bulletins, which the Director of the Federal Register approved for incorporation by reference as of August 4, 2020 (85 FR 42687, July 15, 2020):

- Diamond Aircraft Industries Mandatory Service Bulletin No. MSB 40–087, Revision 3, dated November 5, 2019.

- Diamond Aircraft Industries Mandatory Service Bulletin No. MSB F4-037, Revision 3, dated November 5, 2019.

- Diamond Aircraft Industries Work Instruction WI-MSB 40-087, Revision 0, dated July 1, 2019.

- Diamond Aircraft Industries Work Instruction WI-MSB F4-037, Revision 0, dated July 1, 2019.

- Diamond Aircraft Industries Work Instruction WI-MSB 40 NG-064, Revision 0, dated July 1, 2019.

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 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 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 the same actions as AD 2020-14-06 and would require updated material to be used for the Model DA 40 NG airplanes.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 987 airplanes 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
Inspect the fuel tank chambers	1 work-hour × \$85 per hour = \$85	\$0	\$85	\$83,895
Remove detached rubber material	5 work hours × \$85 per hour = \$425	0	425	419,475
Replace fuel tank connection hose	10 work hours × \$85 per hour = \$850	383	1,233	1,216,971

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some 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 that the 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:

■ a. Removing Airworthiness Directive AD 2020-14-06, Amendment 39-21160 (85 FR 42687, July 15, 2020); and

■ b. Adding the following new airworthiness directive:

Diamond Aircraft Industries Inc.: Docket No. FAA-2025-5397; Project Identifier MCAI-2025-00972-A.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by February 6, 2026.

(b) Affected ADs

This AD replaces AD 2020-14-06, Amendment 39-21160 (85 FR 42687, July 15, 2020); (AD 2020-14-06).

(c) Applicability

This AD applies to all Diamond Aircraft Industries Inc. Model DA 40, DA 40 F, and DA 40 NG airplanes (including Model DA 40 NG airplanes that have been converted from the Model DA 40 D), certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 1410, Hoses and tubes.

(e) Unsafe Condition

This AD was prompted by reports of fuel tank connection hose deterioration and reports of affected parts that were installed during production on Model DA 40 NG airplanes. The FAA is issuing this AD to detect and address such deterioration, which, if not corrected, could result in contamination of the fuel system and restriction of fuel flow, and could lead to fuel starvation and reduced control of the airplane.

(f) Compliance

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

(g) Definitions

(1) For the purpose of this AD, "affected part" means a fuel tank connection hose that meets the criteria in paragraph (g)(1)(i), (ii), or (iii) of this AD.

(i) Part number (P/N) D4D-2817-10-70 installed during production on Model DA 40

NG airplanes with a serial number listed in Section I.2. of Diamond Aircraft Industries Mandatory Service Bulletin MSB 40NG-064 Rev. 3, dated January 23, 2025; or

(ii) P/N D4D-2817-10-70 or BENOLPRESS (no part number) purchased between July 13, 2017, and February 26, 2019, as listed in Section I.11 of Diamond Aircraft Industries Mandatory Service Bulletin No. MSB 40-087, Revision 3, dated November 5, 2019; Diamond Aircraft Industries Mandatory Service Bulletin No. MSB 40NG-064 Rev. 3, dated January 23, 2025; or Diamond Aircraft Industries Mandatory Service Bulletin No. MSB F4-037, Revision 3, dated November 5, 2019; or

(iii) P/N D4D-2817-10-70 installed as a replacement part on or after July 13, 2017, if it is unknown whether the part meets the criteria in paragraph (g)(1)(i) or (ii) of this AD.

(h) Required Actions

Within 100 hours time-in-service or within 2 months, whichever occurs first after the effective date of this AD, replace each affected part as defined in paragraph (g) of this AD, inspect the main fuel tank chambers, and remove any detached rubber material in accordance with Sections III.1 and III.2 of the Instructions in Diamond Aircraft Industries Work Instruction WI-MSB 40-087, Revision 0, dated July 1, 2019; Diamond Aircraft Industries Work Instruction WI-MSB F4-037, Revision 0, dated July 1, 2019; or Diamond Aircraft Industries Work Instruction WI-MSB 40NG-064, Revision 0, dated July 1, 2019; as applicable to your model airplane.

(i) No Reporting Requirement

Although the service material specifies to submit information to the manufacturer, this AD does not require that action.

(j) Installation Prohibition

As of the effective date of this AD, do not install an affected part, as defined in paragraph (g) of this AD, on any airplane.

(k) Credit for Previous Actions

This paragraph provides credit for the actions required by paragraph (h) of this AD if those actions were performed before the effective date of this AD, and the affected part for the Model DA 40 NG airplane was identified using Diamond Aircraft Industries Mandatory Service Bulletin No. MSB 40NG-064, Revision 2, dated August 29, 2019.

(l) 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 (m)(1) of this AD and email it 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.

(m) Additional Information

(1) For more information about this AD, contact Joseph Catanzaro, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (516) 228-7366; email: joseph.catanzaro@faa.gov.

(2) Material identified in this AD that is not incorporated by reference is available at the address specified in paragraph (n)(5) of this AD.

(n) 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.

(3) The following material was approved for IBR on February 6, 2026.

(i) Diamond Aircraft Industries Mandatory Service Bulletin MSB 40NG-064 Rev. 3, dated January 23, 2025.

(ii) [Reserved]

(4) The following material was approved for IBR on August 4, 2020 (85 FR 42687, July 15, 2020).

(i) Diamond Aircraft Industries Mandatory Service Bulletin No. MSB 40-087, Revision 3, dated November 5, 2019.

(ii) Diamond Aircraft Industries Mandatory Service Bulletin No. MSB F4-037, Revision 3, dated November 5, 2019.

(iii) Diamond Aircraft Industries Work Instruction WI-MSB 40-087, Revision 0, dated July 1, 2019.

(iv) Diamond Aircraft Industries Work Instruction WI-MSB 40NG-064, Revision 0, dated July 1, 2019.

(v) Diamond Aircraft Industries Work Instruction WI-MSB F4-037, Revision 0, dated July 1, 2019.

(5) For Diamond Aircraft Industries material identified in this AD, contact Diamond Aircraft Industries Inc., 1560 Crumlin Sideroad, London, Ontario, Canada, N5V 1S2; phone: (519) 457-4041, fax: (519) 457-4045; email: support-canada@diamondaircraft.com.

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

(7) 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 December 16, 2025.

Steven W. Thompson,

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

[FR Doc. 2025-23794 Filed 12-22-25; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF THE TREASURY

Office of the Secretary

31 CFR Part 5

Fiscal Service

31 CFR Parts 256 and 285

[DOCKET NO. FISCAL-2023-0004]

RIN 1530-AA17

Debt Collection Authorities Under the Debt Collection Improvement Act of 1996

AGENCY: Bureau of the Fiscal Service, Fiscal Service, Treasury.

ACTION: Notice of proposed rulemaking with request for comment.

SUMMARY: The Department of the Treasury (“Treasury”), Bureau of the Fiscal Service (“Fiscal Service”), proposes to revise its existing regulations regarding the Treasury Offset Program (“TOP”) for several reasons, including to: restore statutory flexibility that was unnecessarily restricted; implement new authorities; eliminate repetitive and unnecessary language; reword certain provisions for clarity, consistent with the requirements of the Plain Writing Act of 2010 and Executive Order 12866; and better organize the regulations for easier comprehension.

DATES: Comments must be received by February 23, 2026.

ADDRESSES: Fiscal Service participates in the U.S. Government’s eRulemaking Initiative by publishing rulemaking information on www.regulations.gov. *Regulations.gov* offers the public the ability to comment on, search, and view publicly available rulemaking materials, including comments received on rules.

Instructions for comment submission:

Comments on this rule, identified by docket FISCAL-2023-0004, may be submitted using the Federal eRulemaking Portal: www.regulations.gov. Follow the instructions on the website for submitting comments. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Director, TOP Division, Disbursing and Debt Management, Bureau of the Fiscal Service, Landover Warehouse, 3201 Pennsy Drive, Landover, MD 20785.

All submissions received must include the agency name (“Bureau of the Fiscal Service”) and docket number (“FISCAL-2023-0004”) for this rulemaking. In general, comments will be published on *Regulations.gov*

without change, including any business or personal information provided. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

FOR FURTHER INFORMATION CONTACT:

Director, TOP Division, Disbursing and Debt Management, Bureau of the Fiscal Service at (202) 874–6810.

SUPPLEMENTARY INFORMATION:

I. Background

Legal Authorities. The Debt Collection Improvement Act of 1996 (“DCIA”), Public Law 104–134, 110 Stat. 1321–358 *et seq.* (April 26, 1996), among other things, authorized Federal disbursing officials to withhold eligible Federal payments to pay the payee’s delinquent nontax debt owed to the United States. *See* 31 U.S.C. 3716(c). The DCIA also provided that Federal nontax payments may be offset to collect delinquent debts owed to States, including past-due support, and that payments made by States may be offset to collect delinquent debts owed to the United States. *See* 31 U.S.C. 3716(h). In addition, the DCIA requires Federal agencies to identify Federal employees who owe delinquent nontax debts to the United States. *See* 5 U.S.C. 5514(a)(1). Further, Federal tax refund payments may be offset to collect nontax debt owed to the United States and debts owed to States, including past-due support. *See* 26 U.S.C. 6402, 31 U.S.C. 3720A, and 42 U.S.C. 664. The Supporting America’s Children and Families Act, Public Law 118–258 (Jan. 4, 2025), also permits the offset of tax refund payments to collect past-due support owed to certain Federally recognized Tribes. *See* 26 U.S.C. 6402(c) and 42 U.S.C. 664.

Treasury Offset Program. Fiscal Service administers a centralized offset program, known as the Treasury Offset Program, or TOP, through which it exercises these legal authorities. In general, TOP works as follows:

(1) Creditor agencies submit information about delinquent debts to Fiscal Service, which maintains the information in its delinquent debtor database. The information submitted includes the name and taxpayer identifying number (“TIN”) of the debtor. (2) Payment agencies prepare and certify payments to Fiscal Service and disbursing officials at other Federal agencies. Each payment record contains information about the payment,

including the name and TIN of the person entitled to payment. The disbursing official examines the payment records to determine if they meet the requirements for disbursement. If so, the disbursing official then disburses the payments in accordance with the payment agencies’ instructions, subject to any eligible offset or levy. (3) Before an eligible Federal payment is disbursed, Fiscal Service compares information about persons who are entitled to Federal payments against a database of persons who owe delinquent debts. When a match occurs and all the prerequisites for offset have been met, the payment is offset to satisfy the debt, to the extent legally allowed. Fiscal Service also has agreements with certain States, whereby it collects nontax debts owed to the United States through the offset of certain payments disbursed by those States. (4) Fiscal Service transmits amounts collected through offset to the appropriate creditor agencies after deducting fees, which Fiscal Service charges the creditor agencies to cover the cost of operating the offset program.

Re-write of Existing Regulations. Fiscal Service promulgated 31 CFR part 285, subpart A (the “existing TOP regulations”) to implement the administrative offset of payments pursuant to the authorities listed above. The several sections within the existing TOP regulations were promulgated (and revised) at different times. Fiscal Service proposes to revise the existing TOP regulations for several reasons, including to: (1) restore statutory flexibility that was unnecessarily restricted; (2) implement new authorities; (3) eliminate repetitive and unnecessary language; (4) reword certain provisions for clarity, consistent with the requirements of the Plain Writing Act of 2010 and Executive Order 12866 (Sept. 1993); and (5) better organize the regulations for easier comprehension.

II. Section Analysis

This section describes, section-by-section, the reasoning for the proposed revision (the “proposed rule”) of the existing TOP regulations. To the extent a proposed provision is substantively consistent with the existing TOP regulations, this section does not repeat the reasoning for the provision as such explanations are described in **Federal Register** entries for prior rulemakings. To the extent a proposed provision is substantively consistent with the existing TOP regulations, we have described them as being “consistent” with the existing TOP regulations, even if wording changes were required due to the reorganization of subpart A or if

changes were made for clarity or consistency.

Redesignation of Subpart B and Its Included Sections

To accommodate the reorganization of subpart A, the sections of subpart B require redesignation. Sections 285.11 through 285.13 are proposed to be redesignated as §§ 285.111 through 285.113, respectively. No changes to the content of subpart B are proposed.

Section 285.1—Definitions

The existing TOP regulations contain separate definition sections for each type of offset; certain terms are defined in more than one definition section, at times using slightly different definitions. The definitions in the new definitions section would apply to all types of offset. This will ensure consistency and clarity and avoid unnecessary repetition. The definitions used in this section would apply to 31 CFR part 285, subpart A only. For example, whether a debt is “legally enforceable” for purposes of centralized offset has no bearing on whether the debt is legally enforceable for purposes of placing a lien on the debtor’s property or for some other debt collection purpose.

Address. This term is used but not defined in the existing TOP regulations. The proposed definition clarifies that due process notices and offset notices can be sent via first class mail, email, text message, or other reasonable means. Agencies should determine that the method used for delivering information to an address is consistent with relevant law and security policies. With regard to due process notices, agencies should also determine that the address used to send notice is reasonably calculated to reach the debtor. This definition’s broad view of the term “address” does not require an agency to use non-traditional means of mail.

Centralized offset. The proposed definition is consistent with the existing TOP regulations. It refers to offsets conducted to collect debts that have been referred to TOP and includes TOP’s processing of offsets of Federal payments (whether disbursed by Fiscal Service or by another disbursing official) and State payments. This term excludes offsets conducted by the payment agency prior to disbursement (e.g., internal offsets conducted by the payment agency before the payment agency certifies the payment for disbursement).

Covered benefit payment. This term is similar to the term in the existing TOP regulations. However, some concepts that were included in the definition for

“covered benefit payment” have now been moved to more logical places within the proposed rule.

Creditor agency. The proposed definition includes Federal agencies and States that seek to collect debts through TOP. The term also includes Indian Tribes and Tribal organizations that receive funding under section 455(f) of the Social Security Act (“Tribal IV–D agencies”) in the context of tax refund offset to collect past-due support. The term also includes agencies acting on behalf of the creditor agency. For example, where there is a requirement that the creditor agency take some action, such as providing notice or informing Fiscal Service as to changes in the status of a debt previously referred to TOP, such actions may be taken on behalf of the creditor agency (including, for example, through Fiscal Service’s Cross-Servicing program).

Days delinquent. This term is not defined in the existing TOP regulations. The proposed definition clarifies when Federal agencies must refer their debts to TOP (*i.e.*, by when the debt is over 120 days delinquent) and is consistent with the requirements of 31 U.S.C. 3716(c)(6)(A). For administrative (*i.e.*, non-loan) debts, for example, the delinquency clock generally begins running from the date of the initial demand for payment. The fact that a debt is in a delinquent status does not necessarily mean that there are immediate adverse consequences (*e.g.*, late charges) to the debtor. For administrative debts, there is typically a 30-day grace period from the date of initial demand for payment (*i.e.*, day one of delinquency to day 30 of delinquency) before there are adverse consequences due to delinquency (*see* 31 CFR 901.2(b)(3)). For loan debts to be re-paid in installments pursuant to a promissory note, each missed payment generally constitutes a delinquent debt, until all amounts owed are accelerated into a single debt.

Debt. The proposed definition is generally consistent with the existing TOP regulations, but also now distinguishes between “Federal debt” and “State debt.” It also adds past-due support owed to a Tribal IV–D agency.

Debt record. The proposed definition encompasses the terms “record of debt,” “debt record,” “debtor record,” “delinquent debtor record,” and “delinquent debt record,” as used in the existing TOP regulations.

Debtor. The proposed definition harmonizes the definition of “debtor” across the different types of offset. Depending on the type of offset involved, a debtor can be a person who

owes a debt to a Federal agency, a State, or a Tribal IV–D agency.

Delinquent or past-due. The proposed definition is consistent with the existing TOP regulations. However, this definition clarifies that not all payment arrangements avoid or cure delinquency. For example, a debt’s delinquent status is generally not altered by a due date in a post-delinquency payment agreement. A post-delinquency payment agreement should only restart the clock on delinquency if the agreement explicitly cures the delinquency. Many post-delinquency payment agreements used by Fiscal Service in its Cross-Servicing program (*see* 31 CFR 285.12, proposed to be redesignated as 31 CFR 285.112), for example, are not meant to cure delinquency, but are meant to provide relief from certain types of collection actions. Also see the definition of “Days delinquent.” As another example, an administrative debt generally is delinquent as of the date of the agency’s initial demand for payment, even if the agency provides a thirty-day grace period in which to pay the debt. However, the agency generally may take no adverse action to collect the debt (such as through TOP) until after the grace period. If the debt is not paid by the end of the grace period, it will generally be deemed to have been delinquent as of the date of the agency’s initial demand for payment.

Disbursing official. The proposed definition is consistent with the existing TOP regulations.

Disposable pay. The proposed definition is consistent with the existing TOP regulations.

Federal agency. The proposed definition is intended to distinguish between Federal agencies, States, and Tribal IV–D agencies. The existing TOP regulations use the term “agency,” which can be ambiguous when talking about Federal agencies, State agencies, and Tribal IV–D agencies.

Federal benefit payment. This term is not defined in the existing TOP regulations. The proposed definition is intended to distinguish between amounts a debtor may receive under “Federal benefit programs cited under clause (i) within a 12-month period” and “all Federal benefit payments made during such 12-month period.” *See* 31 U.S.C. 3716(c)(3)(ii).

Federal debt or Federal nontax debt. The proposed definition is consistent with the existing TOP regulations.

Federal employee. The proposed definition is consistent with the existing TOP regulations.

Federally recognized Tribe. This term is not used or defined in the existing

TOP regulations. The existing TOP regulations use the term “Indian tribe.” This definition is added for clarity.

Federal nontax payment. This term is not defined in the existing TOP regulations. The proposed definition is intended to more clearly distinguish between types of payments.

Federal payment. This term is used but not defined in the existing TOP regulations. The proposed definition is consistent with the statutory text and current operational practice. The term “administrative offset” is defined by statute as “withholding funds payable by the United States . . . to, or held by the United States for, a person to satisfy a claim.” 31 U.S.C. 3701(a)(1). Agencies are permitted to collect their debts by “administrative offset.” 31 U.S.C. 3716(a). And, disbursing officials are required to offset “the amount of a payment which a payment certifying agency has certified to the disbursing official for disbursement.” 31 U.S.C. 3716(c)(1)(A).

Given the language of the applicable statutes, Fiscal Service has consistently taken the position that any payment that is certified to a disbursing official is subject to administrative offset, unless the payment is otherwise exempt from offset. The proposed definition makes clear that the source of funds for a payment, such as whether the payment is made from public funds or funds held in trust, has no bearing on whether the payment is a “Federal payment.”

The proposed definition also makes clear that the term “Federal payment” includes any payment made by the United States through an escrow agent or other person with the responsibility to hold and/or further disburse the funds to a person.

Federal payment offset. This term is not defined in the existing TOP regulations. The proposed definition is intended to more clearly distinguish between types of offset.

Fiscal Service. The proposed definition is consistent with the existing TOP regulations.

HHS. The proposed definition is consistent with the existing TOP regulations.

Internal Revenue Code. This term is not defined in the existing TOP regulations. It is added for clarity.

IRS. The proposed definition is consistent with the existing TOP regulations.

Legally enforceable. The proposed definition is consistent with the existing TOP regulations.

Lump-sum benefit payment. This term is not defined in the existing TOP regulations. The proposed definition reflects a substantive change regarding

the offset of benefit payments that are paid as a lump sum. Under the proposed rule, offset of one-time payments of benefits that have accrued over a period of more than one month can be offset by no more than 15% and must leave a minimum floor (see proposed § 285.30(c)(2)(viii)). The existing TOP regulations do not clearly address how the \$9,000 floor (required by 31 U.S.C. 3716(c)(3)(A)(ii)) should be applied for lump-sum benefit payments and how it should be prorated. The proposed rule explains how the floor should be calculated.

Because the statute, in establishing the offset floor, refers to the amount that a debtor may “receive” under the specified Federal benefit programs within a 12-month period, Fiscal Service determined that the floor for a lump-sum benefit payment should generally be the lesser of: (1) \$9,000; or (2) an amount equal to \$750 times the number of months’ worth of benefits represented by the lump-sum benefit payment. While the floor should generally be the lower amount of those two calculations, Fiscal Service may select the first option when it lacks sufficient information to calculate the second option or when it is more administratively feasible to do so.

The calculation of the floor can be further complicated in the event the person entitled to payment was receiving other amounts as Federal benefit payments; in such circumstances, Fiscal Service can reduce the floor by those other amounts, if it determines that it is administratively feasible and otherwise appropriate to do so.

The following examples demonstrate how this calculation would work:

Example #1: If a debtor is being paid a lump-sum benefit payment of \$10,000, representing 13 months of accrued benefit payments, and was not receiving any other Federal benefit payments, the offset floor would be \$9,000, calculated as the lesser of: (1) \$9,000; or (2) \$750 times 13 (i.e., \$9,750). Because taking an offset of 15% of the \$10,000 payment (i.e., \$1,500) would reduce the payment below the lump-sum benefit payment floor (i.e., \$10,000 minus \$1,500 is less than \$9,000), the offset would be \$1,000 (i.e., \$10,000 minus \$9,000).

Example #2: If a debtor is being paid a lump-sum benefit payment of \$6,000, representing 3 months of accrued benefit payments, and was not receiving any other Federal benefit payments, the offset floor would be \$2,250, calculated as the lesser of: (1) \$9,000; or (2) \$750 times 3 (i.e., \$2,250). Because taking an offset of 15% of the payment (i.e., \$900) would not reduce the payment below

the lump-sum benefit payment floor (i.e., \$6,000 minus \$900 is more than \$2,250), the offset amount would be \$900.

Example #3: If a debtor is being paid a lump-sum benefit payment of \$10,000, representing an unknown number of months of accrued benefit payments, and had received \$8,000 of OPM annuity payments over the past 12 months, the lump-sum benefit payment floor would be \$1,000, calculated as the lesser of: (1) \$9,000; or (2) \$750 times 12 minus \$8,000 (i.e., \$1,000). Because taking an offset of 15% of the payment (i.e., \$1,500) would not reduce the payment below the lump-sum benefit payment floor (i.e., \$10,000 minus \$1,000 is more than \$1,000), the offset amount would be \$1,500.

Lump-sum benefit payment floor. This term is not defined in the existing TOP regulations. See the proposed definition for “lump-sum benefit payment” for an explanation.

Match. The existing regulations describe their treatment of what constitutes a match between a payment record and a debt record. This treatment could differ depending on the type of offset being conducted. For example, current section 285.1, which governs the offset of Federal nontax payments for the collection of past-due support, requires that the TIN of a payment record be the “same” as the TIN of a debt record. Current section 285.5, which governs offset of Federal payments to collect Federal nontax debts, implies that a derivative of the TIN can be used to determine whether the TIN on the payment and debt records are the “same.” The proposed definition defines the term “match” for offset purposes in a manner that restores statutory flexibility for disbursing officials in determining when the person entitled to payment on a payment record is the same person as the debtor on a debt record. The proposed definition would allow disbursing officials to determine whether there is a match by using information *derived* from the payment and debt records, which would not necessarily require an *exact* match on the name or TIN. The relevant statutory provisions do not require that the name (or name control) and TIN be exact matches on the debt record and the payment record. A person entitled to payment and the debtor may be the same person in circumstances where the name and TIN are not exact matches (for example, because either the debt record or payment record contains a transcription or other human input error). This definition would allow (but not require) disbursing officials to use

an algorithm to correct for such errors on names and TINs in a manner that results in more accurate matches. It would also allow disbursing officials to use information (other than the name and TIN) from the payment and debt records to determine whether the payee and debtor are the same person. This more flexible definition of “match” will enable disbursing officials to more closely comply with their requirements under the offset statutes.

Means-tested program. This term’s definition is embedded into the text of current sections 285.1(k) and 285.5(e)(7)(i), rather than in the definition sections for sections 285.1 and 285.5. The proposed definition is added for clarity.

Monthly benefit payment. This term is not defined in the existing TOP regulations. The proposed definition for “monthly benefit payment” is consistent with the term “monthly covered benefit payment,” as used in the existing TOP regulations.

OASDI overpayment. The proposed definition is consistent with the existing TOP regulations.

Offset. The proposed definition is consistent with the existing TOP regulations but uses the more precise term of “PEP” rather than “payee.”

Participating SRP State. This term is not defined in the existing TOP regulations. It is consistent with the term “participating State,” as used in the existing TOP regulations.

Past-due support. The proposed definition expands the definition to include debts owed to Tribal IV–D agencies, to implement the new authority to collect child support debts from the Supporting America’s Children and Families Act, codified in relevant part at 26 U.S.C. 6402(c), and is otherwise consistent with existing TOP regulations.

Payee. The proposed definition clarifies the difference between the terms “payee” and “person entitled to payment” or “PEP.” While the payee and the PEP are generally the same person, there may be some circumstances where they are different people. For example, a nursing home might serve as the representative payee for a beneficiary that is entitled to benefit payments. Or, an attorney representing an individual who has a claim against the United States might receive payment to her attorney trust account as a payee, while her client is the “person entitled to payment.”

Payment. This proposed definition is added for clarity.

Payment agency. The proposed definition incorporates the definition for this term in the existing TOP regulations

and adds a sentence that covers States making payments in the context of offsets under reciprocal agreements. It is intended to broadly cover agencies making payments, whether such agencies disburse payments on their own or through another agency. In the context of Federal payments, the function of the payment agency and the disbursing official are often, though not always, segregated. The payment agency, through a certifying officer, is generally responsible for determining that the payment is permitted by law, that funds have been appropriated for the payment, that the name, address, and dollar amount are correct, whether the payment is subject to offset, and that the payment is not a duplicate payment. The disbursing official, on the other hand, disburses payments properly certified by a payment agency's certifying officer and/or withholds all or part of the payment to satisfy a delinquent debt.

Payment record. The proposed definition incorporates the definition for this term in the existing TOP regulations and adds a sentence that covers States making payments in the context of offsets under reciprocal agreements.

PEP or person entitled to payment. This term is not used or defined in the existing TOP regulations; the existing regulations use the phrase "person entitled to receive the benefit of all or part of the payment." The proposed definition was added to distinguish between the terms "payee" and "person entitled to payment."

Person. The proposed definition is consistent with the existing TOP regulations.

Reciprocal agreement. The proposed definition is consistent with the existing TOP regulations.

Recurring payment. The proposed definition is consistent with the existing TOP regulations.

Salary offset. The proposed definition is consistent with the existing TOP regulations.

Salary payment agency. This term is used in the existing TOP regulations but is not defined. The proposed definition is added for clarity.

Secretary. The proposed definition is consistent with the existing TOP regulations.

Separate guidance. This term is not used or defined in the existing TOP regulations. Fiscal Service may issue more detailed guidance on certain aspects of this rule. Such guidance may include instructions to agencies on how to comply with the rules set forth in the proposed rule (e.g., how to submit a debt to the TOP system) or specify how Fiscal Service or an agency may exercise

discretion within the bounds permitted by the proposed rule (e.g., the dollar threshold for referrals of debt to TOP, which may be changed based on costs of collection; or time periods on agency action, which may be changed based on operational capabilities).

State. The proposed definition is consistent with the existing TOP regulations.

State debt. The proposed definition is consistent with the existing TOP regulations, except that it excludes debts owed by Federally recognized Tribes. With regard to the State Reciprocal Program, Fiscal Service determined that certain debts should be excluded from collection through Federal payment offset. In the existing TOP regulations, debts that are excluded from the definition of "State debt" include debts owed to a State by the United States, a foreign sovereign, another State, or local governments within a State. The rationale for these exclusions is that TOP is not an appropriate tool for resolving issues of indebtedness between a State and local government, a State and a State, or a State and a foreign government. This rationale applies equally to issues of indebtedness between States and Federally recognized Tribes. Federally recognized Tribes possess certain inherent rights of self-government. As a result of this Tribal sovereignty, these Tribes have a special relationship with the United States. The proposed definition would codify the current operational practice to exclude debts owed by Federally recognized Tribes from the types of debts that a State may collect under a reciprocal agreement. This rule would not change or affect any other rights or remedies States may have to collect debts owed to them by Federally recognized Tribes outside of TOP. While States may not collect debts owed to them by Federally recognized Tribes through TOP, Federal agencies may collect debts owed by Federally recognized Tribes through TOP.

State income tax obligation. The proposed definition is consistent with the definition used in the existing TOP regulations.

State payment. This term is used but not defined in the existing TOP regulations. The proposed definition is added for clarity.

State payment offset. The proposed definition is consistent with the definition used in the existing TOP regulations.

State reciprocal program. This term is not used or defined in the existing TOP regulations. The proposed definition is added for clarity.

Tax refund offset. The proposed definition is consistent with the existing TOP regulations.

Tax refund payment. The proposed definition is consistent with the existing TOP regulations.

Taxpayer identifying number or TIN. The proposed definition is consistent with the existing TOP regulations. For individuals, the TIN is generally (but not always) the individual's social security number. TINs also include employer identification numbers and individual taxpayer identification numbers issued by the IRS.

Treasury Offset Program or TOP. This term is used but not defined in the existing TOP regulations. The proposed definition is added for clarity.

Tribal IV-D agency. This term is not used or defined in the existing TOP regulations. It is added to implement the new authority to collect child support debts from the Supporting America's Children and Families Act, codified in relevant part at 26 U.S.C. 6402(c). The term refers to Indian Tribes and Tribal organizations that receive funding under section 455(f) of Title IV, Part D, of the Social Security Act.

Unemployment compensation debt. The proposed definition is consistent with the existing TOP regulations.

Section 285.2—General Provisions

The existing TOP regulations repeat certain general rules for each type of offset, at times using slightly different language to describe the same requirements. This proposed section would consolidate general offset rules into a single section that would apply to all types of offset under TOP. This will improve consistency and clarity and avoid unnecessary repetition. To the extent specific rules are required for a specific type of offset, those rules will be spelled out in a separate section for each type of offset.

(a) **Scope.** Proposed paragraph (a) describes the scope of this subpart, which governs the centralized offset of Federal payments and State payments to collect delinquent debts owed to the United States or a State. This subpart does not apply to administrative offsets that occur outside of TOP (known as "non-centralized offsets"). Non-centralized offsets are governed by other law, including but not limited to common law, the Federal Claims Collection Standards (see 31 CFR 901.3(c)), and agency-specific regulations. Laws governing garnishments and levies do not apply to offsets under this subpart. Offsets are not garnishments or levies. An offset occurs when the United States or a State withholds money owed to a person to

satisfy a claim owed by that same person to the United States or a State. Garnishment is a process whereby a creditor attaches wages or other property belonging to a debtor which is in the possession of a third party (for example, *see* 31 U.S.C. 3720D). A levy is the means by which the Internal Revenue Service or other tax collecting authority seizes the delinquent taxpayer's property. *See* 26 U.S.C. 6331.

This subpart applies only to Federal payments and State payments (as those terms are defined) made to or on behalf of a PEP. *See* the definitions for "PEP" and "payee." It generally does not apply to downstream PEPs and payees. For example, in the context of purchases made by Federal agencies using a government credit card, the vendor is paid by the financial institution that issues the credit card, and the United States pays the financial institution. Absent an agreement between the financial institution and the United States requiring the payment from the financial institution to be offset for debts owed by the vendor, the payment by the financial institution to the vendor is not subject to offset under this subpart. On the other hand, the payment from the United States to the financial institution is subject to offset for debts owed by the financial institution. When determining whether to use a government purchase card, agencies must determine whether the use of the purchase card is an appropriate payment mechanism. *See* proposed section 285.2(e)(2)(iii).

Lastly, the pursuit or receipt of collections pursuant to this subpart does not preclude a creditor agency from pursuing all other available debt collection remedies simultaneously.

(b) *General rules for Federal agencies.* Proposed paragraph (b) is consistent with the existing TOP regulations. Proposed paragraph (b)(1)(iii) clarifies that agencies must complete the 60-day notification process prior to the debt becoming 121 days delinquent, so that the agency can complete the due process prerequisites and refer the debt to TOP by the statutory deadline.

(c) *General rule for States and Tribal IV-D agencies.* Proposed paragraph (c) is consistent with the existing TOP regulations. It also incorporates Tribal IV-D agencies to implement the new authority in the Supporting America's Children and Families Act.

(d) *Requirements for all creditor agencies.* Proposed paragraph (d) is generally consistent with the existing TOP regulations. However, notable clarifications and/or changes are as follows:

- Proposed paragraph (d)(1)(i)(C) modifies the debt eligibility requirements to remove the reference to a \$25 minimum threshold. Under both the existing TOP regulations and the proposed rule, Fiscal Service is permitted to establish a dollar threshold for referred debts. Fiscal Service may adjust this threshold as appropriate in separate guidance. In establishing this threshold, Fiscal Service may consider, among other things, the cost of conducting an offset.

- Proposed paragraph (d)(1)(i)(D) explains the circumstances in which a debt is not eligible for referral when referral would interfere with a Federal agency's ability to preserve its rights to collateral and when referral would interfere with the United States' interest in enforcing antitrust laws or protecting its interests when it becomes aware of the possibility of fraud, false claim, or misrepresentation with regard to the debt.

- Proposed paragraph (d)(1)(ii) sets forth the due process prerequisites with which the creditor agency must comply. As required by statute, these due process prerequisites include the requirement to provide the debtor with the opportunity to review the creditor agency's determination regarding the debt.

- Proposed paragraph (d)(3) describes the facts to which creditor agencies must certify upon referral of a debt to TOP. Creditor agencies can (and generally do) provide the written certification electronically.

- Proposed paragraph (d)(4) adds language that more explicitly addresses creditor agencies' obligations to correct and update data on debts subject to collection in TOP. This obligation is provided for under the existing TOP regulations, but the added language will remind agencies of the importance of maintaining accurate and up-to-date information. This will reduce the risk of improper collections and will assist Fiscal Service in delivering offset notices to the correct addresses. This paragraph makes clear that creditor agencies may make updates to increase the debt balance when they have complied with other prerequisites; this, however, does not permit creditor agencies to aggregate more than one debt into a single debt record, unless otherwise permitted by Fiscal Service.

(e) *Federal payments.* Proposed paragraph (e) is generally consistent with the existing TOP regulations. However, notable clarifications and/or changes are as follows:

- Proposed paragraph (e)(2)(i) explicitly addresses the requirement to identify the PEP or PEPs, as is current operational practice. The existing TOP regulations reflect this requirement, but do not distinguish between "payee" and "PEP." When paying more than one PEP, the proposed paragraph also requires payment agencies to determine whether the payment is owed jointly to the PEPs or if it must be allocated among the PEPs. These requirements help ensure that payments are matched for PEPs, rather than payees who might not be PEPs. This paragraph also permits agencies to make a payment to a person other than the PEP if the payment agency determined that the PEP does not owe a debt.

- Proposed paragraph (e)(2)(iii) addresses the mechanisms through which payment may be made. Each year, the Federal government disburses billions of payments. Most of these payments are automatically matched against the TOP database during the disbursement process. A small portion of these payments are disbursed in a manner that, due to current operational restraints, do not allow the payment to be automatically matched with debts in TOP. The proposed rule explicitly addresses the requirement that payment agencies work with Fiscal Service to identify and employ alternative processes to avoid missed offset collections when payment mechanisms do not allow for automated matching in TOP.

For example, payments for purchases made using a government credit card are not automatically matched against the TOP database because, in such a scenario, the PEP, *i.e.*, the vendor, is actually being paid by the financial institution issuing the credit card, and not a Federal agency. Similarly, payments made by class administrators who are responsible for disbursing payments to PEPs do not automatically match against TOP.

Before using a payment mechanism that does not allow for automated matching in TOP, a Federal agency should determine whether a PEP owes a delinquent debt that has been referred to TOP. Fiscal Service can assist agencies with making this determination. If no such debt is owed, then this provision would not preclude the Federal agency from proceeding with making the payment through that mechanism. However, if such a debt is owed, then the payment agency must make the payment in a manner that will permit the payment to be offset.

(f) *Procedures for centralized offset.*

Proposed paragraph (f) is generally consistent with the existing TOP regulations. However, notable clarifications and/or changes are as follows:

- Proposed paragraph (f)(1) describes the requirement for a disbursing official to take an offset. There must be a match between the debtor (from the debt record) and the PEP (from the payment record). *See* the definition for "match." For operational reasons, this match may take place several days before the date of the offset. For example, some payment agencies submit batch payment records to Fiscal Service. To properly process these records, Fiscal Service may need to receive those batch records and conduct the matching process prior to the date on which the payment will be disbursed in accordance with the payment agency's instructions.

- Proposed paragraphs (f)(2) and (4) describe related, but different concepts. Paragraph (f)(2) describes circumstances where the PEP directs delivery of the payment to a different person but does not assign the legal ownership of the payment to that person. For example, a nursing home might serve as the representative payee for an elderly person who is entitled to social security benefit payments. In this case, the elderly person did not assign her legal ownership of the benefit payments to her

nursing home but directed the payments to be paid to the nursing home and administered by the nursing home for her benefit, because she is unable to manage her own finances. As such, the benefit payments would be subject to offset for debts owed by the elderly person, but not for debts owed by the nursing home.

- Proposed paragraph (f)(4) describes assigned payments. The proposed paragraph is intended to simplify and clarify how TOP treats assigned payments.

- A request by a PEP to legally transfer to a third party the right to a payment is typically referred to as an “assignment.” To be valid as to the United States, the “transfer” or “assignment” of a claim against the United States must meet the requirements of applicable law, including the Anti-Assignment Act, 31 U.S.C. 3727, and the laws that apply to TOP. If the requirements are not satisfied, the assignment is not valid as to the United States for purposes of this rule.

- Nothing in this proposed rule would require Fiscal Service (absent instructions from a payment agency), a payment agency, or a creditor agency to recognize an assignment.

- In general, assigned payments are legally subject to offset for debts of both the assignor (*i.e.*, the original PEP) and the assignee (*i.e.*, the person to whom the payment was assigned, also a PEP).

- In general, disbursing officials should offset the payment first for debts owed by the assignor and then, if anything is left, for debts owed by the assignee. Under current operations, a payment agency generally must issue a payment to the assignor, unless the payment agency confirms that the assignor does not owe any debts in TOP, in which case the payment agency may make the payment to the assignee (assuming the payment agency had authority to recognize the assignment). Fiscal Service provides specific rules to payment agencies regarding how to issue payments in the context of assigned payments in separate guidance.

- A frequent scenario involving assigned payments is the award of attorneys’ fees under the Equal Access to Justice Act (EAJA), where the “prevailing party” (*i.e.*, the PEP) wants to assign an EAJA award to their attorney, 28 U.S.C. 2412. In such cases, the agency may recognize the assignment only if the prevailing party does not owe any debts that could be collected through offset of the EAJA payment. The Supreme Court unanimously held in *Astrue v. Ratliff*, 560 U.S. 586 (2010), that the EAJA term “prevailing party” refers to a claimant and not the claimant’s attorney, and thus the offset of an EAJA award to collect a claimant’s debt to the government is proper. If the prevailing party does not owe any debts, the payment agency could recognize the assignment to the attorney, and the payment would be subject to offset for debts owed by the attorney (*i.e.*, the new PEP).

- Proposed paragraph (f)(3) explains that payments that are jointly owed to more than one PEP (such as a joint tax refund payment) are subject to offset for the debts owed by any PEP.

- Proposed paragraph (f)(5), among other things, more clearly addresses the amount to

be offset when a payment being disbursed is subject to partial exemption and the payment has been subject to an internal offset prior to payment certification and submission of the payment instructions to the disbursing official. For example, payment agencies might conduct their own internal offset prior to certifying the payment to Fiscal Service for offset, but Fiscal Service may lack knowledge of whether an internal offset has occurred prior to payment certification or, if so, how much of the payment was offset. Because Fiscal Service has decided, as a policy matter, that it would like to have the flexibility to calculate the percentage that may be offset of a partially exempt payment by accounting for prior offsets when it knows that a prior offset has taken place, Fiscal Service has determined that a disbursing official may either: (1) not offset the payment if the disbursing official knows that the payment agency has already taken an offset from the payment, or (2) if the disbursing official has sufficient information about the prior offset, calculate the additional amount by which the payment may be offset. Additionally, Fiscal Service would have the flexibility to disregard any prior offset conducted by the payment agency. For example, if Fiscal Service is disbursing a covered benefit payment certified by the Social Security Administration (SSA), and it knows that SSA already offset the payment, but does not know by how much the payment was offset, the Fiscal Service disbursing official could bypass offset for that payment; alternatively, if SSA informed Fiscal Service that the payment that it is certifying for disbursement for \$1,950 was originally \$2,000 (*i.e.*, it took a \$50 internal offset), Fiscal Service could take another \$250 (because \$250 + \$50 is 15% of the original payment amount). However, the disbursing official may also choose to disregard any prior offset when calculating the appropriate offset amount. For example, if the original payment amount was \$2,000, but SSA certified a payment in the amount of \$1,950, the Fiscal Service disbursing official could offset \$292.50 (*i.e.*, 15% of \$1,950). Fiscal Service also notes that, when calculating the offset amount, the disbursing official must disregard any prior levy on that payment. For example, if a covered benefit payment, certified in the amount of \$2,000, was levied by 15% for a Federal tax debt through TOP, a disbursing official must offset that payment by another 15% for a nontax debt in TOP. In such a scenario, after levy and offset, the payment amount that would be disbursed to the payee would be \$1,400 (with \$300 going to the IRS and another \$300 going to the other agency). The proposed paragraph is consistent with the last paragraph in 31 U.S.C. 3716(c)(3)(A)(ii).

- Proposed paragraph (f)(6) describes the priority scheme for how a payment must be applied when the person entitled to the payment owes multiple debts. While this subpart does not apply to the way in which Fiscal Service levies payments for the purpose of collecting Federal tax debts, the proposed paragraph acknowledges that such levies take priority over the collection of debts through offset under this subpart. Within each category, Fiscal Service will

generally give priority to older debts first. In some circumstances, for operational reasons, Fiscal Service may alter this intra-category priority. For example, if a Federal agency refers to TOP a Federal nontax debt, and Fiscal Service starts collecting that debt through salary offset, Fiscal Service may continue collecting that debt through salary offset, even if another Federal agency later refers an older Federal nontax debt that is also eligible for collection through salary offset.

(g) *Notification of offset to debtor.*
Proposed paragraph (g) contains the following notable clarifications and/or changes:

- Proposed paragraph (g) would revise the requirement in the existing TOP regulations that a warning notice be sent to the debtor prior to commencing offset of recurring payments, and would go beyond what is required by statute, which does not require any warning notice but does, in the case of periodic benefit payments, require notice be sent on or before the date of the offset. See 31 U.S.C. 3716(c)(7)(B). The proposed rule would generally require that a disbursing official (or Fiscal Service on behalf of the disbursing official) send a warning notice to a debtor before commencing offset of monthly benefit payments. This requirement would not apply to any other recurring payments or one-time payments. The requirement would also not apply when it is administratively infeasible for the disbursing official (or Fiscal Service on behalf of the disbursing official) to send the letter, such as when a current address is unavailable or when a system glitch results in the failure of such letters to be sent. Fiscal Service will generally send warning notices before offsetting recurring payments, but notes that it is statutorily obligated to conduct offset and that its failure to send a notice does not change this obligation or impair any future offset taken.

- Proposed paragraph (g) also clarifies the address to which this notice can be sent.

- The term “payee” is used by 31 U.S.C. 3716, but section 3716’s use of this term conflates the concepts of “payee” and “PEP” (see the proposed definitions of these terms).

- Consistent with Congress’ intent to provide notification of the offset to the affected person, the proposed rule clarifies that this notice can be sent either to the payee or the PEP, depending on the address available.

- If the disbursing official has an address only for the payee, the disbursing official may send the notice to the payee, even if the payee is a different person than the PEP.

- Similarly, if the disbursing official has an address only for the PEP, the disbursing official may send the notice to the PEP, even if the PEP is a different person than the payee.

- If the disbursing official has an address for both the payee and the PEP, the disbursing official may determine which address to use, regardless of whether the payee and the PEP are the same person. Under current operational practice, which is subject to change, Fiscal Service generally sends the notice to the payee, rather than the

debtor/PEP, since the address for the payee would be obtained from the payment record which generally would have been submitted to Fiscal Service more recently than the debt record. If the payment record does not include an address for the payee, the disbursing official generally will use the address on the debt record. Fiscal Service's current operational practice generally assumes that the more current information is likely better information. However, the proposed rule would give Fiscal Service the flexibility to change its current operational approach.

- Proposed paragraph (g) also makes clear that the failure of a disbursing official to send a notice (or the failure of a payee or PEP to receive such a notice) does not impair the validity of the offset. There may be circumstances where the address(es) provided on the payment record and the debt record are incorrect or outdated. In other circumstances, the addresses may be missing from those records. Such circumstances make it difficult, if not impossible, for the disbursing official to deliver a notice of offset. The disbursing official, however, is still under a statutory requirement to offset certain payments. Thus, the inability to send a notice to a valid address does not preclude offset.

(h) *Notification of offset to creditor and payment agencies.* Proposed paragraph (h) is consistent with the existing TOP regulations.

(i) *Disposition of amounts collected.* Proposed paragraph (i) is consistent with the existing TOP regulations. However, proposed paragraph (i)(2) addresses the status of an offset when the payment that was offset was made in error. Except as specified in § 285.42(e), addressing tax refund offset to collect past-due support, there is no time limitation on when a payment agency may request a payment reversal.

(j) *Fees.* Proposed paragraph (j) restores statutory flexibility to Fiscal Service's fee-charging authority. The existing TOP regulations do not address Fiscal Service's fee-charging authority consistently. Some provisions in the existing regulations require Fiscal Service to charge creditor agencies for the full cost for certain types of offset, even though the applicable statutes permit Fiscal Service to charge "up to" full cost. Where the statute permits Fiscal Service to charge up to full cost, the proposed rule would allow Fiscal Service to charge anywhere between \$0 and full cost. Statutes permitting Fiscal Service to charge between \$0 and full cost include: 26 U.S.C. 6402(e) (offset of tax refund payments to collect State income tax obligations); 26 U.S.C. 6402(f) (offset of tax refund payments to collect unemployment compensation debt); and 31 U.S.C. 3716(c)(4) (offset of Federal nontax payments and State payments). Statutes that require Fiscal

Service to charge full cost include: 42 U.S.C. 664(b) (offset of tax refund payments to collect past-due support obligations); and 31 U.S.C. 3720A(d) (offset of tax refund payments to collect Federal nontax debts).

(k) *Social Security Numbers.* Proposed paragraph (k) is consistent with the existing TOP regulations and addresses the restrictions imposed by the Social Security Number Fraud Prevention Act of 2017, Public Law 115–59.

Section 285.30—Offset of Federal Nontax Payments and State Payments

This section consolidates the rules that apply generally to the offset of Federal nontax payments and State payments.

(a) *Scope.* Proposed paragraph (a) describes the scope of this and its related sections (*i.e.* §§ 285.30, 285.31, 285.32, 285.33, and 285.34), which govern offset of Federal nontax payments and State payments. It also describes that the scope of sections 285.30 through 285.34 do not apply to Federal debts or Federal payments arising under the tariff laws of the United States or the Social Security Act, except to the extent provided under sections 204(f) and 1631(b)(4) of such Act and 31 U.S.C. 3716(c). This limitation is required due to the language of 31 U.S.C. 3701(d), which states that 31 U.S.C. 3711(e) and 3716–3719 "do not apply to a claim or debt under, or to an amount payable under—(1) the Internal Revenue Code of 1986 (26 U.S.C. 1 *et seq.*), (2) the Social Security Act (42 U.S.C. 301 *et seq.*), except to the extent provided under sections 204(f) and 1631(b)(4) of such Act and section 3716(c) of this title, or (3) the tariff laws of the United States." The definition of "Federal debt" excludes debts arising under the Internal Revenue Code, and the definition of "Federal nontax payment" excludes payments arising under the Internal Revenue Code. The provision excluding Federal debts or Federal payments arising under the Social Security Act except to the extent provided under sections 204(f) and 1631(b)(4) of such Act and 31 U.S.C. 3716(c) means that, among other things, Federal debts and Federal payments arising under the Social Security Act are subject to TOP as long as they are carried out in accordance with the applicable requirements provided for in the cross-referenced statutory provisions.

(b) *General rule.* Proposed paragraph (b) describes the payments generally subject to offset.

(c) *Exemptions of Federal nontax payments from centralized offset.*

Proposed paragraph (c) describes Fiscal Service's authority to exempt payments from offset under TOP. It also lists the Federal payments that are exempt from offset under TOP.

- Proposed paragraph (c)(1) explains how Federal payment agencies may request that a class of payments be exempted from offset under TOP. It describes Fiscal Service's authority to grant and withdraw payment exemptions.

- Proposed paragraph (c)(2) lists certain payment types that are exempt by statute and by the existing TOP regulations. It also lists payment types that Fiscal Service proposes to exempt through this proposed rule, including the following:

- Proposed paragraph (c)(2)(viii) describes the treatment of lump-sum benefit payments. See the proposed definition for "lump-sum benefit payment."

- Proposed paragraph (c)(2)(ix) describes Fiscal Service's authority to establish minimum thresholds for the referral of debt. This assists Fiscal Service in recognizing that, in certain circumstances, the costs of an offset warrant exemption from offset. For example, in some cases, a payment amount may be so small that the only amount that could be collected from the payment is the cost of an offset or less; offset in such a scenario would not be warranted. See 31 CFR 903.3(a)(3).

- Proposed paragraphs (c)(2)(x) and (xi) describe that payments are exempted from offset through TOP when they are for: (1) attorneys' fees and litigation costs for class counsel made under prevailing party fee-shifting statutes to satisfy court judgments or settlements in actions certified as class actions pursuant to Federal Rule of Civil Procedure 23(b)(2) when the members of the class are not ascertainable; or (2) attorneys' fees and litigation costs for class counsel and administrative costs for distributing settlements made under prevailing party fee-shifting statutes to satisfy settlements in actions certified as class actions pursuant to Federal Rule of Civil Procedure 23(b)(3). In both these situations, the person legally entitled to a fee or cost payment is the prevailing party (*i.e.*, each member of the class), not the class counsel or class administrator. As such, absent exemption, fee and cost payments awarded under these class actions would be allocated among the various class members and would be subject to offset for the debts of those class members, rather than for the debts of the class counsel or class administrator.

- In actions certified as class actions pursuant to Federal Rule of Civil Procedure 23(b)(2), offset may not be administratively feasible. Rule 23(b)(2) allows a person to sue on behalf of a class of litigants a person who has taken or refused to take action with respect to the class where injunctive or declaratory relief is sought as final relief. An incidental claim for monetary relief may also be included, such as where the substantive law under which the class is suing provides for attorneys' fees to be paid to the prevailing party (*i.e.*, every member of the class). However, in some situations, it would be impractical—and sometimes impossible—to

identify all of the persons who fall within a Rule 23(b)(2) class (*i.e.*, the persons whose debts would be properly offset in the absence of an exemption from offset). As such, an exemption from offset for these situations is warranted.

○ In actions certified as class actions pursuant to Federal Rule of Civil Procedure 23(b)(3), the Department of Justice has informed Fiscal Service that offsetting these payments for the debts of the class members risks adversely affecting the Government's ability to settle these cases on the most favorable terms to the United States and interferes with its plenary authority over litigation. The Department of Justice further noted that offset would further complicate negotiation dynamics that are already highly charged and challenging. For example, the Department of Justice stated that class counsel might attempt to negotiate higher settlement amounts to ensure that their fees would not be reduced by the offsets for the debts of class members. Because offset of these types of payments runs the substantial risk of interfering with the Government's ability to effectively represent the interests of the United States in litigation, exemption is appropriate.

○ Proposed paragraph (c)(2)(xii) describes that payments are exempted from offset through TOP when offset is impractical, as determined by Fiscal Service in separate guidance. Such guidance may address, for example, situations in which the payment agency is unable to obtain a TIN for the PEP. Payment agencies are required to include a TIN on their certified payment vouchers (see the proposed definition for "payment record" and 31 U.S.C. 3325(d)). Disbursing officials are responsible for examining certified payment vouchers to determine whether such vouchers are in the proper form. 31 U.S.C. 3325(a)(2)(A). And, TOP's matching process requires TIN information to be on the payment record for an offset to take place. If a TIN is missing from a payment voucher, there is the potential for a missed offset. However, there are some circumstances where obtaining a TIN on a required payment is impossible or impractical. Some of the barriers to collecting and providing TINs include, for example:

- payments to foreign persons who do not have TINs;
- payments under a witness protection program, for undercover operations, or to informants where collection of the TIN information may interfere with the Government's efforts to protect a person's identity or otherwise have a detrimental effect on a law enforcement operation, military operation, national security, or emergency relief effort; and
- payments made by a payment agency that does not have the legal authority to require a PEP to submit a TIN and in which the agency cannot independently obtain a TIN through reasonable efforts.

○ There are certain statutes that explicitly exempt payments from "offset" or "setoff." See, e.g., 31 U.S.C. 3701(d), 3716(c)(1)(C); 47 U.S.C. 309(j)(8)(C)(ii). Proposed paragraph (c)(2)(xiii) explicitly states that such payments are exempt from offset under this subpart. Other statutes exempt the payment

from levies, garnishments, and other legal process; these statutes do not affect an agency's authority to conduct offsets.

○ Proposed paragraph (c)(2)(xiv) exempts classes of payments for which the Secretary has granted an exemption.

(d) *Certification of amount to be offset if different than maximum allowed by law.* Proposed paragraph (d) describes the authority of a creditor agency to reduce the amount by which a payment is offset if it determines the reduction is necessary given the debtor's financial situation. This applies to the offset of State payments and Federal nontax payments; it does not apply to the offset of tax refund payments.

Section 285.31—Offset of Covered Benefit Payments To Collect Federal Nontax Debts

(a) *Scope.* Proposed paragraph (a) describes the scope of this section, which governs the offset of covered benefit payments. This section does not govern the offset of lump-sum benefit payments. See proposed § 285.30(c)(2)(viii).

(b) *General Rule.* Proposed paragraph (b) states the general rule that Federal agencies collect their delinquent debt through the offset of covered benefit payments.

(c) *Offset amount.* Proposed paragraph (c)(1) describes the limitation on the amount by which a monthly benefit payment may be offset. It restates the limitations that are specified in the existing TOP regulations. Proposed paragraph (c)(2) would permit, but not require, disbursing officials to aggregate the amount of Federal benefit payments received by a PEP within a 12-month period (or within the prior month, on a prorated basis). This more closely aligns with 31 U.S.C. 3716(c)(3)(A)(ii).

Section 285.32—Offset of Federal Salary Payments To Collect Federal Nontax Debts

(a) *Scope.* Proposed paragraph (a) describes the scope of this section, which governs salary offset. This section does not apply to the offset of final lump-sum payments of Federal salary, which are subject to 100% offset and are not subject to the additional procedures required for salary offset.

(b) *General Rule.* Proposed paragraph (b) restates the general rule that, like other types of offset, Federal agencies must refer certain debts to TOP for collection through salary offset. Because of the additional and generally more costly due process requirements for salary offset (as compared with other types of offset), Fiscal Service has determined that salary offset only be

required for debts over a certain amount, as Fiscal Service may prescribe in separate guidance. Creditor agencies would be permitted, but not required, to conduct salary offset for lower dollar debts, subject to minimums that Fiscal Service may establish. If a creditor agency has complied with all the prerequisites for collecting a debt through offset except for the prerequisites regarding the offset of salary payments, it may refer the debt to TOP for offset against all payments other than salary payments; if salary offset is required, the creditor agency must work toward completing the prerequisites for salary offset after such a referral.

(c) *Additional due process.* Proposed paragraph (c) describes the requirement that the creditor agency make a reasonable attempt to provide a debtor with the opportunity for a hearing prior to attempting to collect the debt through salary offset. This is consistent with the existing TOP regulations.

(d) *Procedures for salary offset.* Proposed paragraph (d) sets forth the procedures for salary offset. These procedures are consistent with the existing TOP regulations.

In the existing TOP regulations, there is a provision regarding the establishment of an interagency consortium. The establishment and maintenance of this consortium is required by 5 U.S.C. 5514(a)(1). While Fiscal Service maintains this consortium, it determined that there was no need to address this in regulations. This proposed rule, therefore, proposes to eliminate that provision. While the proposed rule would eliminate this provision, Fiscal Service notes that the consortium will continue to exist.

Section 285.33—Offset of Federal Nontax Payments To Collect Past-Due Support

The introductory text clarifies that HHS, acting on behalf of a State, is the creditor agency for purposes of this section.

(a) *Scope.* Proposed paragraph (a) describes the scope of this section, which governs the offset of Federal nontax payments to collect past-due support that is referred to TOP by HHS. It does not govern the offset of Federal nontax payments to collect past-due support that is referred to TOP directly by a State.

(b) *General Rule.* Proposed paragraph (b) describes that disbursing officials will collect past-due support through offset of Federal nontax payments, in accordance with the provisions of this subpart.

For purposes of this section, there is no requirement that States conduct offset to collect Federal debts. By referring a debt to TOP (or to HHS for the purpose of referring to TOP), the State agrees to the terms of this regulation, which constitutes the reciprocal agreement required by 31 U.S.C. 3716(h)(1)(B).

(c) *Due process.* Proposed paragraph (c) explains that the due process described in proposed § 285.2(d)(1)(ii) must be provided, but that the notice described in that section need only be sent a minimum of 30 days prior to referring the debt to TOP (as opposed to 60 days).

(d) *Coordination.* Proposed paragraph (d) requires HHS and States to coordinate to ensure that the same debt is not referred to TOP twice.

(e) *Payments not subject to offset.* Proposed paragraph (e) lists the types of Federal payments that may not be offset to collect past-due support under this section. As with offset of Federal nontax payments to collect other types of debt, payments can be partially or fully exempt. However, unlike the collection of other types of debt, covered benefit payments may not be offset through TOP to collect past-due support. Offset of tax refund payments for past due support is covered by § 285.42.

(f) *Special provisions applicable to Federal salary payments.* Proposed paragraph (f) describes the way in which Federal salary payments may be offset to collect past-due support. It describes the amount by which Federal salary payments may be offset and the due process requirements.

Section 285.34—Offset Under Reciprocal Agreements With States

(a) *Scope.* Proposed paragraph (a) describes the scope of this section, which governs offsets under the State Reciprocal Program, which is a program within TOP through which certain Federal debts and State debts are collected under the terms of reciprocal agreements through the offset of State payments and Federal nontax payments.

(b) *General Rule.* Proposed paragraph (b) states that Fiscal Service and disbursing officials and participating SRP States will comply with the terms of the applicable reciprocal agreement.

(c) *Reciprocal agreements.* Proposed paragraph (c) describes what terms must be in a reciprocal agreement. Neither Fiscal Service nor a State is required to enter into a reciprocal agreement.

(d) *Offsetting Federal payments to collect State debt.* Proposed paragraph (d) describes the requirement that States certify that their debts meet certain prerequisites prior to referring the debts

to TOP. It also describes the types of Federal payments that are exempt from offset under the State Reciprocal Program.

(e) *Offsetting State payments to collect Federal debt.* Proposed paragraph (e) describes the requirement that a creditor agency must certify its Federal debt for it to be collected under the State Reciprocal Program.

(f) *Fees.* Proposed paragraph (f) describes that Fiscal Service may charge participating SRP States a fee for the cost of offsetting a Federal payment to collect a State debt. The amount of that fee may be anywhere between \$0 and the full cost of applying the offset procedure. While Fiscal Service may charge a participating SRP State a fee, the participating SRP State may not charge Fiscal Service or the creditor agency a fee.

Section 285.40—Offset of Tax Refund Payments To Collect Federal Nontax Debts, State Debts, and Debts Owed to Tribal IV–D Agencies

This section consolidates the rules that apply generally to the offset of tax refund payments.

(a) *Scope.* Proposed paragraph (a) describes the scope of this and its related sections (*i.e.* §§ 285.40, 285.41, 285.42, and 285.43), which govern the offset of tax refund payments through TOP.

(b) *General Rule.* Proposed paragraph (b) describes the general rule that tax refund payments are subject to collection for Federal debts, for certain State debts, and for certain debts owed to Tribal IV–D agencies.

(c) *Reasonable efforts.* Proposed paragraph (c) describes the requirement that a creditor agency must make a reasonable effort to collect the debt prior to attempting to collect the debt through tax refund offset. Sending a demand letter and complying with statutory and regulatory prerequisites is an example of making reasonable efforts to collect.

(d) *Notification of offset to the debtor.* Proposed paragraph (d) describes the requirement to send the person or persons entitled to the tax refund payment a notice that the offset has occurred.

Section 285.41—Offset of Tax Refund Payments To Collect Federal Nontax Debts

The introductory text clarifies the definition for the term “match,” when used as noun, as applied to this section. The definition is essentially the same as the definition provided in section 285.1, except that it requires the use of a name control and a TIN (or derivatives thereof). The definition for “match” in

section 285.1, does not necessarily require the use of a name (or name control) and a TIN, though TOP does make use of those data points currently and anticipates doing so in the foreseeable future. The definition for “match” in the introductory text of § 285.41, on the other hand, does require the use of name control and TIN, though an exact match on those data fields is not required. *See* 31 U.S.C. 3720A(h)(3) (describing a “match” in the context of the offset of tax refund payments to collect Federal nontax debt). Note, the term “name control” is a term used by the IRS and generally refers to a sequence of characters derived from the name of a taxpayer.

(a) *Scope.* Proposed paragraph (a) describes the scope of this section, which governs tax refund offset to collect Federal debts through TOP.

(b) *General Rule.* Proposed paragraph (b) states that Federal agencies generally must collect Federal debts over 120 days delinquent by referring them to TOP for tax refund offset.

(c) *OASDI overpayment.* Proposed paragraph (c) describes the additional requirements to collecting an OASDI overpayment through tax refund offset.

(d) Proposed paragraph (d) recognizes that, unlike many other types of offset that permit Fiscal Service to charge anywhere from \$0 per offset up to the full cost of offset (*see* proposed § 285.2(j)), Fiscal Service must charge Federal agencies for the full cost of applying the offset procedure in the context of tax refund offset to collect Federal nontax debts. *See* 31 U.S.C. 3720A(d).

Section 285.42—Offset of Tax Refund Payments To Collect Past-Due Support

(a) *Scope.* Proposed paragraph (a) describes the scope of this section, which governs tax refund offset to collect past-due support through TOP.

(b) *General Rule.* Proposed paragraph (b) describes the circumstances under which HHS, a State, or a Tribal IV–D agency may refer past-due support to TOP.

(c) *Referral of past-due support to TOP.* Proposed paragraph (c) explains the circumstances under which HHS may submit past-due support to TOP. It also permits States and Tribal IV–D agencies to refer past-due support to TOP, but only if authorized by HHS rules.

(d) *Additional due process.* Proposed paragraph (d) describes the additional due process requirements for past-due support that is being enforced by more than one State or Tribal IV–D agency.

(e) *Time limitation on reversals.* Proposed paragraph (e) addresses the

time limitation imposed on IRS for reversing an improper tax refund payment. This time limitation was imposed on December 30, 2015, through an interim final rule (80 FR 81463). The comments received pursuant to that interim final rule will be addressed along with comments to this proposed rule.

(f) *Fees*. Proposed paragraph (f) recognizes that, unlike many other types of offset that permit Fiscal Service to charge anywhere from \$0 per offset up to the full cost of offset (see proposed § 285.2(j)), Fiscal Service must charge States and Tribal IV–D agencies for the full cost of applying the offset procedure in the context of tax refund offset to collect past-due support. See 42 U.S.C. 664(b). If the full cost of an offset exceeds the statutory maximum (currently \$25), Fiscal Service will charge the statutory maximum.

Section 285.43—Offset of Tax Refund Payments To Collect State Income Tax and Unemployment Compensation Debts

There are no additional definitions unique to this section.

(a) *Scope*. Proposed paragraph (a) describes the scope of this section, which governs tax refund offset to collect State income tax obligations and unemployment compensation debts.

(b) *General Rules*. Proposed paragraph (b) states that States may (but are not required to) refer to TOP State income tax obligations and unemployment compensation debts. If States refer such debts, Fiscal Service will collect those debts through offset, subject to the provisions of the proposed rule.

(c) *Additional due process*. Proposed paragraph (c) explains the due process requirements (beyond those required under the proposed § 285.2(d)(1)(ii)) for collecting State income tax obligations and unemployment compensation debts through tax refund offset.

Fiscal Service invites commenters' views on all aspects of the proposed rule, including whether the proposed rule is appropriately tailored and clear.

III. Procedural Analyses

Federalism

This proposed rule has been reviewed under Executive Order 13132, Federalism. This proposed rule would

not have substantial direct effects on States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this proposed rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this proposed rule would not impose information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

Regulatory Flexibility Act Analysis

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), it is hereby certified that the proposed rule would not have a significant economic impact on a substantial number of small entities because this rule only impacts persons who receive payments from Federal agencies or States and who are delinquent on debts owed to Federal agencies, States, or Tribal IV–D agencies. Accordingly, an initial regulatory flexibility analysis under the Regulatory Flexibility Act is not required. Fiscal Service seeks comment on whether the certification made herein should be reconsidered and, if so, on what basis.

Regulatory Planning and Review

This proposed rule is not a significant rule for purposes of Executive Order 12866 and has not been reviewed by the Office of Management and Budget. This rule is anticipated to be designated a deregulatory action for purposes of Executive Order 14192.

Unfunded Mandates Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532 (Unfunded Mandates Act), requires that the agency prepare a budgetary impact statement before promulgating any rule likely to result in a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the

private sector, of \$100 million or more in any one year. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires the agency to identify and consider a reasonable number of regulatory alternatives before promulgating the rule. We have determined that this rule would not result in expenditures by State, local, and Tribal governments, or by the private sector, of \$100 million or more in any one year. Accordingly, we have not prepared a budgetary impact statement or specifically addressed any regulatory alternatives.

List of Subjects

31 CFR Part 5

Claims, Government employees, Income taxes, Wages.

31 CFR Part 256

Claims.

31 CFR Part 285

Administrative practice and procedure, Black lung benefits, Child support, Child welfare, Claims, Credit, Disability benefits, Garnishment of wages, Government employees, Income taxes, Loan programs, Privacy, Railroad retirement, Railroad unemployment insurance, Social Security, Supplemental Security Income, Taxes, Unemployment compensation, Veteran, Wages.

For the reasons set forth in the preamble, Treasury proposes to amend 31 CFR part 5 and Fiscal Service proposes to amend 31 CFR parts 256 and 285 as follows:

PART 5—TREASURY DEBT COLLECTION

■ 1. The authority citation for part 5 continues to read as follows:

Authority: 5 U.S.C. 5514; 26 U.S.C. 6402; 31 U.S.C. 321, 3701, 3711, 3716, 3717, 3718, 3720A, 3720B, 3720D.

§§ 5.1, 5.4, 5.9, 5.11, 5.13, 5.17, 5.20 [Amended]

■ 2. In the table below, for each section indicated in the left column, remove the reference indicated in the middle column from wherever it appears in the section, and add the reference indicated in the right column:

Section	Remove	Add
5.1	285.11	285.111
5.1	285.2(a)	285.1
5.4	285.13	285.113
5.9	285.12	285.112
5.9	285.12(b)(2)	285.112(b)(2)
5.9	285.12(i)	285.112(i)

Section	Remove	Add
5.9	285.12(g)	285.112(g)
5.11	285.2	285.40
5.11	285.2(d)	285.40(c)
5.13	285.11	285.111
5.13	285.11(f)	285.111(f)
5.13	285.11(f)(4)	285.111(f)(4)
5.13	285.11(f)(5)	285.111(f)(5)
5.17	285.13	285.113
5.20	285.2	285.40

PART 256—OBTAINING PAYMENTS FROM THE JUDGMENT FUND AND UNDER PRIVATE RELIEF BILLS

■ 3. The authority citation for part 256 continues to read as follows:

Authority: 31 U.S.C. 1304, 3728; 41 U.S.C. 612; 5 U.S.C. 2301 note.

§ 256.21 [Amended]

■ 4. Amend § 256.21 by removing “285.5” and adding in its place “part 285, subpart A,”.

PART 285—DEBT COLLECTION AUTHORITIES UNDER THE DEBT COLLECTION IMPROVEMENT ACT OF 1996

■ 5. The authority citation for part 285 continues to read as follows:

Authority: 5 U.S.C. 5514; 26 U.S.C. 6402; 31 U.S.C. 321, 3701, 3711, 3716, 3719, 3720A, 3720B, 3720D; 42 U.S.C. 664; E.O. 13019, 61 FR 51763, 3 CFR, 1996 Comp., p. 216.

§§ 285.11 through 285.13 [Redesignated as §§ 285.111 through 285.113]

■ 6. Redesignate §§ 285.11 through 285.13 within subpart B as §§ 285.111 through 285.113, respectively.

■ 7. Revise subpart A to read as follows:

Subpart A—Disbursing Official Offset

Sec.

285.1 Definitions.

285.2 General provisions.

285.30 Offset of Federal nontax payments and State payments.

285.31 Offset of covered benefit payments to collect Federal nontax debts.

285.32 Offset of Federal salary payments to collect Federal nontax debts.

285.33 Offset of Federal nontax payments to collect past-due support.

285.34 Offset under reciprocal agreements with States.

285.40 Offset of tax refund payments to collect Federal nontax debts, State debts, and debts owed to Tribal IV–D agencies.

285.41 Offset of tax refund payments to collect Federal nontax debts.

285.42 Offset of tax refund payments to collect past-due support.

285.43 Offset of tax refund payments to collect State income tax and unemployment compensation debts.

Subpart A—Disbursing Official Offset

§ 285.1 Definitions.

As used in this subpart, unless otherwise specified, the following definitions will apply:

Address means physical street address, post office box number, electronic address (including electronic mail and telephone numbers capable of receiving text messages or similar alerts), or other reasonable address through which written notice can be delivered to a debtor or payee. For the purposes of § 285.43(b)(2)(i), the term “address” is limited to a physical street address or post office box.

Centralized offset means offset conducted through TOP.

Covered benefit payment means a Federal payment payable to an individual under the Social Security Act (42 U.S.C. 301 *et seq.*), part B of the Black Lung Benefits Act, or any law administered by the Railroad Retirement Board (other than payments that such Board determines to be tier 2 benefits).

Creditor agency means any Federal agency that is owed a debt that seeks to collect that debt through offset of Federal or State payments. For purposes of §§ 285.2, 285.30, 285.33, 285.34, 285.40, 285.42, and 285.43, the term “creditor agency” also includes any State that is owed a debt that seeks to collect the debt through offset of Federal payments. For purpose of § 285.42, the term “creditor agency” also includes Tribal IV–D agencies.

Days delinquent refers to the number of days that a debt has been in a delinquent status. For administrative debts (*e.g.*, debts arising from fines, penalties, and overpayments), the first day of delinquency generally is the date of the creditor agency’s initial written demand for payment. For debts that arise from the extension of credit through direct loans, loan guarantees, or insurance, the date of delinquency generally is the due date specified in the applicable agreement or instrument.

Debt means Federal debt, State debt, and/or past-due support owed to a Tribal IV–D agency. For purposes of §§ 285.31, 285.32, and 285.41, the term

“debt” means Federal debt. For purposes of §§ 285.2, 285.30, 285.34, and 285.40, the term “debt” means either a Federal debt, a State debt, or a debt owed to a Tribal IV–D agency. For the purposes of § 285.42, the term “debt” means State debt or past-due support owed to a Tribal IV–D agency. For the purposes of §§ 285.33 and 285.43, the term “debt” means State debt.

Debt record means information about a debt in TOP, including, but not limited to, the amount of the debt and the debtor’s name, address, and taxpayer identifying number.

Debtor means a person who owes a debt.

Delinquent or *past-due* refers to the status of a debt and means a debt has not been paid by the date specified in the creditor agency’s initial written demand for payment or applicable agreement or instrument, unless other payment arrangements satisfactory to the creditor agency have been made and such payment arrangements cure the delinquency.

Disbursing official, in the context of the offset of a Federal payment, means an official who has authority to disburse money pursuant to Title 31, Subtitle III, Chapter 33, Subchapter II of the United States Code or another Federal law and, in the context of the offset of a State payment, means the participating SRP State.

Disposable pay means that part of current basic pay, special pay, incentive pay, retired pay, retainer pay, or in the case of an employee not entitled to basic pay, other authorized pay remaining after the deduction of any amount required by law to be withheld (other than deductions to execute garnishment orders in accordance with parts 581 and 582 of this chapter). Among the legally required deductions that must be applied first to determine disposable pay are levies pursuant to the Internal Revenue Code (title 26, United States Code) and deductions described in § 581.105(b) through (f) of this chapter. See 5 CFR 550.1103.

Federal agency means a department, agency, subagency, court, court

administrative office, or instrumentality in the executive, judicial, or legislative branch of the Federal Government, including government corporations.

Federal benefit payment is a payment made under a Federal entitlement program or for an annuity, including, but not limited to, payments for Social Security, Supplemental Security Income, Black Lung, Civil Service Retirement, Railroad Retirement annuity and Railroad Unemployment and Sickness benefits, Department of Veterans Affairs Compensation and Pension, and Worker's Compensation.

Federal debt or *Federal nontax debt* has the meaning contained in 31 U.S.C. 3701(b)(1), except that it excludes debts arising under the Internal Revenue Code. The term "Federal debt" includes debt administered by a third party acting as an agent for the Federal Government. The term "Federal debt" also includes interest, penalties, and administrative costs that have been assessed on the principal amount of the debt.

Federal employee means a current employee of a Federal agency, including a current member of the Armed Forces or a Reserve of the Armed Forces, an employee of the United States Postal Service, and any seasonal or temporary employee.

Federally recognized Tribe means an entity listed on the Department of the Interior's list under the Federally Recognized Indian Tribe List Act of 1994, which the Secretary of the Interior currently acknowledges as an Indian Tribe and with which the United States maintains a government-to-government relationship.

Federal nontax payment is a Federal payment other than an amount payable under the Internal Revenue Code.

Federal payment is any payment certified by a payment agency to a disbursing official on a voucher or other similar form in accordance with Title 31, Subtitle III, Chapter 33, Subchapter II of the United States Code or other Federal disbursement authority. The term "Federal payment" also includes any payment made by the United States through an escrow agent or other person with the responsibility to hold and/or further disburse the funds to a person. Types of Federal payments include, but are not limited to, wage, salary, retirement, vendor, expense reimbursement, benefit, travel advances, travel reimbursement, grant, fee, refund (including a tax refund payment), judgment (including those certified for payment pursuant to 31 U.S.C. 1304 or 3728), return of funds held by the United States for a person, and any other payment type made by the United

States (including payments made by the United States on behalf of a State government) to a person.

Federal payment offset means, in the context of offset under a reciprocal agreement, offset of a Federal payment to collect a State debt.

Fiscal Service means the Bureau of the Fiscal Service, a bureau of the Department of the Treasury.

HHS means the Department of Health and Human Services, Office of Child Support Enforcement.

Internal Revenue Code means the Internal Revenue Code of 1986, as amended.

IRS means the Internal Revenue Service, a bureau of the Department of the Treasury.

Legally enforceable refers to a characteristic of a debt and means there has been a final agency determination that the debt, in the amount stated, is due, and there are no legal bars to collection by offset. A debt would not be legally enforceable, for example, if the debt is:

(1) Subject to the automatic stay in bankruptcy proceedings;

(2) The subject of a pending administrative review required by a statute or regulation that prohibits collection action during the review process; or

(3) Governed by a statute that precludes collection through offset.

Lump-sum benefit payment is a covered benefit payment and refers to a one-time payment made in lieu of recurring payments (or a portion of such payments) that would otherwise be paid over a period of time.

Lump-sum benefit payment floor is calculated, in Fiscal Service's discretion and depending on the information available, as one of the following:

(1) \$9,000;

(2) \$750 times the number of months to which the lump-sum benefit payment relates;

(3) \$750 times the number of months to which the lump-sum benefit payment relates minus any other amounts the PEP received as Federal benefit payments during those months; or

(4) \$9,000 minus any other amounts the PEP received as Federal benefit payments within a 12-month period.

Match, when used as a noun, means that the person entitled to payment on a payment record is the same person as the debtor on a debt record, as determined by Fiscal Service using information derived from the payment record and the debt record. When used as a verb, the term "match" means to conduct the process that results in a match.

Means-tested program refers to a program that bases eligibility on a

determination that the income and/or assets of the PEP are inadequate to provide the PEP with an adequate standard of living without program assistance.

Monthly benefit payment is a Federal payment and means a covered benefit payment payable on a recurring basis at monthly intervals.

OASDI overpayment means any overpayment of benefits made to an individual under title II of the Social Security Act (42 U.S.C. 401 *et seq.*) (*Federal Old Age, Survivors and Disability Insurance*).

Offset means withholding funds payable by the United States (including funds payable by the United States on behalf of a State government) or a State to, or held by the United States or a State for, a PEP to collect a debt owed by the PEP.

Participating SRP State means a State that has entered into a reciprocal agreement.

Past-due support means the amount of a delinquency, determined under a court order or an order of an administrative procedure established under State law, for support and maintenance of a child, or of a child and the parent with whom the child is living, which has not been paid. The term "child" as used in this definition is not limited to minor children. "Past-due support" also includes any past-due support being enforced by a State, including but not limited to amounts a State is enforcing pursuant to a cooperative agreement with an Indian Tribe or Tribal organization that receives funding under section 455(f) of the Social Security Act. For purposes of § 285.42, past-due support also means the amount of a delinquency, determined under a court order or an order of an administrative procedure established under Tribal law, for support and maintenance of a child, or of a child and the parent with whom the child is living, which has not been paid.

Payee means any person identified on the payment record as the recipient of the payment. Typically, the payee and PEP are the same person.

Payment means a Federal payment or a State payment.

Payment agency means, with regard to a Federal payment, any Federal agency that transmits payment requests, in the form of certified payment vouchers or other similar forms, to a disbursing official for disbursement. For § 285.34, the term "payment agency" also includes, with regard to a State payment, a participating SRP State.

Payment record, for purposes of Federal payments, means information contained on a payment request, in the

form of a certified payment voucher or other similar form that has been transmitted to a disbursing official for disbursement in accordance with the provisions of 31 U.S.C. 3325 and 3528 or other applicable law. For the purposes of State payments, the term “payment record” means information in a State’s records regarding a State payment eligible for offset under a reciprocal agreement.

PEP or person entitled to payment means the person legally entitled to the payment.

Person means an individual, corporation, partnership, association, organization, State or local government, Federally recognized Tribe, or any other type of entity other than the United States or a Federal agency.

Reciprocal agreement means a written agreement between Fiscal Service and a State, entered into pursuant to 31 U.S.C. 3716(h), that provides for Federal payment offset and State payment offset.

Recurring payment means a payment to an individual that is expected to be payable at regular intervals, at least four times annually, except that the term “recurring payment” does not include payments made pursuant to a Federal contract, grant, or cooperative agreement.

Salary offset means the collection of a debt through offset of disposable pay.

Salary payment agency means the agency that employs the Federal employee who owes the debt and authorizes the payment of their pay. A salary payment agency also includes any Federal agency that performs payroll services on behalf of the employing agency.

Secretary means the Secretary of the Treasury.

Separate guidance refers to guidance that Fiscal Service may issue regarding the operation of TOP, which may include a chapter in the Treasury Financial Manual, **Federal Register** documents, technical bulletins, rules of behavior, requirements documents, or other similar guidance.

State means each of the several States of the United States, the District of Columbia, American Samoa, Guam, the United States Virgin Islands, the Commonwealth of the Northern Mariana Islands, and the Commonwealth of Puerto Rico. The term “State” includes agencies of the State.

State debt means any amount of money, funds, or property that has been determined by an appropriate State official to be owed to that State by a person, including debt administered by a third party acting as an agent for the State. State debt also includes past-due support. For the purposes of “State

debt,” a “person” does not include a foreign sovereign, a Federally recognized Tribe, another State, or any local government within a State.

State income tax obligation is a type of State debt and means “past-due, legally enforceable State income tax obligation,” as defined by 26 U.S.C. 6402(e)(5), and includes any local income tax administered by the chief tax administration agency of the State.

State payment means an amount payable by a State to a person, as specified in a reciprocal agreement.

State payment offset means offset of a State payment to collect a Federal debt.

State Reciprocal Program or SRP refers to the program under which debts are collected pursuant to a reciprocal agreement.

Tax refund offset means offset of a tax refund payment to collect a debt.

Tax refund payment includes any overpayment of Federal taxes to be refunded to the person(s) making the overpayment after the IRS makes the appropriate credits as provided in 26 U.S.C. 6402(a) for any Federal tax liabilities on the part of the person(s) who made the overpayment.

Taxpayer identifying number means the identifying number described under section 6109 of the Internal Revenue Code.

Treasury Offset Program or TOP refers to the program administered by Fiscal Service through which Fiscal Service and other disbursing officials conduct offsets.

Tribal IV-D agency means an Indian Tribe or Tribal organization that receives funding under section 455(f) of the Social Security Act.

Unemployment compensation debt is a type of State debt and means “covered unemployment compensation debt,” as defined in 26 U.S.C. 6402(f)(4).

§ 285.2 General provisions.

(a) *Scope.* (1) This subpart governs the centralized offset of Federal payments and State payments to collect delinquent debts owed to the United States, a State, or a Tribal IV-D agency in accordance with 31 U.S.C. 3716 and 3720A, 5 U.S.C. 5514, 26 U.S.C. 6402, and 42 U.S.C. 664.

(2) This section sets forth the general rules applicable to centralized offset. Specific rules for each type of offset are set forth in §§ 285.30 through 285.34 and 285.40 through 285.43. To the extent there is a conflict between the general rules and the specific rules, the specific rules apply.

(3) The receipt of collections pursuant to this subpart does not preclude a creditor agency from pursuing other debt collection remedies in conjunction with centralized offset.

(b) *General rules for Federal agencies—(1) Mandatory referral of delinquent debts.* Federal agencies must refer debts to TOP for offset against all payment types subject to offset through TOP in accordance with this subpart.

(i) The requirement in this paragraph (b)(1) applies to any debt over 120 days delinquent, other than debts owed by foreign sovereigns or debts that fail to meet the requirements of paragraph (d)(1)(i) of this section.

(ii) If a debt that is over 120 days delinquent is not legally enforceable solely because it is under review as described in paragraph (d)(1)(ii)(C) of this section, the Federal agency must refer the debt to TOP within 30 days after completing its review.

(iii) Federal agencies must send the 60-day notice required in section (d)(1)(ii) at least 60 days prior to the debt becoming 121 days delinquent.

(2) *Discretionary referral of delinquent debts.* Federal agencies may refer to TOP a debt that is owed by a foreign sovereign or is less than 121 days delinquent.

(3) *Federal agency regulations.* Before referring a debt to TOP, Federal agencies must prescribe regulations in accordance with the requirements of 31 U.S.C. 3716(b) and 31 U.S.C. 3720A(a). Before referring debts to TOP for salary offset, Federal agencies must also prescribe regulations pursuant to 5 U.S.C. 5514(b) and 5 CFR 550.1104.

(c) *General rule for States and Tribal IV-D agencies.* States and Tribal IV-D agencies may refer delinquent debts to TOP in accordance with this subpart.

(d) *Requirements for all creditor agencies—(1) Referral prerequisites.* (i) A debt referred to TOP must be:

(A) Past-due in the amount stated by the creditor agency;

(B) Legally enforceable;

(C) More than the dollar threshold established by Fiscal Service in separate guidance; and

(D) To the extent it is a Federal debt:

(1) Not secured by collateral subject to a pending foreclosure action, unless the creditor agency determines that offset will not adversely affect the creditor agency’s rights to the secured collateral or the creditor agency has determined it may relinquish rights to such collateral;

(2) Not based in whole or in part on conduct in violation of the antitrust laws; and

(3) Not appearing to arise from or involve fraud, a false claim, or a misrepresentation, except to the extent permitted by the Department of Justice or if the provisions of 31 CFR 900.3 do not apply.

(ii) The creditor agency must have made a reasonable attempt to provide each debtor with:

(A) Written notification, at least 60 days before referring the debt to TOP, to the debtor's address last known to the creditor agency, identifying:

(1) The nature and the amount of the debt;

(2) The intention of the creditor agency to collect the debt through the offset of Federal and State payments; and

(3) The debtor's rights and how the debtor may exercise those rights;

(B) An opportunity to inspect and copy the records of the creditor agency pertaining to the debt;

(C) An opportunity for a review within the creditor agency of the determination of indebtedness, including an opportunity to present evidence that all or part of the debt is not past-due or legally enforceable; and

(D) An opportunity to enter into a written repayment agreement with the creditor agency.

(2) *Delinquent debt information requirements.* For each debt referred to TOP, the creditor agency must provide to Fiscal Service the following:

(i) The name and taxpayer identifying number of the debtor;

(ii) The debtor's address last known to the creditor agency, if known;

(iii) The amount of the debt;

(iv) The date on which the debt became delinquent;

(v) Contact information for an individual or office within the creditor agency who will handle questions, concerns or communications regarding the debt;

(vi) Written certification as required in paragraph (d)(3) of this section; and

(vii) Any other information requested by Fiscal Service.

(3) *Creditor agency certification.* At the time the creditor agency refers a debt to TOP, the creditor agency must provide, in the manner required by Fiscal Service, written certification that:

(i) The debt meets the requirements described in paragraph (d)(1)(i) of this section;

(ii) The creditor agency has satisfied all the requirements described in paragraph (d)(1)(ii) of this section;

(iii) The creditor agency has complied with all statutes, regulations, policies, and contract provisions applicable to the creditor agency's assessment of interest, penalties, and administrative costs, and has provided written notice to each debtor explaining the creditor agency's obligations to accrue and assess any such charges;

(iv) The creditor agency has satisfied any other requirements applicable to the

collection of the debt through offset as set forth in this subpart;

(v) The creditor agency has satisfied such other requirements as Fiscal Service may impose; and

(vi) The individual making the certification has the delegated authority to do so on behalf of the head of the creditor agency.

(4) *Correcting and updating debt information.* (i) After a debt has been referred to TOP, the creditor agency must provide, at least annually, in the manner and timeframes required by Fiscal Service, written certification that the debt continues to be legally enforceable and that all the information in the debt record, including the amount of the debt, is correct.

(ii) On an ongoing basis, the creditor agency must update:

(A) The amount of the debt in the debt record to reflect any collections the creditor agency receives outside of TOP;

(B) Address information for the debtor; and

(C) Any other information on the debt record.

(iii) The creditor agency may update debt records to reflect any increases in the amount of the debt referred to TOP so long as the creditor agency has complied with the requirements of paragraph (d)(1)(ii) of this section with regard to the increased amounts. Creditor agencies may not update a debt record to add an amount associated with a separate debt, unless otherwise permitted by Fiscal Service.

(iv) The creditor agency must notify Fiscal Service immediately of any change in the legal enforceability of the debt, including notice that the debtor has filed for bankruptcy protection.

(5) *Duplication not required.* Nothing in this subpart requires any creditor agency to duplicate any notice or opportunity for hearing or review before referral of the debt to TOP.

(e) *Federal payments—(1) Payments eligible for centralized offset.* All Federal nontax payments, except as set forth in § 285.30(c)(2), and all tax refund payments, except as exempted by statute, are eligible for centralized offset.

(2) *Payment agency responsibilities—(i) Determination of PEP or PEPs.* (A) Unless the payment agency determines (in a time and manner specified by Fiscal Service in separate guidance) that the PEP does not owe a debt that has been referred to TOP:

(1) The payment agency must identify the PEP on the payment record, and

(2) the payment agency must submit a separate payment voucher for each PEP, unless a payment is owed jointly to more than one PEP.

(B) If the payment agency determines that the PEP does not owe a debt that has been referred to TOP, these regulations do not prohibit the payment agency from making the payment to a different person from the PEP, if otherwise appropriate.

(ii) *Payment vouchers.* Payment agencies must prepare, submit, and certify payment vouchers in the manner prescribed by the disbursing official, including for the purpose of ensuring that all eligible payments will be subject to centralized offset for debts owed by PEPs and that all ineligible payments will not be subject to centralized offset.

(iii) *Payment mechanism.* In general, unless a payment is exempt from offset, a payment agency must ensure its payment is disbursed through a payment mechanism that will automatically match with debts that have been referred to TOP. This may limit the circumstances in which an agency may use a credit card to make a payment. To the extent a payment agency disburses its payments through a payment mechanism that does not automatically match with debts that have been referred to TOP, or to the extent the payment agency makes a payment to a third party who subsequently disburses the money to the PEPs, the payment agency must work with Fiscal Service to match the payments through a manual process.

(3) *Payment agencies and disbursing officials have satisfied the obligation underlying the payment.* When an offset occurs, the debtor has received payment in full for the underlying obligation represented by the payment. Pursuant to 31 U.S.C. 3716(c)(2)(A), neither the disbursing official nor the payment agency may be held liable for the amount of the offset on the basis that the underlying obligation was not satisfied.

(f) *Procedures for centralized offset—(1) Disbursing official requirement.* When a match occurs and all other requirements for centralized offset have been met, the disbursing official will offset a payment to satisfy, in whole or part, any debt owed by the PEP.

(2) *Payments offset for debts owed by PEPs.* If a payment is made to a payee that is not a PEP with respect to that payment and if the payment agency properly identifies the PEP and payee in the payment record, the disbursing official will offset that payment only to collect debts owed by the PEP.

(3) *Payments made jointly to more than one PEP.* If more than one person is jointly entitled to a payment (*i.e.*, there is more than one PEP for a payment), the entire payment will be subject to offset for a debt of any PEP, unless otherwise prohibited by law. If a

tax refund payment is offset, any non-debtor PEP filing a joint return with a debtor may secure their proper share of a tax refund payment from which an offset was made by filing a Form 8379, *Injured Spouse Allocation*, or successor form, with the IRS. IRS will then pay the non-debtor PEP their share of the refund and request that Fiscal Service deduct that amount from amounts payable to the creditor agency. Fiscal Service and the creditor agency will adjust their debt records accordingly. A successful injured spouse claim does not mean that the initial tax refund payment was erroneous or otherwise not due to the taxpayer.

(4) *Assigned payments.* Unless prohibited by Federal statute, if a person (an “assignor”) assigns the right to receive a Federal payment to a third party (an “assignee”), the assigned payment will be subject to centralized offset to collect any delinquent debt owed by either the assignee or the assignor.

(5) *Offset amount.* The disbursing official will offset the lesser of:

- (i) The amount of the payment as shown on the payment record;
- (ii) The amount of the debt;
- (iii) The amount specified by a creditor agency, pursuant to § 285.30(d); or

(iv) In the case of a payment that is partially exempted under § 285.30(c), at the disbursing official’s option:

(A) The amount of the un-exempted portion of the payment, calculated based on the amount of the payment as shown on the payment record;

(B) The amount specified in paragraph (f)(5)(iv)(A) of this section less any reduction taken by the payment agency through internal offset; or

(C) If the amount specified in paragraph (f)(5)(iv)(B) of this section cannot be calculated, \$0.

(6) *Priority of offsets.* (i) A levy pursuant to the Internal Revenue Code takes precedence over offsets under this subpart.

(ii) When a debtor owes more than one debt referred under this subpart, amounts offset will be applied:

(A) First, to satisfy any past-due support;

(B) Second, to satisfy any Federal debts; and

(C) Third, to any State debts other than past-due support.

(iii) To the extent a debtor owes more than one debt in one of the categories specified in paragraph (f)(6)(ii) of this section, amounts offset will be applied first against older debts or as otherwise determined by Fiscal Service in separate guidance.

(g) *Notification of offset to debtor—*(1) *Warning Letter.* Before offsetting a

recurring payment, the disbursing official (or Fiscal Service on behalf of the disbursing official) may, but is not required, to notify either the payee or the PEP (depending on what address information is available) in writing of when offsets are expected to begin and any other such information that the disbursing official (or Fiscal Service on behalf of the disbursing official) deems appropriate. With regard to monthly benefit payments, when administratively feasible, the disbursing official (or Fiscal Service on behalf of the disbursing official) will notify either the payee or the PEP (depending on what address information is available) in writing of when offsets are expected to begin and any other such information that the disbursing official (or Fiscal Service on behalf of the disbursing official) deems appropriate. The disbursing official (or Fiscal Service on behalf of the disbursing official) will determine in its discretion whether sending this notice is administratively feasible and may consider factors such as whether it has an accurate address to which to send such a letter and whether systems are functioning as expected. If the offset of a stream of monthly benefit payment is suspended or reduced for any reason, the disbursing official (or Fiscal Service on behalf of the disbursing official) need not send any additional notice. Failure to send a warning notice will not affect the validity of any offset.

(2) *Post-Offset Notification Letter.*

When an offset occurs under this subpart, the disbursing official (or Fiscal Service on behalf of the disbursing official) will notify either the payee or the PEP (depending on what address information is available) in writing of the offset. Failure to send an offset notice will not affect the validity of any offset. The offset notice will include:

(i) A description of the payment, the amount of the offset, and the date on which the offset occurred;

(ii) The purpose of the offset (*e.g.*, to satisfy past-due support, Federal debt, State income tax obligation, or unemployment compensation debt, or other State debt);

(iii) The identity of the creditor agency requesting the offset; and

(iv) Contact information for an individual or office within the creditor agency who will handle concerns regarding the offset.

(h) *Notification of offset to creditor and payment agencies—*(1) *Notification to creditor agencies.* Fiscal Service will notify the creditor agency of all offsets made to collect the creditor agency’s debts. This notification will include identifying information for each debtor,

the total amounts collected from each debtor’s payment with regard to the creditor agency’s debts, and the amount of any fees charged to the creditor agency by Fiscal Service and any other disbursing official conducting offsets. Except as provided in paragraph (h)(2) of this section or in separate guidance, Fiscal Service and other disbursing officials generally will not advise the creditor agency of the source of payment from which the offset amounts were collected.

(2) *Notification to HHS.* Upon request from HHS, Fiscal Service and other disbursing officials will share with HHS information contained in the payment records of persons who owe past-due support if that information would assist in the collection of such debts.

(3) *Notification to Fiscal Service.* When a non-Treasury disbursing official conducts an offset, that disbursing official will transmit to Fiscal Service all of the information necessary for Fiscal Service to send the notification under paragraphs (g) and (h) of this section, including the amount of any fees that the creditor agency is responsible for paying.

(4) *Notification to payment agencies.* Fiscal Service will make available to the payment agency the information contained in the offset notice so the payment agency may direct any questions about the offset to the appropriate contact point in the creditor agency.

(i) *Disposition of amounts collected—*(1) *Transmission of amounts collected.*

Fiscal Service will transmit amounts collected through centralized offset, less fees charged pursuant to paragraph (j) of this section, to the appropriate creditor agency or agencies. Alternatively, Fiscal Service may transmit all amounts collected through centralized offset and then separately bill the creditor agency or agencies for any fees charged pursuant to paragraph (j) of this section.

(2) *Payment errors.* If a payment agency discovers that a payment that was offset (either in whole or in part) should not have been made and determines that the payment should be reversed, the payment agency must promptly reverse the amount of the payment that is available for reversal. Fiscal Service will notify the creditor agency of the reversal and, in Fiscal Service’s discretion, will either:

(i) Deduct the portion of the reversed payment that was offset from future amounts payable to the creditor agency; or

(ii) Require the creditor agency to return promptly to the disbursing official an amount equal to the portion of the reversed payment that was offset.

(3) *Refunds.* In the event that a refund of an offset is appropriate, the disbursing official is generally not responsible for refunding the amount of the offset. The creditor agency must make any appropriate refunds and must notify Fiscal Service if it refunds all or any part of an offset taken through TOP.

(4) *Records.* If any payment (or portion thereof) that was offset is reversed or if any amount of an offset is refunded, Fiscal Service and the creditor agency will adjust their records accordingly.

(j) *Fees.* Unless otherwise provided by statute, Fiscal Service may charge creditor agencies fees sufficient to cover up to the full cost of implementing the offset procedures described in this subpart.

(k) *Social Security numbers.* Fiscal Service will ensure that an individual's social security number will not be visible on the outside of any package it sends by mail. In addition, Fiscal Service generally will redact or partially redact social security numbers in documents it sends by mail; however, to administer TOP, Fiscal Service (and other disbursing officials) may need to include social security numbers in mailed documents, including, for example:

(1) In interoffice and interagency communications;

(2) In notices, including notices to the PEP or payee that an offset has or will occur, when the social security number is (or is embedded in) a creditor agency's account number, debt identification number, or debtor identification number;

(3) In response to a request of a debtor or a debtor's representative for records of Fiscal Service's offset activities; and

(4) When required by law.

§ 285.30 Offset of Federal nontax payments and State payments.

(a) *Scope.* This section and §§ 285.31 through 285.34 set forth rules applicable to the offset of Federal nontax and State payments. This section and §§ 285.31 through 285.34 do not apply to Federal debts or Federal payments arising under:

(1) the tariff laws of the United States; or

(2) the Social Security Act, except to the extent provided under sections 204(f) and 1631(b)(4) of such Act and 31 U.S.C. 3716(c).

(b) *General rule.* Except as set forth in paragraph (c)(2) of this section, all Federal nontax payments are eligible for centralized offset for the collection of Federal debts and, to the extent permitted under §§ 285.33 and 285.34, for State debts. State payments are

eligible for centralized offset for the collection of Federal debts to the extent permitted under § 285.34.

(c) *Exemptions of Federal nontax payments from centralized offset—(1) Agency requests for exemptions.* To request an exemption of a Federal nontax payment from centralized offset pursuant to 31 U.S.C. 3716(c)(3)(B), the head of a payment agency must make a request for an exemption in writing and in compliance with the procedures established by Fiscal Service in separate guidance. Fiscal Service may only exempt classes of payments from centralized offset and will not consider requests to exempt classes of debt from centralized offset. Fiscal Service may withdraw a previously granted exemption if it determines that the exemption is no longer warranted.

(i) *Means-tested program payments.* Fiscal Service will exempt from centralized offset classes of payments made under means-tested programs upon the request of the payment agency.

(ii) *Payments made under programs that are not means-tested.* Fiscal Service may exempt from centralized offset classes of payments that are not made under means-tested programs upon the request of the payment agency. Payment agencies may request that Fiscal Service exempt 100% or a specific lesser percentage or amount of each payment in a payment class. Fiscal Service will consider such requests under standards it prescribes in separate guidance. Such standards will give due consideration to whether offset would tend to interfere substantially with or defeat the purpose of the payment agency's program.

(2) *Exempted payments.* The following payments are exempt from centralized offset:

(i) Black Lung Part C benefit payments;

(ii) Railroad Retirement tier 2 payments;

(iii) Payments made under the tariff laws of the United States;

(iv) Payments made under any program administered by the Secretary of Education under title IV of the Higher Education Act of 1965 for which payments are certified by the Department of Education;

(v) Federal loan payments (other than travel advances);

(vi) 75% of the amount of the payment as shown on the payment record of any payment of retirement annuity certified by the Office of Personnel Management;

(vii) 85% of the amount of a payment as shown on the payment record of a covered benefit payment;

(viii) In the case of a lump-sum benefit payment, the greater of:

(A) the amount specified in paragraph (c)(2)(vii) of this section; and

(B) the lump-sum benefit payment floor;

(ix) Any payment that is below the threshold established by Fiscal Service under § 285.2(d)(1)(i)(C);

(x) Any payment for attorneys' fees and/or litigation costs for class counsel made under prevailing party fee-shifting statutes to satisfy court judgments or settlements in actions certified as class actions pursuant to Federal Rule of Civil Procedure 23(b)(2) when the members of the class are not ascertainable;

(xi) Any payment for attorneys' fees and/or litigation costs for class counsel and administrative costs for distributing settlements made under prevailing party fee-shifting statutes to satisfy settlements in actions certified as class actions pursuant to Federal Rule of Civil Procedure 23(b)(3);

(xii) Any payment type for which offset is impracticable, as determined by Fiscal Service in separate guidance;

(xiii) Any other payments for which an exemption is explicitly provided for by Federal statute; and

(xiv) Any other payments for which an exemption has been granted in accordance with 31 U.S.C. 3716(c)(3)(B).

(d) *Certification of amount to be offset if different than maximum allowed by law.* If the creditor agency determines and certifies to Fiscal Service that the maximum amount allowed by law to be offset from Federal nontax payments would result in financial hardship to the debtor and that a lesser offset amount (specified either in dollar amount or as a percentage of the payment) is reasonable and appropriate based on the debtor's financial circumstances, then the disbursing official will offset such lesser amount specified by the creditor agency.

§ 285.31 Offset of covered benefit payments to collect Federal nontax debts.

(a) *Scope.* This section sets forth special rules applicable to the offset of covered benefit payments, other than lump-sum benefit payments, to collect delinquent Federal debts through TOP.

(b) *General rule.* To the extent required by § 285.2(b)(1), Federal agencies must refer delinquent debts to TOP for collection through the offset of monthly benefit payments.

(c) *Offset amount.* (1) The amount offset from a monthly benefit payment will be the lesser of:

(i) The amount of the debt;

(ii) An amount equal to 15% of the monthly benefit payment; or

(iii) The amount, if any, by which the monthly benefit payment exceeds \$750.

(2) The disbursing official may disregard the offset limitation specified

in paragraph (c)(1)(iii) of this section if the PEP has received either:

(i) An amount equal to at least \$9,000 in Federal benefit payments within the prior 12 months; or

(ii) An amount equal to at least \$750 in Federal benefit payments within the prior month.

§ 285.32 Offset of Federal salary payments to collect Federal nontax debts.

(a) *Scope.* (1) This section sets forth special rules applicable to salary offset to collect delinquent Federal debts through TOP.

(2) This section does not govern offset of final salary payments or lump-sum payments made to employees who have left a Federal agency's employ.

(b) *General rule.* To the extent required by § 285.2(b)(1), Federal agencies must refer debts to TOP for collection through salary offset. The requirement to collect debts through salary offset applies only with regard to debts over a threshold that Fiscal Service may establish in separate guidance.

(c) *Additional due process.* In addition to the requirements of § 285.2(d)(1)(ii), the creditor agency must have made a reasonable attempt to provide each debtor with an opportunity for a hearing, in accordance with 5 U.S.C. 5514 and agency regulations issued in accordance with 5 CFR 550.1104.

(d) *Procedures for salary offset.* (1) Each salary payment agency will compare debt records with records of Federal salary payments that it will disburse or certify to a disbursing official for disbursement. When a match occurs and all other requirements for salary offset have been met:

(i) The disbursing official will offset the Federal employee's salary payment to satisfy, in whole or part, the debt owed by the Federal employee; or

(ii) The salary payment agency, on behalf of the disbursing official, will deduct the offset amount from a Federal employee's disposable pay before it certifies the Federal employee's salary payment to a disbursing official for disbursement.

(2) *Offset amount.* (i) The amount offset from a salary payment under this section will be the lesser of:

(A) The amount of the debt;

(B) An amount equal to 15% of the debtor's disposable pay. The salary payment agency will use such records as it deems necessary to accurately calculate the debtor's disposable pay; or

(C) The amount determined under § 285.30(d).

(ii) Alternatively, the amount offset may be an amount greater than the

amount specified in paragraph (d)(2)(i) of this section if agreed upon, in writing, by the debtor and the creditor agency.

§ 285.33 Offset of Federal nontax payments to collect past-due support.

As used in this section, HHS, acting on behalf of a State, is the creditor agency.

(a) *Scope.* This section sets forth special rules applicable to the offset of Federal nontax payments to collect past-due support through TOP. This section applies only to the referral of past-due support by HHS. For referral of past-due support directly by a State that has entered into a reciprocal agreement with Fiscal Service, see § 285.34.

(b) *General rule.* A disbursing official will offset any Federal nontax payment subject to offset under this subpart to collect past-due support.

(c) *Due process.* Either the State to which the past-due support is owed or HHS must provide the due process specified by § 285.2(d)(1)(ii), except that the notice referred to in that section may be sent 30 days prior to referral of the past-due support to TOP.

(d) *Coordination.* HHS and the States will coordinate to ensure that there are no duplicative referrals of past-due support to TOP.

(e) *Payments not subject to offset.* The following Federal payments are not eligible for offset under this section:

(1) Payments exempted from offset under § 285.30(c)(2);

(2) Covered benefit payments; and

(3) Tax refund payments.

(f) *Special provisions applicable to Federal salary payments—(1) Offset amount.* (i) Unless a lower maximum

offset limitation is provided by applicable State law, the maximum part of a Federal salary payment subject to offset to collect past-due support may not exceed those amounts set forth in 15 U.S.C. 1673(b)(2)(A) and (B). If a lower maximum offset limitation is provided by applicable State law, the creditor agency must advise Fiscal Service of the lower maximum offset limitation.

(ii) *Garnishment for support.* The maximum allowable offset amount must be reduced by the amount of any deductions in pay resulting from a garnishment order for support. Nothing in this section will alter any rules applicable to processing garnishment orders for child support or alimony.

(2) *Pre-offset notice.* At least 30 days before offset, the disbursing official will send written notice to the debtor:

(i) Requesting that the debtor submit documentation that the disbursing official determines is needed to determine the applicable offset

limitation under 15 U.S.C. 1673(b)(2)(A) and (B); and

(ii) Providing the amount (by percentage or otherwise) that will be deducted if the debtor fails to submit the requested documentation.

§ 285.34 Offset under reciprocal agreements with States.

(a) *Scope.* This section sets forth the special rules applicable to offset of Federal nontax payments and State payments to collect debt under reciprocal agreements with participating SRP States.

(b) *General rule.* In accordance with the terms of any applicable reciprocal agreement and this section, Fiscal Service and other disbursing officials will conduct Federal payment offset to collect delinquent State debts, and participating SRP States will conduct State payment offset to collect delinquent Federal debts.

(c) *Reciprocal agreements.* (1) Fiscal Service and a State may enter into a reciprocal agreement.

(2) A reciprocal agreement must:

(i) Set forth all of the State's requirements associated with State payment offset, including requirements of State law and any prohibitions on offsetting joint payments in accordance with § 285.2(f)(3);

(ii) Require the State to prescribe procedures to govern the collection of delinquent State debts;

(iii) Require that the State notify the payee or PEP of the State payment offset, providing the information required by § 285.2(g);

(iv) Set forth the types of Federal payments that will be subject to offset to collect the State's debts;

(v) Set forth the types of State payments that will be subject to offset to collect Federal debts;

(vi) Not impose any due process requirements on the collection of Federal debts beyond what is already required by this subpart; and

(vii) Contain any other requirements that Fiscal Service considers appropriate.

(d) *Offsetting Federal payments to collect State debt—(1) Certification of State debt.* At the time a participating SRP State refers a debt to TOP for collection by Federal payment offset under this section, the State must provide, in the manner required by Fiscal Service, written certification that:

(i) The debt meets the requirements described in § 285.2(d)(1);

(ii) The State has complied with all Federal and State statutes, regulations, policies, and contract provisions applicable to the collection of the debt through offset under this subpart;

(iii) The individual making the certification has the delegated authority to make the certification on behalf of the State;

(iv) With regard to past-due support, the State is authorized by HHS rules to refer the past-due support directly to TOP; and

(v) The State has met such other requirements as Fiscal Service may from time to time impose.

(2) *Federal payments exempt from offset under this section.* The following Federal payments are not eligible for offset under this section:

(i) Payments exempted from offset under § 285.30(c)(2);

(ii) Covered benefit payments; and

(iii) Tax refund payments.

(e) *Offsetting State payments to collect Federal debt.* Fiscal Service will refer a Federal debt to a participating SRP State only if Fiscal Service has received a certification from the creditor agency that the prerequisites specified in § 285.2(b) have been satisfied.

(f) *Fees.* Fiscal Service may charge creditor agencies fees sufficient to cover up to the full cost of implementing Federal payment offset and State payment offset. A participating SRP State may not charge any Federal agency a fee for its cost of implementing offset under this section.

§ 285.40 Offset of tax refund payments to collect Federal nontax debts, State debts, and debts owed to Tribal IV–D agencies.

(a) *Scope.* This section and §§ 285.41 through 285.43 set forth rules applicable to the offset of tax refund payments through TOP.

(b) *General rule.* All tax refund payments are eligible for centralized offset for the collection of Federal debts and, to the extent permitted under §§ 285.42 and 285.43, for State debts, and to the extent permitted under § 285.42, for past-due support owed to Tribal IV–D agencies.

(c) *Reasonable efforts.* Before referring a debt to TOP for collection by tax refund offset, the creditor agency must make reasonable efforts to collect the debt. The requirement to make reasonable efforts can be satisfied by making written demand for payment from the debtor and complying with any other prerequisites established by the creditor agency.

(d) *Notification of offset to the debtor.* When a tax refund offset occurs, Fiscal Service will notify the debtor PEP and, if applicable, any non-debtor PEP. In addition to the requirements of § 285.2(g), this notice will also include information regarding the steps any non-debtor PEP who may have filed a joint return with the debtor may take to

secure their proper share of the tax refund. Failure to send an offset notice will not affect the validity of any offset.

§ 285.41 Offset of tax refund payments to collect Federal nontax debts.

With respect to the term “match,” as applied to this section, the Fiscal Service will use information to determine that the person entitled to payment on a payment record is the same person as the debtor on a debt record, including name control, taxpayer identifying number, and other necessary identifiers, if any.

(a) *Scope.* This section sets forth special rules applicable to the offset of tax refund payments to collect delinquent Federal debts through TOP.

(b) *General rule.* To the extent required by § 285.2(b)(1), Federal agencies must refer debts to TOP for collection through offset of tax refund payments, except that any agency subject to section 9 of the Act of May 18, 1933 (16 U.S.C. 831h) may, but is not required to, refer delinquent debts to TOP for collection through offset of tax refund payments.

(c) *OASDI overpayments.* Prior to referring a debt that resulted from an OASDI payment to an individual to TOP, the Social Security Administration must:

(1) Determine that the individual is not currently entitled to monthly insurance benefits under title II of the Social Security Act;

(2) In addition to the notice described in § 285.2(d)(1)(ii)(A), notify the debtor of the conditions under which the Social Security Administration is required to waive recovery of an overpayment, as provided under section 204(b) of the Social Security Act; and

(3) If the waiver referred to in paragraph (c)(2) of this section is requested within the 60-day period referred to in § 285.2(d)(1)(ii)(A), render a decision on the waiver request under section 204(b) of the Social Security Act.

(d) *Fees.* Fiscal Service will charge creditor agencies a fee to reimburse it for the full cost of applying the offset procedure.

§ 285.42 Offset of tax refund payments to collect past-due support.

As used in this section, the terms “debt” and “past-due support” are synonymous.

(a) *Scope.* This section sets forth special rules applicable to the offset of tax refund payments to collect past-due support through TOP.

(b) *General rule.* In accordance with this section, HHS, a State, or a Tribal IV–D agency may refer past-due support to TOP, if either:

(1) There has been an assignment of the support obligation to the State or Tribal IV–D agency; or

(2) The State or Tribal IV–D agency is providing support collection services under 42 U.S.C. 654(4) or 45 CFR part 309 and the amount of the past-due support is not less than \$500.00.

(c) *Referral of past-due support to TOP—(1) By HHS.* (i) A State or Tribal IV–D agency notifying HHS of past-due support must:

(A) Do so in the manner and format prescribed by HHS; and

(B) Certify that it has complied with the requirements in paragraph (d) of this section and with any of other requirements under State or Tribal law applicable to the offset of Federal tax refund payments to collect past-due support.

(ii) HHS will refer to TOP the past-due support about which it received notice under paragraph (c)(1)(i) of this section.

(iii) When HHS has knowledge that the debt is being enforced by a State or Tribal IV–D agency, HHS will inform any such State or Tribal IV–D agency when it receives any collections through offset under this subpart.

(2) *By States or Tribal IV–D agencies.*

(i) If authorized by HHS rules, a State or Tribal IV–D agency may refer past-due support directly to TOP. Otherwise, the State or Tribal IV–D agency must notify HHS of past-due support in accordance with the provisions of paragraph (c)(1) of this section.

(ii) A State or Tribal IV–D agency referring past-due support directly to TOP must:

(A) Do so in the manner and format prescribed by Fiscal Service in separate guidance; and

(B) Certify that it has complied with all requirements of this subpart and applicable State or Tribal law.

(iii) When a State or Tribal IV–D agency has knowledge that the debt is being enforced by more than one State or Tribal IV–D agency, the State or Tribal IV–D agency referring the debt to TOP must inform any such other State or Tribal IV–D agency when it receives any collections through offset under this subpart.

(d) *Additional due process.* The State or Tribal IV–D agency, or HHS if the State or Tribal IV–D agency requests and HHS agrees, must provide the due process specified by § 285.2(d)(1)(ii). In cases when a debt is being enforced by more than one State or Tribal IV–D agency, the written notification to the debtor must also advise the debtor of their opportunities to request a review with the State or Tribal IV–D agency enforcing collection or the State or

Tribal IV–D agency issuing the support order as prescribed by the provisions of 42 U.S.C. 664(a)(3), 45 CFR 303.72(e), and 45 CFR part 309.

(e) *Time limitation on reversals.*

Notwithstanding § 285.2(i)(2), Fiscal Service will not reverse the offset of a tax refund payment that was erroneous or otherwise not due to the taxpayer if:

(1) IRS notifies Fiscal Service that a tax refund payment that was offset was erroneous or otherwise not due to the taxpayer;

(2) The date of IRS's notification to Fiscal Service under paragraph (e)(1) of this section is more than six months after the date the tax refund payment was offset (*i.e.*, the tax refund payment date); and

(3) The State or Tribal IV–D agency has already forwarded the funds collected through the offset as required or authorized by 42 U.S.C. 657 or 45 CFR 309.115.

(f) *Fees.* Fiscal Service will charge States and Tribal IV–D agencies a fee to reimburse it for the full cost of applying the offset procedure. To the extent full costs exceed the amount specified by 42 U.S.C. 664(b)(2)(B), Fiscal Service will charge a fee equal to the amount specified by 42 U.S.C. 664(b)(2)(B).

§ 285.43 Offset of tax refund payments to collect State income tax and unemployment compensation debts.

As used in this section, the term “debt” means a State income tax obligation or unemployment compensation debt.

(a) *Scope.* This section sets forth special rules applicable to the offset of tax refund payments to collect State income tax obligations and unemployment compensation debts.

(b) *General rules.* (1) States may refer to TOP State income tax obligations and unemployment compensation debts.

(2) Fiscal Service will offset tax refund payments in accordance with this subpart to collect:

(i) State income tax obligations, but only if the address shown on the Federal tax return for the taxable year of the overpayment is an address within the State seeking the offset; and

(ii) Unemployment compensation debts.

(c) *Additional due process.* In addition to the requirements of § 285.2(d)(1)(ii), a State must:

(1) With respect to an unemployment compensation debt described by 26 U.S.C. 6402(f)(4)(A), provide the debtor an opportunity to dispute the State's determination that the debt resulted from fraud or the debtor's failure to report earnings; and

(2) With respect to State income tax obligations:

(i) Send the notice referred to in § 285.2(d)(1)(ii) by certified mail, return receipt requested; and

(ii) Where the debtor claims that they are immune from State taxation by reason of being an enrolled member of a Federally recognized Tribe who lives on a reservation and derives all of their income from that reservation, have procedures that include a *de novo* review on the merits, unless such claims have been previously adjudicated by a court of competent jurisdiction.

Gary Grippo,

Acting Fiscal Assistant Secretary.

[FR Doc. 2025–23704 Filed 12–22–25; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2025–0703]

RIN 1625–AA87

Security Zones; Vessels Carrying Dangerous Cargo, Corpus Christi and La Quinta Ship Channels, Corpus Christi, TX

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a security zone around vessels carrying Certain Dangerous Cargos (CDCs), for which the Captain of the Port, Corpus Christi deems enhanced security measures are necessary on a case-by-case basis. This security zone is needed to safeguard these vessels, the public, and the surrounding area from sabotage or other subversive acts, accidents, or other events of a similar nature. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before January 22, 2026.

ADDRESSES: You may submit comments identified by docket number USCG–2025–0703 using the Federal Docket Management System at <https://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments. This notice of proposed rulemaking with its plain-language, 100-word-or-less proposed rule summary will be available in this same docket.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Lieutenant Tim Cardenas, Sector Corpus Christi Waterways Management Division, U.S. Coast Guard; telephone 361–244–4784, email Timothy.J.Cardenas@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CDC Certain Dangerous Cargo
CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background and Authority

This proposed rule would establish a permanent security zone that could be activated as necessary to protect vessels carrying CDC bound for the Port of Corpus Christi. Vessels carrying CDC within the Captain of the Port Corpus Christi Zone are potential targets of terrorist attacks, or potential launch platforms for terrorist attacks on other vessels, waterfront facilities, and adjacent population centers. In the last 2 years, the Port of Corpus Christi has seen more than 450 vessels enter or depart the port carrying CDCs, with that number projected to almost double in the next 15 years.

The Coast Guard has previously created temporary security zones for individual vessel transits, see for example 89 FR 96533, December 5, 2024. Continuing to create individual security zones will result in a significant administrative burden to the unit based on the expected number of future transits, and it will also delay public notice for individual security zone activations. Therefore, the Coast Guard is proposing to establish this permanent security zone to protect waterfront facilities, persons, and vessels from subversive or terrorist acts. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70051 and 70124.

Due to the potential of terrorist attacks, this proposed rule would allow the Captain of the Port to activate security zones around vessels carrying CDC as deemed necessary, on a case-by-case basis. By limiting access to the area immediately around these vessels, the Coast Guard is reducing potential methods of attack on these vessels, and potential use of the vessels to launch attacks on waterfront facilities and adjacent population centers located within the Captain of the Port zone. Vessels having need to enter these security zones must obtain express

permission from the Captain of the Port or his designated representative prior to entry.

III. Discussion of the Proposed Rule

The Coast Guard proposes to establish a security zone around certain vessels carrying CDC, for which the Captain of the Port Corpus Christi deems enhanced security measures necessary on a case-by-case basis. These security zones would be activated for certain vessels within the COTP zone laden with CDC and transiting the Corpus Christi or La Quinta Shipping Channels. These security zones would encompass a 500-yard radius around these vessels while transiting the ship channel, or when moored at a facility and loading or unloading CDC. These security zones are needed to safeguard the vessels, the public, and the surrounding area from sabotage or other subversive acts, accidents, or other events of a similar nature.

Vessels may transit through the security zone but must maintain the minimum speed necessary to maintain course, except no vessel may come within 100 yards of a vessel carrying CDC unless they first receive permission from the COTP. Vessels can request permission from the COTP to enter or transit through a security zone on VHF-FM channel 16 or by telephone at 361-939-0450. If permission is granted, all persons and vessels must comply with the instructions of the COTP or designated representative. The COTP or a designated representative will inform the public of the activation of security zones for CDC vessels through Broadcast Notice to Mariners and Marine Safety Information Bulletins (MSIBs) as appropriate for the enforcement times and dates for these security zones.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders.

A. Impact on Small Entities

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

have a significant economic impact on a substantial number of small entities for the following reasons.

This rule will impact a small, designated area of 500-yards around a moving vessel in the Corpus Christi or La Quinta Shipping Channels over a period of six hours or less. Most vessels will be able to move around the security zone and therefore the impediment to the movement of other vessels will be minimal. Moreover, the rule allows other vessels to seek permission from the COTP to enter the zone.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), if this proposed rule will affect your small business, organization, or governmental jurisdiction and you have questions, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Small businesses may send comments to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards by calling 1-888-REG-FAIR (1-888-734-3247).

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

We have analyzed this proposed rule under Executive Order 13132, Federalism, and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in that Order.

Also, this proposed 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

As required by The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the Coast Guard certifies

that this proposed rule will not result in an annual expenditure of \$100,000,000 or more (adjusted for inflation) by a State, local, or tribal government, in the aggregate, or by the private sector.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment.

This proposed rule involves establishing a security zone around vessels laden with CDC as they transit through the Corpus Christi or La Quinta Shipping Channels. These transits typically last up to six hours. It will prohibit entry within a 500-yard radius of these vessels while transiting, and when loaded with CDC at the pier. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Docket Management System at <https://www.regulations.gov>. To do so, go to <https://www.regulations.gov>, type USCG–2025–0703 in the search box and click “Search.” Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using <https://www.regulations.gov>, call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select “Supporting & Related Material” in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the <https://www.regulations.gov> Frequently Asked Questions web page. Also, if you click on the Dockets tab and then the proposed rule, you should see a “Subscribe” option for email alerts. The option will notify you when comments are posted, or a final rule is published.

Personal information. We accept anonymous comments. Comments we post to <https://www.regulations.gov> will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS’s eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 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 § 165.848 to read as follows:

§ 165.848 Security Zones; Vessels Carrying Dangerous Cargo, Corpus Christi and La Quinta Ship Channels, Corpus Christi, TX.

(a) *Location.* The following area is a security zone: All waters within the Corpus Christi or La Quinta Shipping Channel, from surface to bottom, encompassing a 500-yard radius around vessels loaded with certain dangerous cargo.

(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 security zone.

Certain dangerous cargo or CDC means a material defined as CDC in 33 CFR 160.202.

(c) *Regulations.* (1) No vessel may approach within 500 yards of a passenger vessel or vessel carrying a CDC within the Captain of the Port Corpus Christi zone, unless traveling at

the minimum speed necessary to navigate safely.

(2) Under the general security zone regulations in subpart D of this part, no vessel or person may approach within 100 yards of a vessel carrying a CDC within the Corpus Christi or La Quinta Ship Channels, unless authorized by the COTP Sector Corpus Christi or his or her designated representative.

(3) Persons or vessels desiring to enter or pass through the zone must request permission from the COTP Sector Corpus Christi on VHF–FM channel 16 or by telephone at 361–939–0450. If permission is granted, all persons and vessels must comply with all lawful orders and directions of the COTP or the COTP’s designated representative.

(d) *Enforcement.* When this security zone is activated for vessels carrying CDC within the location above, the COTP or a designated representative will provide notice to the public of the specific dates, times, and vessel names through Broadcast Notices to Mariners (BNMs) or Marine Safety Information Bulletins (MSIBs) of the enforcement times and dates for this security zone. The COTP may also enlist the aid and cooperation of any Federal, state, county, or municipal law enforcement agency to assist in the enforcement of the regulation.

T.H. Bertheau,

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

[FR Doc. 2025–23773 Filed 12–22–25; 8:45 am]

BILLING CODE 9110–04–P

Notices

Federal Register

Vol. 90, No. 244

Tuesday, December 23, 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

International Trade Administration
[C-570-074]

Common Alloy Aluminum Sheet From the People's Republic of China: Final Results of Countervailing Duty Administrative Review; 2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies were provided to Yinbang Clad Material Co., Ltd. and Henan Mingtai Al. Industrial Co., Ltd., producers and/or exporters of common alloy aluminum sheet (aluminum sheet) from the People's Republic of China (China), during the period of review (POR) of January 1, 2023, through December 31, 2023.

DATES: Applicable December 23, 2025.

FOR FURTHER INFORMATION CONTACT: Amber Hodak or Theodora Mattei, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue

NW, Washington, DC 20230; telephone: (202) 482-8034 or (202) 482-4834, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 12, 2025, Commerce published the *Preliminary Results* of this administrative review in the **Federal Register** and invited interested parties to comment.¹ Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.² Additionally, due to a backlog of documents that were electronically filed via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.³ Accordingly, the deadline for these final results is now December 17, 2025. For a complete description of the events that occurred since the *Preliminary Results*, see the Issues and Decision Memorandum.⁴

Scope of the Order⁵

The merchandise covered by the *Order* is aluminum sheet from China. For a complete description of the scope of the of the *Order*, see the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised by the interested parties in their case briefs and rebuttal briefs are addressed in the Issues and

Decision Memorandum. A list of the issues raised is attached as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via ACCESS, which is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Changes Since the Preliminary Results

Based on a review of the record and analysis of comments received from interested parties, we made changes to the *Preliminary Results*. For a full description of these revisions, see the Issues and Decision Memorandum.

Methodology

Commerce conducted this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found to be countervailable, we determine that there is a subsidy, *i.e.*, a financial contribution from a government or public entity that gives rise to a benefit to the recipient, and that the subsidy is specific.⁶ The subsidy programs under review, and the issues raised in case and rebuttal briefs submitted by the interested parties, are discussed in the Issues and Decision Memorandum.

Final Results of Administrative Review

Commerce determines the following net countervailable subsidy rates for the period January 1, 2023, through December 31, 2023:⁷

Company	Subsidy rate (percent <i>ad valorem</i>)
Yinbang Clad Material Co., Ltd	9.76
Henan Mingtai Al. Industrial Co., Ltd. (also known as Henan Mingtai Industrial Co., Ltd. and Henan Mingtai Aluminum Industrial Co., Ltd.) ⁸ ...	112.82

¹ See *Common Alloy Aluminum Sheet from the People's Republic of China: Preliminary Results and Partial Rescission of Countervailing Duty Administrative Review; 2023*, 90 FR 24783 (June 12, 2025) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

² See Memorandum, "Deadlines Affected by the Shutdown of the Federal Government," dated November 14, 2025.

³ See Memorandum, "Tolling of all Case Deadlines," dated November 24, 2025.

⁴ See Memorandum, "Issues and Decision Memorandum for the Final Results of the Countervailing Duty Administrative Review of Common Alloy Aluminum Sheet from the People's Republic of China; 2023" dated concurrently with this notice (Issues and Decision Memorandum).

⁵ See *Common Alloy Aluminum Sheet from the People's Republic of China: Countervailing Duty Order*, 84 FR 2157 (February 6, 2019) (*Order*).

⁶ See sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

⁷ As noted in the *Preliminary Results* PDM, we determined that Wuxi Yinbang Defense Technology Co., Ltd., Yinbang (Anhui) New Energy Technology Co., Ltd., and Guizhou Liyang Tianxing Technology Co., Ltd. are cross-owned with Yinbang with the meaning of 19 CFR 351.525(b)(6)(vii). In addition, Commerce previously found Henan Gongdian Thermal Co., Ltd. to be cross-owned with Henan Mingtai Al. Industrial Co., Ltd. and Zhengzhou Mingtai Industry, Co., Ltd. See *Common Alloy*

Aluminum Sheet from the People's Republic of China: Preliminary Affirmative Countervailing Duty (CVD) Determination, Alignment of Final CVD Determination with Final Antidumping Duty Determination, and Preliminary CVD Determination of Critical Circumstances, 83 FR 17651 (April 23, 2018) and accompanying PDM at 10-11, unchanged in *Countervailing Duty Investigation of Common Alloy Aluminum Sheet from the People's Republic of China: Final Affirmative Determination*, 83 FR 57427 (November 15, 2018), and accompanying IDM at 5.

⁸ Certain changes were made with respect to Henan Mingtai Al. Industrial Co., Ltd.'s AFA rate for these final results. See Issues and Decision Memorandum at 6-7 and Appendix II.

Disclosure

Commerce intends to disclose to the interested parties the calculations and analysis performed for these final results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of final results in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment

Pursuant to section 751 (a)(2)(C) of the Act and 19 CFR 351.212(b)(2), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries of subject merchandise in accordance with the final results of this review, for the above-listed companies at the applicable *ad valorem* assessment rates. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

Cash Deposit Instructions

In accordance with section 751(a)(2)(C) of the Act, Commerce also intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for each company above on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, except where the rate calculated in the final results is zero or *de minimis*. For all non-reviewed firms, we will instruct CBP to collect cash deposits of estimated countervailing duties at the most recent company specific or all-others rate applicable to the company, as appropriate. These cash deposit requirements, effective upon publication of these final results, shall remain in effect until further notice.

Administrative Protective Order (APO)

This notice also serves as a final reminder to parties subject to an APO of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order, is hereby requested. Failure to comply

with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

Commerce is issuing the final results and publishing this notice in accordance with sections 751(a)(l) and 777(i)(l) of the Act, and 19 CFR 351.221(b)(5).

Dated: December 17, 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. Use of Facts Otherwise Available and Application of Adverse Inferences
- V. Subsidies Valuation Information
- VI. Analysis of Programs
- VII. Programs Determined to Confer a Non-Measurable Benefit During the POR
- VIII. Programs Determined to Be Not Used
- IX. Changes Since the *Preliminary Results*
- X. Discussion of the Issues
 - Comment 1: Whether Commerce Should Attribute Certain Countervailable Assistance Received by Yinbang's Wholly-Owned Subsidiary
 - Comment 2: Whether Commerce Should Correct Value-Added Tax Paid by Yinbang on Certain Primary Aluminum Purchases
 - Comment 3: Whether Commerce Should Select a Different Basic-Fee Benchmark to Calculate Yinbang's Benefit from the Electricity for Less Than Adequate Remuneration Program
 - Comment 4: Whether Commerce Should Revise Yinbang's Grant Calculations
- XI. Recommendation

[FR Doc. 2025-23699 Filed 12-22-25; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-108, C-570-109]

Ceramic Tile From the People's Republic of China: Notice of Court Decision Not in Harmony With Final Scope Ruling and Notice of Amended Final Scope Ruling Pursuant to Court Decision

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On October 20, 2025, the U.S. Court of International Trade (CIT) issued its final judgment in *Elysium Tiles, Inc. et al v. United States*, Court No. 23-00041, sustaining the U.S.

Department of Commerce (Commerce)'s second remand redetermination pertaining to the scope ruling for the antidumping duty and countervailing duty orders on ceramic tile from the People's Republic of China. Commerce is notifying the public that the CIT's final judgment is not in harmony with Commerce's scope ruling, and that Commerce is amending the scope ruling to find that Elysium Tiles, Inc. and Elysium Tile Florida, Inc. (collectively, Elysium)'s composite tile is not covered by the scope of the *Orders*.¹

DATES: Applicable October 30, 2025.

FOR FURTHER INFORMATION CONTACT:

George McMahon, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-1167.

SUPPLEMENTARY INFORMATION:

Background

On January 25, 2023, Commerce found Elysium's composite tile to be covered by the scope of the *Orders*.² On July 18, 2024, the CIT remanded Commerce's final scope ruling as unsupported by substantial evidence and not in accordance with law.³

The CIT held that Commerce: (1) failed to provide an adequate summary of an *ex parte* meeting; and (2) failed to show with substantial evidence that either, under 19 CFR 351.225(k)(1), the *Orders*' scope language contemplates products such as marble composite tile, or that, under 19 CFR 351.225(k)(2), the marble composite tile truly is considered a form of ceramic tile in purpose, function, advertising, and use.⁴ In its first remand redetermination,⁵ Commerce supplemented the *ex parte* memorandum to provide a more detailed summary, and Commerce continued to find that Elysium's composite tile was within the scope

¹ See *Ceramic Tile from the People's Republic of China: Antidumping Duty Order*, 85 FR 33089 (June 1, 2020); and *Ceramic Tile from the People's Republic of China: Countervailing Duty Order*, 85 FR 33119 (June 1, 2020) (collectively, the *Orders*).

² See Memorandum, "Final Scope Ruling on Elysium's Composite Tile," dated January 25, 2023 (Final Scope Ruling).

³ See *Elysium Tiles, Inc. v. United States*, 719 F. Supp. 3d 1289 (CIT 2024) (*Remand Order*).

⁴ See *Remand Order* at 18-19 and 11 n.5 (noting that because Elysium submitted its scope application prior to Commerce's recent revisions to the scope regulation, all citations are to the prior regulations); see also 19 CFR 351.225(k) (2023).

⁵ See *Final Results of Redetermination Pursuant to Court Remand, Elysium Tiles, Inc., and Elysium Tile Florida, Inc., v. United States*, Court No. 23-00041, Slip. Op. 24-80 (CIT July 18, 2024), dated October 29, 2024 (*First Remand Redetermination*), available at: <https://access.trade.gov/public/FinalRemandRedetermination.aspx>.

based upon the plain language of the scope, which included ceramic tile with decorative features.

On March 11, 2025, the CIT sustained, in part, and remanded, in part, Commerce's *First Remand Redetermination*.⁶ In the *Second Remand Order*, the CIT held that the summary of the *ex parte* meeting was adequate.⁷ However, the CIT remanded Commerce's *First Remand Redetermination*, instructing Commerce to consider the five additional factors set out in 19 CFR 351.225(k)(2)(i).⁸ Pursuant to the *Second Remand Order*, in its final remand redetermination, Commerce analyzed the factors set out in 19 CFR 351.225(k)(2)(i) and determined, based on those factors, that Elysium's composite tile is not covered by the scope of the *Orders*.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 section 516A(c) and (e) of the Tariff Act of 1930, as amended (the Act), Commerce must 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 October 20, 2025, judgment constitutes a final decision of the CIT that is not in harmony with Commerce's Final Scope Ruling. Thus, this notice is published in fulfillment of the publication requirements of *Timken*.

Amended Final Scope Ruling

In accordance with the CIT's October 20, 2025, final judgment, Commerce is amending its Final Scope Ruling and finds that the scope of the order does not cover the products addressed in the Final Scope Ruling.

Liquidation of Suspended Entries

Commerce will instruct U.S. Customs and Border Protection (CBP) that, pending any appeals, the cash deposit rate will be zero percent for Elysium's composite tile. In the event that the CIT's final judgment is not appealed or is upheld on appeal, Commerce will instruct CBP to liquidate entries of ceramic tile without regard to antidumping and countervailing duties and to lift suspension of liquidation of such entries.

At this time, Commerce remains enjoined by the CIT from liquidating entries not covered by the scope of the *Orders* by the Final Scope Ruling. These entries will remain enjoined pursuant to the terms of the injunction 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: December 18, 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. 2025–23698 Filed 12–22–25; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Inclusions to the Section 232 National Security Adjustments to Automobile Parts Imports

AGENCY: International Trade Administration, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before February 23, 2026.

ADDRESSES: Interested persons are invited to submit written comments to Julien Tuya, International Trade Specialist, Office of Transportation and Machinery, International Trade Administration, by email to AutoInclusions@trade.gov or PRA@trade.gov. Please reference OMB Control Number 0625–0284 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or specific questions related to collection activities should be directed to Julien Tuya, International Trade Specialist, Office of Transportation and Machinery, International Trade Administration, by email to AutoInclusions@trade.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

On March 26, 2025, the President issued Proclamation 10908, "Adjusting Imports of Automobiles and Automobile Parts Into the United States," 90 FR 14705 (April 3, 2025) (Automobile Proclamation), which finds that imports of automobiles and certain automobile parts continue to threaten to impair the national security of the United States and imposes specified tariffs to adjust imports of automobiles and certain automobile parts so that such imports will not threaten to impair national security pursuant to Section 232 of the Trade Expansion Act of 1962 ("Section 232"). Section 232 authorizes the President to adjust the imports of an article and its derivatives that are being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security of the United States so that such imports will not threaten to impair national security. The Automobile Proclamation imposed a 25 percent tariff on certain imports of automobiles, effective April 3, 2025, and certain imports of automobile parts, effective May 3, 2025.

The Automobile Proclamation also required the Secretary of Commerce (Secretary) to establish a process for including additional automobile parts articles within the scope of the tariffs imposed by the President in the Automobile Proclamation. In addition to inclusions made by the Secretary, the process is to provide for including additional automobile parts articles at the request of a domestic producer of an automobile or automobile parts article, or an industry association representing one or more such producers, where the request establishes that imports of

⁶ See *Elysium Tiles, Inc. v. United States*, 762 F. Supp. 3d 1352 (CIT 2025) (*Second Remand Order*).

⁷ See *Second Remand Order* at 2 and 4.

⁸ *Id.* at 12.

⁹ See "Final Results of Redetermination Pursuant to Court Remand," Court No. 23–00041, Slip. Op. 25–25 (CIT March 11, 2025), dated June 6, 2024 (*First Remand Redetermination*), available at: <https://access.trade.gov/public/FinalRemandRedetermination.aspx>.

¹⁰ See *Elysium Tiles, Inc. v. United States*, No. 23–00041, Slip. Op. 25–138, 2025 Ct. Int'l Trade LEXIS 145 (Ct. Int'l Trade October 20, 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*).

additional automobile parts articles have increased in a manner that threatens to impair the national security or otherwise undermines the objectives set forth in Proclamation 9888 (84 FR 23433, May 17, 2019), the Automobile Proclamation, or in any proclamation issued under Section 232 of the Trade Expansion Act of 1962, as amended (Section 232) or any additional information submitted to the President by the Secretary pursuant to those proclamations. When the Secretary receives such a request from a domestic producer or industry association, the Secretary, after consultation with the United States International Trade Commission and U. S. Customs and Border Protection, is to issue a determination regarding whether to include the articles within 60 days of receiving the request.

The automotive industry is in a state of rapid development for various technologies, including in the areas of alternative propulsion systems, autonomous driving capabilities, and other advanced technologies. It is important that manufacturers supporting both the commercial vehicle industry and the defense sector have the opportunity to identify new and emerging automotive products with importance for defense applications to be considered under the scope of this action. In addition, there are many automotive products that fall under broad tariff codes that include parts beyond the automotive sector. While the Department made a best estimate of the most important tariff codes to apply to the scope of the 232 action, industry experts may be aware of broad Harmonized Tariff Schedule (HTS) codes that have become increasingly important to automotive uses that were not originally considered under this investigation.

II. Method of Collection

Domestic producers of automobiles or automobile parts articles, or any industry association representing one or more such producers, may submit automobile parts articles inclusion requests during two-week submission windows that ITA will open four times annually. Submissions of inclusions requests must be submitted in PDF format via email to AutoInclusions@trade.gov. ITA will review the requests received on a rolling basis during the two-week submission window to validate that each request received contain all the required elements and does not exceed the page limitation. In the instance where the requestor does not include all the required elements or otherwise improperly filed the

submission, at the discretion of the Under Secretary for International Trade, the requestor will be granted a 48-hour window to submit a proper filing. The use of fixed submission windows will provide predictability to industry and will be the most efficient use of ITA resources given the short timeframes to secure and process public comments and provide recommendations.

III. Data

OMB Control Number: 0625–0284.

Form Number(s): None.

Type of Review: Regular submission, extension of a current information collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 50.

Estimated Time per Response: 8 hours.

Estimated Total Annual Burden Hours: 400 hours.

Estimated Total Annual Cost to Public: \$30,190.

Respondent's Obligation: Voluntary.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we

cannot guarantee that we will be able to do so.

Sheleen Dumas,

Departmental PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2025–23768 Filed 12–22–25; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–873, C–122–874]

Notice of Extension of the Deadline for Determining the Adequacy of the Antidumping and Countervailing Duty Petitions: Fresh Mushrooms From Canada

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce

DATES: Applicable December 15, 2025.

FOR FURTHER INFORMATION CONTACT: Kelsie Hohenberger or Gene Calvert, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2517 or (202) 492–3586, respectively.

Extension of Initiation of Investigation

The Petitions

On September 16, 2025, the U.S. Department of Commerce (Commerce) received antidumping and countervailing duty petitions on imports of fresh mushrooms from Canada, filed in proper form on behalf of the Fresh Mushrooms Fair Trade Coalition and its individual members (collectively, the petitioners), domestic producers of fresh mushrooms.¹

Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.² Additionally, due to a backlog of documents that were electronically filed via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized

¹ See Petitioners' Letter, "Petitions for the Imposition of Antidumping and Countervailing Duties," dated September 16, 2025 (Petition). The individual members of the Fresh Mushrooms Fair Trade Coalition are Giorgio Fresh Co. (including Donna Bella Farms LLC and Giorgi Mushroom Co.), J–M Farms LLC, Kennett Square Mushroom Operation LLC, Modern Mushroom Farms, Inc., Needham's Mushroom Farms, Inc., and Sher-Rockee Mushroom Farms.

² See Memorandum, "Deadlines Affected by the Shutdown of the Federal Government," dated November 14, 2025.

Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.³

Determination of Industry Support for the Petitions

Sections 702(b)(1) and 732(b)(1) of the Tariff Act of 1930, as amended (the Act), require that a petition be filed by or on behalf of the domestic industry. To determine that the petition has been filed by or on behalf of the industry, sections 702(c)(4)(A) and 732(c)(4)(A) of the Act require that the domestic producers or workers who support the petition account for: (i) at least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, sections 702(c)(4)(D) and 732(c)(4)(D) of the Act provide that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, Commerce shall: (i) poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) if there is a large number of producers, determine industry support using a statistically valid sampling method to poll the industry.

Extension of Time

Sections 702(c)(1)(A) and 732(c)(1)(A) of the Act provide that within 20 days of the filing of an antidumping or countervailing duty petition, Commerce will determine, *inter alia*, whether the petition has been filed by or on behalf of the U.S. industry producing the domestic like product. Sections 702(c)(1)(B) and 732(c)(1)(B) of the Act provide that the deadline for the initiation determination, in exceptional circumstances, may be extended by 20 days in any case in which Commerce must “poll or otherwise determine support for the petition by the industry.” Because it is not clear from the Petitions whether the industry support criteria have been met, Commerce has determined it would be appropriate in these cases to poll the industry and extend the time period for determining whether to initiate the investigations in order to further examine the issue of industry support.

Commerce will need additional time to gather and analyze additional information regarding industry support. Therefore, it is necessary to extend the deadline for determining the adequacy of the Petitions by an additional 20 days. As a result, in accordance with sections 702(c)(1)(B) and 732(c)(1)(B) of the Act, Commerce’s initiation determination will now be due no later than January 2, 2026.

International Trade Commission Notification

Commerce will contact the U.S. International Trade Commission (ITC) and will make this extension notice available to the ITC.

Dated: December 15, 2025.

Scot Fullerton

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2025–23640 Filed 12–22–25; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–979]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People’s Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that the companies to which it granted a separate rate sold subject merchandise at prices below normal value (NV) during the period of review (POR), December 1, 2022, through November 30, 2023. Commerce also determines that certain companies did not ship subject merchandise during the POR. Additionally, Commerce is rescinding this review with respect to one company and denying a separate rate to one company.

DATES: Applicable December 23, 2025.

FOR FURTHER INFORMATION CONTACT: Benjamin Blythe, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3457.

SUPPLEMENTARY INFORMATION:

Background

On April 11, 2025, Commerce published the *Preliminary Results* in the **Federal Register** and invited interested parties to comment on those results.¹ On July 31, 2025, Commerce extended the deadline for issuing the final results of this review by 60 days until October 8, 2025.² Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.³ Additionally, due to a backlog of documents that were electronically filed via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.⁴ Accordingly, the deadline for these final results is now December 15, 2025. For details regarding the events that occurred subsequent to publication of the *Preliminary Results* in the **Federal Register**, see the Issues and Decision Memorandum.⁵ Commerce conducted this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order⁶

The products covered by the *Order* are crystalline silicon photovoltaic cells, and modules, laminates, and panels, consisting of crystalline silicon photovoltaic cells, whether or not partially or fully assembled into other products, including, but not limited to,

¹ See *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People’s Republic of China: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2022–2023*, 90 FR 15439 (April 11, 2025) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

² See Memorandum, “Extension of Deadline for Final Results of Antidumping Duty Administrative Review,” dated July 31, 2025.

³ See Memorandum, “Deadlines Affected by the Shutdown of the Federal Government,” dated November 14, 2025.

⁴ See Memorandum, “Tolling of all Case Deadlines,” dated November 24, 2025.

⁵ See Memorandum, “Issues and Decision Memorandum for the Final Results of the Antidumping Duty Order on Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People’s Republic of China; 2022–2023,” dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

⁶ See *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People’s Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order*, 77 FR 73018 (December 7, 2012) (*Order*).

³ See Memorandum, “Tolling of All Case Deadlines,” dated November 24, 2025.

modules, laminates, panels and building integrated materials. For a complete description of the scope of the *Order*, see the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs that parties submitted in this review are addressed in the Issues and Decision Memorandum. A list of the issues that parties raised, and to which we responded in the Issues and Decision Memorandum, is provided in Appendix I to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Final Determination of No Shipments

In the *Preliminary Results*, Commerce determined that Jinko Solar,⁷ Longi Solar Technology Co. Ltd. (Longi Solar), and Zhejiang Aiko Solar Energy Technology Co., Ltd. (Zhejiang Aiko) did not ship subject merchandise to the United States during the POR. No parties filed timely arguments disputing Commerce's no shipment determination.⁸ In these final results of review, we continue to find that Jinko Solar, Longi Solar, and Zhejiang Aiko did not ship subject merchandise to the United States during the POR.

Rescission of Administrative Review, in Part

In the *Preliminary Results*, Commerce determined that there were no entries of Red Sun Energy Long An Company Limited's (Red Sun) solar cells/modules into the United States during the POR that were suspended and subject to antidumping duties, and thus, consistent with its practice, Commerce stated that it intended to rescind this review with respect to Red Sun. No

parties commented on this preliminary determination. In the absence of any suspended entries of subject merchandise from Red Sun during the POR, Commerce is rescinding this review with respect to Red Sun.

Separate Rates

No parties commented on Commerce's preliminary determination to grant separate rates to certain companies⁹ and to not grant a separate rate to Anji DaSol Solar Energy Science & Technology Co., Ltd. We have made no changes to Commerce's preliminary separate rates determination in these final results of review.

Dumping Margins for Separate Rate Companies

The statute and Commerce's regulations do not address what dumping margin to apply to respondents that are not selected for individual examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the dumping margin for respondents that are not individually examined in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally "equal to the weighted average of the estimated weighted average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* dumping margins, and any dumping margins determined entirely {on the basis of facts available}." Because we calculated a dumping margin that is not zero, *de minimis*, or based entirely on facts available for Sungold, the sole participating mandatory respondent, we assigned the separate rate recipients that we did not individually examine a dumping margin equal to Sungold's dumping margin consistent with Commerce's practice and section 735(c)(5)(A) of the Act. For additional information, see the Issues and Decision Memorandum.

China-Wide Entity

Commerce's policy regarding conditional review of the China-wide entity applies to this administrative

review.¹⁰ Under this policy, the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested that Commerce review the China-wide entity in this segment of the proceeding, the China-wide entity is not under review and its dumping margin (*i.e.*, 238.95 percent¹¹) is not subject to change. Because there were no entries of subject merchandise from the companies listed in Appendix II of this notice during the POR, none of which had a separate rate during the POR, these companies remain in the China-wide entity.¹² In addition, because Commerce did not grant a separate rate to Anji DaSol Solar Energy Science & Technology Co., Ltd., this company is part of the China-wide entity.

Final Results of Review

Commerce determines that the following estimated weighted-average dumping margins exist for the period December 1, 2022, through November 30, 2023:

Exporter	Weighted-average dumping margin (percent)
Shenzhen Sungold Solar Co., Ltd	5.25
Separate Rate Companies:	
BYD H.K. Co., Ltd	5.25
BYD (Shangluo) Industrial Co., Ltd	5.25
Maodi Solar Technology (Dongguan) Co., Ltd	5.25
Trina Solar Energy Development Company Limited	5.25
Trina Solar Science & Technology (Thailand) Ltd	5.25

Disclosure

Pursuant to 19 CFR 351.224(b), Commerce intends to disclose the

¹⁰ See *Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings*, 78 FR 65963 (November 4, 2013).

¹¹ The China-wide entity rate was last changed in the first administrative review of this proceeding and has been the applicable rate for the entity in each subsequent review, including the most recently completed review. See *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2012-2013*, 80 FR 40998, 41002 (July 14, 2015); see also *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Final Results and Final Partial Rescission of Antidumping Duty Administrative Review; and Final Determination of No Shipments; 2021-2022*, 89 FR 55562 (July 5, 2024).

¹² See *Preliminary Results PDM*.

⁷ Jinko Solar refers to the following companies which Commerce has previously treated as a single entity: Jinko Solar Import and Export Co., Ltd.; Jinko Solar Co., Ltd.; JinkoSolar Technology (Haining) Co., Ltd.; Yuhuan Jinko Solar Co., Ltd.; Zhejiang Jinko Solar Co., Ltd.; Jiangsu Jinko Tiansheng Solar Co., Ltd.; JinkoSolar (Chuzhou) Co., Ltd.; JinkoSolar (Yiwu) Co., Ltd.; and JinkoSolar (Shangrao) Co., Ltd.

⁸ On August 27, 2025, Jinko Solar filed untimely arguments regarding its no shipments claim which Commerce rejected. See Commerce's Letter, "Rejection of Letters," dated November 24, 2025; see also Memorandum, "Rejection of Letters," dated November 24, 2025.

⁹ The companies to which Commerce granted a separate rate are: (1) Shenzhen Sungold Solar Co., Ltd. (Sungold); (2) BYD H.K. Co., Ltd.; (3) BYD (Shangluo) Industrial Co., Ltd.; (4) Maodi Solar Technology (Dongguan) Co., Ltd.; (5) Trina Solar Energy Development Company Limited; and (6) Trina Solar Science & Technology (Thailand) Ltd.

calculations that it performed for these final results of review to the parties to this proceeding within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register** in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(1), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise covered by the final results of this review.¹³ Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the publication date of these final results in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

In accordance with 19 CFR 351.212(b)(1), we calculated importer-specific assessment rates for Sungold by dividing the total amount of dumping calculated for all reviewed U.S. sales of subject merchandise entered by an importer by the total entered value of those sales.¹⁴ Where an importer-specific *ad valorem* assessment rate is not zero or *de minimis*, Commerce will instruct CBP to collect the appropriate duties at the time of liquidation. Where an importer-specific *ad valorem* assessment rate is zero or *de minimis*, Commerce will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. Pursuant to a refinement to Commerce's assessment practice, where Sungold did not report a sale of subject merchandise that was entered into the United States during the POR under its company-specific CBP case number, Commerce will instruct CBP to liquidate any entries of such merchandise at the weighted-average dumping margin for the China-wide entity (*i.e.*, 238.95 percent) if there is no rate for the intermediate company(ies) involved in the transaction.¹⁵

¹³ See *Antidumping Proceedings: Calculation of the Weighted Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification*, 77 FR 8101 (February 14, 2012) (*Final Modification*).

¹⁴ We applied the assessment rate calculation method adopted in the *Final Modification*. See *Final Modification*, 77 FR at 8101.

¹⁵ For a full discussion of this practice, see *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

Commerce intends to instruct CBP to assess antidumping duties on all POR entries of subject merchandise exported by the separate rate companies listed in the above table at a rate equal to the estimated dumping margin determined for Sungold.¹⁶

Additionally, Commerce intends to instruct CBP to assess antidumping duties on all subject merchandise entered during the POR under the company-specific CBP case number of Jinko Solar, Longi Solar, or Zhejiang Aiko at the China-wide rate.

Anji DaSol Solar Energy Science & Technology Co., Ltd., and the companies listed in Appendix II of this notice are not eligible for a separate rate and thus are part of the China-wide entity. Commerce intends to instruct CBP to assess antidumping duties on all POR entries of subject merchandise exported by Anji DaSol Solar Energy Science & Technology Co., Ltd., at a rate equal to 238.95 percent (*i.e.*, the China-wide entity rate). Although CBP data on the record does not show any entries of subject merchandise during the POR from the companies listed in Appendix II of this notice, if there are such entries they will be assessed antidumping duties at the China-wide entity rate of 238.95 percent.

Cash Deposit Requirements

The following cash deposit requirements will be in effect for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on, or after, the date of publication of this notice in the **Federal Register**, as provided for by section 751(a)(2)(C) of the Act: (1) for the companies listed in the rate table in the "Final Results of Review" section of this notice above, the cash deposit rate will be equal to the weighted-average dumping margin listed for the company in the table; (2) for previously investigated or reviewed Chinese and non-Chinese companies that are not listed in the rate table above that have separate rates, the cash deposit rate will continue to be the company's existing cash deposit rate; (3) for all China exporters of subject merchandise that do not have a separate rate, the cash deposit rate will be equal to the weighted-average dumping margin assigned to the China-wide entity, which is 238.95 percent, and (4) for all non-China exporters of subject merchandise that do not have a separate rate, the cash deposit rate will be equal to the weighted-average dumping

¹⁶ See *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties*, 76 FR 65694, 65694–95 (October 24, 2011).

margin applicable to the China exporter(s) that supplied that non-China exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties and/or countervailing duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties and/or countervailing duties has occurred, and the subsequent assessment of double antidumping duties, and/or an increase in the amount of antidumping duties by the amount of the countervailing duties.

Administrative Protective Order (APO)

This notice also serves as a final reminder to parties subject to an APO of their responsibility to return or destroy proprietary information disclosed under an APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation subject to sanction.

Notification to Interested Parties

Commerce is issuing and publishing the final results of this administrative review in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: December 15, 2025.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations Enforcement & Compliance

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Changes Since the *Preliminary Results*
- V. Discussion of the Issues
 - Comment 1: Whether Commerce Correctly Applied Adverse Facts Available (AFA) to Sungold
 - Comment 2: Whether Commerce Should Revise the Separate Rate
 - Comment 3: Whether Corrective Instructions Should Be Issued to U.S. Customs and Border Protection (CBP)
 - Comment 4: Whether Liquidation Instructions Should Be Issued Before Pending Litigation is Resolved

VI. Recommendation

Appendix II

Companies That Remain in the China-Wide Entity¹⁷

1. Boviet Solar Technology Co., Ltd.
2. Canadian Solar Manufacturing, Inc.
3. Changzhou Trina PV Ribbon Materials Co., Ltd.
4. Chint Energy (Haining) Co., Ltd.
5. CSI Modules (DaFeng) Co., Ltd.
6. CSI Solar Power Group Co., Ltd. (f.k.a. CSI Solar Power (China) Inc.)
7. De-Tech Trading Limited HK
8. Hengdian Group DMEGC Magnetics Co. Ltd.
9. Hongkong Hello Tech Energy Co., Ltd.
10. Jiawei Solarchina (Shenzhen) Co., Ltd.
11. Jiawei Solarchina Co., Ltd.
12. Jinko Solar (Malaysia) Sdn. Bhd.
13. Jinko Solar International Limited
14. Jinko Solar Technology Sdn. Bhd.
15. Jinkosolar Middle East DMCC
16. Lightway Green New Energy Co., Ltd.
17. Longi (HK) Trading Ltd.
18. Luoyang Suntech Power Co., Ltd.
19. New East Solar Energy Cambodia Co., Ltd.
20. Ningbo ETDZ Holdings, Ltd.
21. Ningbo Qixin Solar Electrical Appliance Co., Ltd.
22. Renesola Jiangsu Ltd.
23. ReneSola Zhejiang Ltd.
24. Risen Solar Technology Sdn. Bhd.
25. Shanghai Nimble Co., Ltd.
26. Sumec Hardware & Tools Co., Ltd.
27. Suntech Power Co., Ltd.
28. Taizhou BD Trade Co., Ltd.
29. tenKsolar (Shanghai) Co., Ltd.
30. Trina Solar Energy Development PTE Ltd.
31. Vina Cell Technology Company Limited

32. Vina Solar Technology Company Limited
33. Wuxi Suntech Power Co., Ltd.
34. Yingli Green Energy International Trading Company Limited

[FR Doc. 2025–23765 Filed 12–22–25; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF375]

Magnuson-Stevens Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permits

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

ACTION: Notice; request for comments.

SUMMARY: The Assistant Regional Administrator for Sustainable Fisheries, Greater Atlantic Regional Fisheries Office (GARFO), NMFS, has made a preliminary determination that an Exempted Fishing Permit (EFP) application contains all of the required information and warrants further consideration. The EFP would allow federally permitted fishing vessels to fish outside fishery regulations in support of exempted fishing activities proposed by the Cape Cod Commercial

Fishermen's Alliance. Regulations under the Magnuson-Stevens Fishery Conservation and Management Act require publication of this notification to provide interested parties the opportunity to comment on applications for proposed EFPs.

DATES: Comments must be received on or before January 7, 2026.

ADDRESSES: You may submit written comments by email: nmfs.gar.efp@noaa.gov. Include in the subject line “CCCFA SCOQ EFP.” All comments received are a part of the public record and may be posted for public viewing without change. All personal identifying information (e.g., name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter “anonymous” as the signature if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Christine Ford, Fishery Management Specialist, christine.ford@noaa.gov, 978–281–9185.

SUPPLEMENTARY INFORMATION: The applicant submitted a complete application for an EFP to conduct commercial fishing activities that the regulations would otherwise restrict. This EFP would exempt the participating vessels from the following Federal regulations:

TABLE 1—REQUESTED EXEMPTIONS

CFR citation	Regulation	Need for exemption
50 CFR 648.14(j)(2)(iii)	Prohibition against offloading unshucked surfclams or ocean quahogs from vessels not capable of carrying cages.	Participating vessels are not capable of carrying cages and ports do not have the infrastructure to safely offload into cages.
50 CFR 648.14(j)(3)(vi)	Prohibition against landing or possessing, after offloading, any cage holding surfclams or ocean quahogs without a cage tag required by § 648.77.	Participating vessels will use alternate/smaller sized containers and alternate tags and will not be tagging as required in § 648.77.
50 CFR 648.77(a)	Cage tag requirements	The tags will not be in increments of 60 ft ³ (32 bushels); the landing containers will be tagged in 16-bushel increments.

TABLE 2—PROJECT SUMMARY

Project title	Use of alternative cage sizes and tag protocols to support a high-quality, niche market for Atlantic surfclam and Ocean Quahog harvested by day-boat vessels on Cape Cod.
Project start	Upon Issuance.
Project end	12/31/2026.
Project objectives	To test the viability of alternate landing containers for smaller vessels; to tag and quantify surfclams and ocean quahogs with a cage tag equivalent; and to evaluate alternative landing procedures to improve the quality and value of surfclams landed with smaller vessels and smaller containers.
Project location	Federal waters around Cape Cod, to include Statistical Areas 521, 514, 526, 537, and 538.
Number of vessels	3.
Number of trips	Up to 105.
Trip duration (days)	1.

¹⁷ This list of companies in the China-Wide Entity is different from the *Preliminary Results* at Appendix III. For the Final Results, we have removed CSI Solar Co., Ltd. (f.k.a. CSI Solar Power

(China) Inc.) and CSI Solar Manufacturing (Fu Ning) Co., Ltd. (f.k.a. CSI–GCL Solar Manufacturing (YanCheng) Co., Ltd.) from the China-Wide Entity list given that Commerce rescinded this review for

these companies in the *Preliminary Results* at Appendix II. See *Preliminary Results*, 90 FR at 15443.

TABLE 2—PROJECT SUMMARY—Continued

Total number of days	Up to 105.
Gear type(s)	Dredge.
Number of tows or sets	35 per trip.
Duration of tows or sets	15–30 minutes.

Project Narrative

This project builds on initial work completed approximately a decade ago from 2014 through 2015, as well as work from a partial season in 2025, and reflects renewed interest in surfclams and ocean quahogs by the Cape Cod small boat fleet and by a new, local dealer/processor that normally buys from state waters surfclam boats and accepts smaller increments. The previous test from 10 years ago using alternative containers and tags showed promise, but buyers at the time would not accept non-standard cages, limiting the market viability of the alternative cages. Between July 11, 2025, and September 30, 2025, 11 trips were taken under the 2025 EFP. Over 2,500 bushels of surfclams were landed, with no safety incidents. Participants were able to sell almost half the catch to live and specialty markets, at a higher price point, as the percentage of broken clams dropped from 30 to 9 percent. This EFP would collect data to support a future regulatory request to permanently allow small boats to land surfclams and ocean quahogs in smaller increments.

This EFP would authorize three vessels to continue to develop the viability of a day-boat Atlantic surfclam and ocean quahog fishery for small vessels based out of Cape Cod by testing alternatives to the large industry-standard cages and 32-bushel (1.7 m³) cage tags. The traditional cages do not fit on smaller day boats and, as a result, vessels not capable of carrying a cage onboard must offload directly into cages. This can be burdensome and dangerous and the extra handling and compression of clams in the cages can lead to damaged product and lower market value. Many ports do not have the infrastructure to safely offload into cages and the local dealer dedicated to buying the catch is not capable of handling 32-bushel cages. All participating vessels would have open access permits and receive tags from one of the participants with allocation.

The participating vessels would use two alternative landing containers: a standard-size fish vat (internal measurements: 44 inch x 39 inch x 27 inch; 1.12 meter (m) x 0.99 m x 0.69 m) capable of holding 16 bushels (0.85 m³); and a standard-size stackable fish tote (internal measurements: 25 inch x 15.8

inch x 10.2 inch; 0.64 m x 0.40 m x 0.26 m) capable of holding 1.5 bushels (0.08 m³). One alternative denomination of a 16-bushel tag would be used, either on a fish vat or on a pallet of 10 1.5-bushel totes wrapped in plastic wrap. The participants acknowledge the loss of 1 bushel (0.05 m³) worth of catch for each pallet tagged. The vats would be constrained to weigh no more than 1,424 pounds (0.65 metric tons (mt)). The totes on a pallet would also be constrained to weigh no more than 1,424 pounds (but likely to only weigh 1,335 pounds (0.61 mt)). Weight samples would be taken by the dealer to verify weights to further develop the experimental containers. The applicant would work with NMFS and the National Band and Tag Company to convert standard cage tags into the alternative tag denomination. Up to 500 32-bushel ocean quahog tags and up to 270 32-bushel surf clam tags would be converted to 16-bushel tags.

Participating fishermen would complete a data sheet for each EFP trip to provide information on price per bushel and weight for each landing increment. Landings data would be verified with collection of dealer reports for each EFP trip. The proportion of breakages vs. live would be tested through collection of processor data detailing surfclam quality and condition. Annual surveys to measure impact and determine progress against the measures of success will be completed and the effects of using modified landing containers and alternative tags will be analyzed to determine what, if any, benefits the EFP protocol provides to economic viability and safety of small boat surfclam/ocean quahog fishing businesses.

If approved, the applicant may request minor modifications and extensions to the EFP throughout the year. EFP modifications and extensions may be granted without further notice if they are deemed essential to facilitate completion of the proposed research and have minimal impacts that do not change the scope or impact of the initially approved EFP request. Any fishing activity conducted outside the scope of the exempted fishing activity would be prohibited.

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

Dated: December 19, 2025.
Kelly Denit,
Director, Office of Sustainable Fisheries,
National Marine Fisheries Service.
[FR Doc. 2025–23757 Filed 12–22–25; 8:45 am]
BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket Nos.: NOAA–NOS–2025–0702;
NOAA–NOS–2025–1330]
RIN 0648–XA003

Deep Seabed Mining: Notice of Receipt of Applications for Deep Seabed Mining Exploration Licenses and Announcement of Public Comment Period and Virtual Public Hearings

AGENCY: Office for Coastal Management, National Ocean Service, National Oceanic Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Notice of receipt of applications for deep seabed mining exploration licenses; request for comments; notice of virtual public hearing.

SUMMARY: Pursuant to the Deep Seabed Hard Mineral Resources Act (DSHMRA or the Act), notice is hereby given that NOAA received, on July 27, 2025, an amended application from The Metals Company USA, LLC (TMC USA) for a license to conduct seabed mining exploration activities within the seabed area beyond national jurisdiction generally known as the Clarion-Clipperton Zone (TMC USA Application A). NOAA received a second amended application from TMC USA on July 28, 2025 (TMC USA Application B). NOAA has determined that these applications are fully compliant with the applicable information requirements of DSHMRA and the Act’s implementing regulations. Subject to applicable public disclosure limitations, interested persons are afforded the opportunity to examine the materials relevant to these applications and may submit written comments to NOAA electronically via the instructions below. These applications are electronically available at the locations listed below under **ADDRESSES**. Please note that the statements made in the TMC USA applications do not necessarily reflect the views of NOAA

or the views of the U.S. Government. As part of the application review process, NOAA will also hold two virtual public hearings to receive oral public comments on these applications.

DATES: Comments on the applications must be received by February 23, 2026. The virtual public hearings are scheduled for January 27, 2026, and January 28, 2026, from 3 p.m. to 7 p.m. Eastern Time each day. Instructions for attending the virtual public hearings are provided below.

ADDRESSES: The TMC USA Application A is electronically available at <https://www.regulations.gov/docket/NOAA-NOS-2025-0702>; The TMC USA Application B is electronically available at <https://www.regulations.gov/docket/NOAA-NOS-2025-1330>.

You may send comments, identified by docket number, by either of the following means:

Written Comments

Comments must be submitted by the date and electronic method described below to ensure that the comments are received, documented, and considered by NOAA. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. Comments that are not related to the applications or that contain profanity, vulgarity, threats, or other inappropriate language will not be considered. To ensure full consideration by NOAA, comments must be submitted in English. Comments that are not submitted in English may not be posted to the public dockets on regulations.gov, or considered by NOAA. All relevant comments received are a part of the public record and will generally be posted for public viewing on www.regulations.gov without change. All personal identifying information (e.g., name, address) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information. NOAA will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous).

- For TMC USA Application A, submit all public written comments via the Federal [regulations.gov](https://www.regulations.gov) e-Portal at <https://www.regulations.gov/docket/NOAA-NOS-2025-0702> or go to www.regulations.gov and enter "NOAA-NOS-2025-0702" in the search bar.

- For TMC USA Application B, submit all public written comments via the Federal [regulations.gov](https://www.regulations.gov) e-Portal at <https://www.regulations.gov/docket/NOAA-NOS-2025-1330> or go to www.regulations.gov and enter "NOAA-NOS-2025-1330" in the search bar.

For each docket, locate the document you wish to comment on from the resulting list and click on the "Submit a comment" icon on the right of that line. Please note that comments will only be considered for the docket to which they are submitted. If your comment is in response to both TMC USA Application A and TMC USA Application B, you must submit two comments, one to each docket.

Oral Comments

You may submit oral comments for either or both applications (TMC USA Application A and/or TMC USA Application B) at either virtual public hearing. At the virtual public hearings, you will be asked to specify whether your comment is in reference to TMC USA Application A, TMC USA Application B, or both.

NOAA will conduct the virtual public hearings via Adobe Connect. Each person who wants to attend either virtual public hearing must electronically register by January 21, 2026, 5 p.m. Eastern Time. Attendance at each virtual public hearing will be limited to 1,000 individuals for each of the two dates; therefore, NOAA requests that individuals register and attend only one hearing, on either January 27 or January 28, 2026. To register for either hearing, use the following link: https://noaabroadcast.adobeconnect.com/evxcqr87egzq/event/event_info.html.

Any person who registers and wants to speak at a virtual public hearing should indicate that they want to speak during registration. Each registered participant will receive an Adobe Connect link for the virtual public hearing. Once the virtual public hearing starts, NOAA will describe the virtual public hearing logistics. NOAA will then start the public comment part of the virtual public hearing and will call on speakers on a first come/first served basis through the raised hand function of Adobe Connect. NOAA will then unmute the person speaking. Each speaker will have three minutes to speak on either or both applications (TMC USA Application A and/or TMC USA Application B). If a speaker does not respond when they are called on, NOAA will move to the next speaker. At the three-minute mark for each speaker, NOAA will mute that speaker. Speakers cannot allot their time to another speaker. Once all speakers have spoken, or at the scheduled end of the virtual public hearing, whichever is earlier, NOAA will end the virtual public hearing. NOAA retains discretion to

extend the virtual public hearing if appropriate and feasible. NOAA will record each hearing and will include transcripts of the hearings on the public dockets for each of the TMC USA Applications on the regulations.gov website at <https://www.regulations.gov/docket/NOAA-NOS-2025-0702> for TMC USA Application A and at <https://www.regulations.gov/docket/NOAA-NOS-2025-1330> for TMC USA Application B. The names provided by each speaker will also be published as part of the transcripts.

The virtual public hearings do not replace the process for submission of written comments. NOAA will not respond during the hearings to oral comments or questions. To ensure full consideration by NOAA, oral comments must be in English. Comments that are not in English may not be transcribed or considered by NOAA.

FOR FURTHER INFORMATION CONTACT:

Kerry Kehoe, (240) 560-8518, kerry.kehoe@noaa.gov.

Authority: 30 U.S.C. 1426(a)(1).

Neil A. Jacobs,

*Under Secretary of Commerce for Oceans and Atmosphere and NOAA Administrator
National Oceanic and Atmospheric Administration.*

[FR Doc. 2025-23795 Filed 12-19-25; 4:15 pm]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XF214]

Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Notice; availability of a proposed evaluation and pending determination for public comment.

SUMMARY: Notice is hereby given that NMFS has received a Hatchery and Genetics Management Plan (HGMP) for seven hatchery programs rearing and releasing fall Chinook salmon, spring Chinook salmon, fall chum salmon, sockeye salmon, coho salmon and steelhead in the Skokomish River basin. The plan describes a hatchery program operated by Washington Department of Fish and Wildlife (WDFW) in collaboration with the Skokomish Indian Tribe and Tacoma Power Utility as co-managers. This document serves to notify the public of the availability

and opportunity to comment on a Proposed Evaluation and Pending Determination Documents (PEPD) on implementing the proposed hatchery program and enforcing the associated HGMP, which concludes that it will not appreciably reduce the likelihood of survival and recovery nor modify or destroy critical habitat of Hood Canal-Strait of Juan de Fuca summer chum salmon, Puget Sound Chinook salmon, or Puget Sound steelhead.

DATES: Comments must be received no later than 5 p.m. Pacific time on January 22, 2026. Comments received after this date may not be considered.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2025–0736, by the following method:

- **Electronic Submission:** Submit all electronic public comments via the Federal e-Rulemaking Portal. Visit <https://www.regulations.gov> and type NOAA–NMFS–2025–0736 in the Search box. Click on the “Comment” icon, complete the required fields, and enter or attach your comments.
- The HGMP is available online concurrently while the comment period for the PEPD is open at: <https://wdfw.wa.gov/fishing/management/hatcheries/hgmp#comment>.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on <https://www.regulations.gov> without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter “N/A” in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Chante Davis at (503) 321–2307; or by email at chante.davis@noaa.gov.

SUPPLEMENTARY INFORMATION:

Endangered Species Act (ESA)-Listed Species Covered in This Notice

- Hood Canal-Strait of Juan de Fuca summer chum salmon (*Oncorhynchus keta*): threatened, naturally and artificially propagated;
- Puget Sound Chinook salmon (*Oncorhynchus tshawytscha*): threatened, naturally and artificially propagated; and
- Puget Sound Steelhead (*Oncorhynchus mykiss*): threatened, naturally and artificially propagated.

Background

The term “take” is defined under the ESA to mean harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. The ESA prohibits the take of endangered salmonids and, pursuant to ESA section 4(d), ESA regulations can be extended to prohibit the take of threatened salmonids. However, NMFS may make exceptions to the take prohibitions for hatchery programs that are approved by NMFS under the limits on the prohibitions outlined in 50 CFR 223.203(b). The operators, WDFW collaborating with tribal co-manager Jamestown S’Klallam Tribe, have submitted an HGMP to NMFS pursuant to NMFS’ Limit 6 of the 4(d) Rule of the ESA for hatchery activities in the Skokomish River basin, Washington. The PEPD is NMFS’ initial determination for how the HGMP addresses the criteria in 50 CFR 223.203(b)(5).

The hatchery program under review is designed to contribute to the reintroduction and recovery of Chinook salmon, sockeye salmon and steelhead in the Skokomish River basin. These fish contribute to the stability of Pacific salmon fish stocks in order to maintain sustainable U.S. fisheries and strengthen the national seafood supply chain. The hatchery programs are intended to contribute to fulfilling federal trust responsibilities toward Tribes with rights guaranteed through treaties, as affirmed in *United States v. Washington* (1974), by contributing to the recovery of ESA-listed salmon. Additionally, the programs are intended to contribute to the survival and recovery of Puget Sound Chinook Salmon and Puget Sound Steelhead, provide information on exploitation rates, and support returns of coho salmon, Chinook salmon, and sockeye salmon to the Skokomish River basin.

Classification

Under section 4 of the ESA, the Secretary of Commerce is required to adopt such regulations as deemed necessary and advisable for the conservation of species listed as threatened. The ESA salmon and steelhead 4(d) Rule (50 CFR 223.203(b)) specifies categories of activities that contribute to the conservation of listed salmonids and sets out the criteria for such activities. The rule further provides that the prohibitions of paragraph (a) of the rule do not apply to actions undertaken in compliance with a plan developed jointly by a state and a tribe and determined by NMFS to be in accordance with the salmon and

steelhead 4(d) Rule (65 FR 42422, July 10, 2000).

Authority: 16 U.S.C. 1531 *et seq.*; 16 U.S.C. 742a *et seq.*

Dated: December 18, 2025.

Jennifer Leigh Quan,

Regional Administrator, West Coast Region, National Marine Fisheries Service.

[FR Doc. 2025–23684 Filed 12–22–25; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Alaska Community Quota Entity (CQE) Program

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public’s reporting burden. Public comments were previously requested via the **Federal Register** on July 15, 2025 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic and Atmospheric Administration, Commerce.

Title: Alaska Community Quota (CQE) Program.

OMB Control Number: 0648–0665.

Form Number(s): None.

Type of Request: Regular submission [revision and extension of a current information collection].

Number of Respondents: 62.

Average Hours per Response:

Application for a Non-profit Corporation to be Designated as a CQE: 200 hours; Transfer applications: 2 hours; Application for a CQE to Receive a Non-trawl Groundfish LLP License: 20 hours; Application for Community Charter Halibut Permit: 1 hour; CQE Annual Report: 40 hours; CQE LLP Authorization Letter: 1 hour.

Total Annual Burden Hours: 1,355 hours.

Needs and Uses: This is a request for revision and extension of an approved information collection. The National

Marine Fisheries Service (NMFS), Alaska Regional Office (AKR), is the sponsor of this information collection. This information collection contains applications, permits, and reports required under the Community Quota Entity (CQE) Program. The revision to this collection incorporates minor updates for clarity and regulatory accuracy. These changes to the forms include updating the Public Reporting Burden Statement to include the form's specific purpose and updating website links. Additionally, the "Application for Transfer of Quota Share to or from a Community Quota Entity" form was updated to include the correct the language from "The party to whom a CQE is seeking to transfer the IFQ must hold a Transfer Eligibility Certificate (TEC) unless they are a resident of the Aleutian Islands (Adak) for at least 12 months" to "The party to whom a CQE is seeking to transfer the IFQ must hold a Transfer Eligibility Certificate (TEC) unless they hold an Aleutian Islands (Adak) TEC." This change accurately reflects current regulations and requirements. No other changes were made to the collection other than adjustments to reflect the most current available data.

NMFS AKR manages the groundfish fisheries in the exclusive economic zone of the Bering Sea and Aleutian Islands management area under the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area. The Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*) authorizes the North Pacific Fishery Management Council to prepare and amend fishery management plans for any fishery in waters under its jurisdiction. The International Pacific Halibut Commission (IPHC) and NMFS AKR manage fishing for Pacific halibut (*Hippoglossus stenolepis*) through regulations established under the authority of the Northern Pacific Halibut Act of 1982, 16 U.S.C. 773c (Halibut Act).

The CQE Program is a Federal program administered by NMFS. The CQE Program allocates to eligible communities in Alaska a portion of the harvest quotas for groundfish, halibut, crab, and prohibited species. The allocations provide these communities the means for starting or supporting commercial fisheries activities that will result in an ongoing, regionally based, fisheries-related economy. Participating communities are represented by a CQE, which is a NMFS-approved non-profit organization.

Under the Pacific Halibut and Sablefish Individual Fishing Quota

(IFQ) Program, a CQE may purchase commercial Halibut and sablefish quota share (QS) for lease to residents of the eligible community. Under the Charter Halibut Limited Access Program, a CQE may request community charter halibut permits for use in southeast Alaska and the central Gulf of Alaska by charter vessel operators designated by the CQE. Under the License Limitation Program (LLP), a CQE may request non-trawl groundfish LLP licenses endorsed for Pacific cod in the central or western Gulf of Alaska for use on vessels designated by the CQE. More information on the CQEs and the CQE Program is provided on the NMFS Alaska Region website at <https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/community-quota-and-license-programs-community-quota-entities>.

This information collection is required in Federal regulations at 50 CFR 300 Subpart E and Part 679. The eligible communities and the community governing body that recommends the CQE are listed in Table 21 to 50 CFR part 679.

This collection contains applications used by a nonprofit corporation to become a CQE; by CQEs to receive non-trawl groundfish LLP licenses and Charter Halibut Permits (CHPs); by CQEs to transfer or receive IFQ QS; by CQEs to transfer IFQ to an eligible community resident or non-resident; and by CQEs to transfer between commercial halibut IFQ and halibut guided angler fish (GAF). In addition, this collection contains two reporting requirements: an annual report and an authorization letter. Annually each CQE must submit a report describing its business operations and fishing activities for each eligible community it represents. CQEs requesting LLP groundfish licenses must annually submit an authorization letter that assigns each community LLP license to a user and vessel.

The type of information collected includes information on the applicants, transferors, transferees, authorized representatives, and communities represented, as well as information on the procedures, criteria, administrative activities, business operations, community fishing activities, sweep-up information, certificate and licensing information, and fishing activities pertaining to the application.

NMFS requires this information for fisheries management and to evaluate the ability of a specific CQE to represent an eligible community. NMFS uses the information collected to establish eligibility of the CQEs; review each CQE's business operations and fishing

activity; monitor participation of the eligible communities in the CQE Program and associated limited access programs; and gather information on distribution and use among these communities of LLP groundfish licenses, CHPs, and halibut and sablefish QS and IFQ.

All of the forms, except for the Application for Community Charter Halibut Permit at § 300.67(k), can now be submitted electronically via email. These forms will be updated accordingly to clarify that electronic submission is allowed.

Affected Public: Not-for-profit institutions; Individuals or households.

Frequency: Annually and occasionally.

Respondent's Obligation: Required to Obtain or Retain Benefits.

Legal Authority: Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*); The Northern Pacific Halibut Act of 1982 (16 U.S.C. 773c).

This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0665.

Sheleen Dumas,

Department PRA Compliance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2025–23767 Filed 12–22–25; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF389]

Atlantic Highly Migratory Species; Schedules for Atlantic Shark Identification Workshops and Protected Species Safe Handling, Release, and Identification Workshops

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

ACTION: Notice of public workshops.

SUMMARY: Free Atlantic Shark Identification Workshops and Safe Handling, Release, and Identification Workshops will be held in January, February, and March of 2026. Certain fishermen and shark dealers are required to attend a workshop to meet regulatory requirements and to maintain valid permits. Specifically, the Atlantic Shark Identification Workshop is mandatory for all federally permitted Atlantic shark dealers. The Safe Handling, Release, and Identification Workshop is mandatory for vessel owners and operators who use bottom longline, pelagic longline, or gillnet gear, and who have also been issued shark or swordfish limited access permits. Additional free workshops will be conducted in 2026 and will be announced in a future notice. In addition, NMFS has implemented online recertification workshops for persons who have already taken an in-person training.

DATES: The Atlantic Shark Identification Workshops will be held on January 15, 2026, February 19, 2026, and March 5, 2026. The Safe Handling, Release, and Identification Workshops will be held on January 8, 2026, February 11, 2026, and March 17, 2026.

ADDRESSES: The Atlantic Shark Identification Workshops will be held in Virginia Beach, VA, Melville, NY, and Wilmington, NC. The Safe Handling, Release, and Identification Workshops will be held in Portsmouth, NH, Marathon, FL, and Houston, TX.

FOR FURTHER INFORMATION CONTACT: Anna Quintrell by email at anna.quintrell@noaa.gov or by phone at 301-427-8503.

SUPPLEMENTARY INFORMATION: Atlantic highly migratory species (HMS) fisheries (swordfish, sharks, tunas, and billfish) are managed under the 2006 Consolidated HMS Fishery Management Plan (FMP) and its amendments pursuant to the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) and consistent with the Atlantic Tunas Convention Act (16 U.S.C. 971 *et seq.*). HMS implementing regulations are at 50 CFR part 635. Section 635.8 describes the requirements for the Atlantic Shark Identification Workshops and Safe Handling, Release, and Identification Workshops. The workshop schedules, registration information, and a list of frequently asked questions regarding the Atlantic Shark Identification and Safe Handling, Release, and Identification workshops

are available online at: <https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/atlantic-shark-identification-workshops> and <https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/safe-handling-release-and-identification-workshops>.

Atlantic Shark Identification Workshops

Since January 1, 2008, Atlantic shark dealers have been prohibited from receiving, purchasing, trading, or bartering for Atlantic sharks unless a valid Atlantic Shark Identification Workshop certificate is on the premises of each business listed under the shark dealer permit that first receives Atlantic sharks (71 FR 58057, October 2, 2006). Dealers who attend and successfully complete a workshop are issued a certificate for each place of business that is permitted to receive sharks. These certificate(s) are valid for 3 years. Thus, certificates that were initially issued in 2023 will expire in 2026.

Currently, permitted dealers may send a proxy to an Atlantic Shark Identification Workshop. However, if a dealer opts to send a proxy, the dealer must designate a proxy for each place of business covered by the dealer's permit that first receives Atlantic sharks. Only one certificate will be issued to each proxy. A proxy must be a person who is currently employed by a place of business covered by the dealer's permit; is a primary participant in the identification, weighing, and/or first receipt of fish as they are offloaded from a vessel; and who fills out dealer reports. Atlantic shark dealers are prohibited from renewing a Federal shark dealer permit unless a valid Atlantic Shark Identification Workshop certificate for each business location that first receives Atlantic sharks has been submitted with the permit renewal application. Additionally, a copy of a valid dealer or proxy Atlantic Shark Identification Workshop certificate must be in any trucks or other conveyances that are extensions of a dealer's place of business.

Workshop Dates, Times, and Locations

1. January 15, 2026, 12 p.m.–4 p.m., The Founders Inn, 5641 Indian River Road, Virginia Beach, VA 23464.

2. February 19, 2026, 12 p.m.–4 p.m., Hilton Long Island, 598 Broad Hollow Road, Melville, NY 11747.

3. March 5, 2026, 12 p.m.–4 p.m., Hilton Garden Inn Wilmington Mayfaire Town Center, 6745 Rock Spring Road, Wilmington, NC 28405.

Registration

To register for a scheduled Atlantic Shark Identification Workshop, please contact Angler Conservation Education at 386-682-0158. Pre-registration is highly recommended, but not required.

Registration Materials

To ensure that workshop certificates are linked to the correct permits, participants will need to bring the following specific items to the workshop:

1. Atlantic shark dealer permit holders must bring proof that the attendee is an owner or agent of the business (such as articles of incorporation), a copy of the applicable permit, and proof of identification.
2. Atlantic shark dealer proxies must bring documentation from the permitted dealer acknowledging that the proxy is attending the workshop on behalf of the permitted Atlantic shark dealer for a specific business location, a copy of the appropriate valid permit, and proof of identification.

Workshop Objectives

The Atlantic Shark Identification Workshops are designed to reduce the number of unknown and improperly identified sharks reported in the dealer reporting form and increase the accuracy of species-specific dealer-reported information. Reducing the number of unknown and improperly identified sharks will improve quota monitoring and the data used in stock assessments. These workshops will train shark dealer permit holders or their proxies to properly identify Atlantic shark carcasses.

Safe Handling, Release, and Identification Workshops

Since January 1, 2007, shark limited access and swordfish limited access permit holders who fish with longline or gillnet gear have been required to submit a copy of their Safe Handling, Release, and Identification Workshop certificate in order to renew either permit (71 FR 58057, October 2, 2006). These certificate(s) are valid for 3 years. Certificates issued in 2023 will expire in 2026. As such, vessel owners who have not already attended a workshop and received a NMFS certificate, or vessel owners whose certificate(s) will expire prior to the next permit renewal, must attend a workshop to fish with, or renew, their swordfish and shark limited access permits. Additionally, new shark and swordfish limited access permit applicants who intend to fish with longline or gillnet gear must attend a Safe Handling, Release, and Identification Workshop and submit a

copy of their workshop certificate before either of the permits will be issued.

In addition to vessel owners, at least one operator on board vessels issued a limited access swordfish or shark permit that uses longline or gillnet gear is required to attend a Safe Handling, Release, and Identification Workshop and receive a certificate. Vessels that have been issued a limited access swordfish or shark permit and that use longline or gillnet gear may not fish unless both the vessel owner and operator have valid workshop certificates on board at all times. Vessel operators who have not already attended a workshop and received a NMFS certificate, or vessel operators whose certificate(s) will expire prior to their next fishing trip, must attend a workshop to operate a vessel with swordfish and shark limited access permits on which longline or gillnet gear is used.

Workshop Dates, Times, and Locations

1. January 8, 2026, 9 a.m.–1 p.m., Residence Inn by Marriott Downtown Portsmouth, 100 Deer Street, Portsmouth, NH 03801.

2. February 11, 2026, 9 a.m.–1 p.m., Faro Blanco, 1996 Overseas Highway, Marathon, FL 33050.

3. March 17, 2026, 9 a.m.–1 p.m., Holiday Inn Express Houston Medical Center, 9300 S Main Street, Houston, TX 77025.

Registration

To register for a scheduled Safe Handling, Release, and Identification Workshop, please contact Angler Conservation Education at 386–682–0158. Pre-registration is highly recommended, but not required.

Registration Materials

To ensure that workshop certificates are linked to the correct permits, participants will need to bring the following specific items with them to the workshop:

1. Individual vessel owners must bring a copy of the appropriate swordfish and/or shark permit(s), a copy of the vessel registration or documentation, and proof of identification.

2. Representatives of a business-owned or co-owned vessel must bring proof that the individual is an agent of the business (such as articles of incorporation), a copy of the applicable swordfish and/or shark permit(s), and proof of identification.

3. Vessel operators must bring proof of identification.

Workshop Objectives

The Safe Handling, Release, and Identification Workshops are designed to teach the owner and operator of a vessel that fishes with longline or gillnet gear the required techniques for the safe handling and release of entangled and/or hooked protected species, such as sea turtles, marine mammals, smalltooth sawfish, Atlantic sturgeon, and prohibited sharks. In an effort to improve reporting, the proper identification of protected species and prohibited sharks will also be taught at these workshops. Additionally, individuals attending these workshops will gain a better understanding of the requirements for participating in these fisheries. The overall goal of these workshops is to provide participants with the skills needed to reduce the mortality of protected species and prohibited sharks, which may prevent additional regulations on these fisheries in the future.

Online Recertification Workshops

NMFS implemented an online option for shark dealers and owners and operators of vessels that fish with longline and gillnet gear to renew their certificates in December 2021. To be eligible for online recertification workshops, dealers and vessel owners and operators need to have previously attended an in-person workshop. Information about the courses is available online at <https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/atlantic-shark-identification-workshops> and <https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/safe-handling-release-and-identification-workshops>. To access the course please visit: <https://hmsworkshop.fisheries.noaa.gov/start>. Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 19, 2025.

Kelly Denit,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2025–23748 Filed 12–22–25; 8:45 am]

BILLING CODE 3510–22–P

CONSUMER FINANCIAL PROTECTION BUREAU

Truth in Lending (Regulation Z); Non-application to Earned Wage Access Products

AGENCY: Consumer Financial Protection Bureau.

ACTION: Advisory opinion.

SUMMARY: The Consumer Financial Protection Bureau (CFPB) is issuing this

advisory opinion to resolve regulatory uncertainty regarding: (1) the applicability of the definition of credit under Regulation Z, which implements the Truth in Lending Act (TILA), to earned wage access (EWA) products that conform to the description of “Covered EWA” provided in part I.C.2 of this advisory opinion; and (2) the applicability of the definition of finance charge under Regulation Z to certain EWA-related charges (expedited delivery fees, tips) to the extent any EWA products meet the Regulation Z definition of credit. The CFPB is also withdrawing a proposed interpretive rule.

DATES: This advisory opinion is effective on December 23, 2025.

FOR FURTHER INFORMATION CONTACT: Dave Gettler, Paralegal Specialist, Office of Regulations, at 202–435–7700. If you require this document in an alternative electronic format, please contact CFPB_Accessibility@cfpb.gov.

SUPPLEMENTARY INFORMATION: The CFPB is issuing this advisory opinion pursuant to its Advisory Opinions Policy.¹

I. Advisory Opinion

A. Market Background

According to the Bureau of Labor Statistics, nearly three-quarters of U.S. private businesses use biweekly, semimonthly, or monthly pay periods.² Several obstacles continue to prevent businesses from readily implementing shorter pay cycles.³ Starting a little over a decade ago, earned wage access (EWA) has emerged as an innovative way for workers to meet short-term liquidity needs that arise between paychecks without turning to potentially more costly alternatives. EWA seeks to address the lag between consumers’ hours worked and receipt of their

¹ 85 FR 77987 (Dec. 3, 2020).

² See Bureau of Labor Statistics, *Length of Pay Periods in the Current Employment Statistics Survey* (last modified Aug. 4, 2023), <https://www.bls.gov/ces/publications/length-pay-period.htm>.

³ This includes, for example, additional costs in both time and money to run payroll more frequently, cash flow limitations, and inertia. See, e.g., Marshall Lux & Cherie Chung, *Earned Wage Access: An Innovation in Financial Inclusion?*, M-RCBG Associate Working Paper Series 2023.214, Harvard University (June 2023), <https://dash.harvard.edu/server/api/core/bitstreams/5cb75832-883a-4d51-9b0e-d959da124354/content>; Mike Kappel, *How Often Should You Run Payroll?* (Weekly, Biweekly, Etc.), Forbes (Apr. 1, 2025), <https://www.forbes.com/sites/mikekappel/2025/04/01/how-often-should-you-run-payroll-weekly-biweekly-etc/>. The CFPB has noted that periodic wage payment may be driven “by efficiency concerns with payroll processing and employers’ cash management.” 82 FR 54472, 54547 (Nov. 17, 2017).

paychecks by facilitating advance access to earned but as yet unpaid wages.

Two main types of EWA exist in the market today. Providers of “employer-partnered” (EP) EWA contract with employers to offer their workers access to amounts not exceeding accrued wages, with the provider generally utilizing the payroll process to deduct accessed amounts at the next payroll event.⁴ EP providers have evolved a variety of methods for making payroll process deductions.⁵ In addition, EP providers generally claim no rights against the worker in the event that the next paycheck is insufficient to support the deduction. “Direct-to-consumer” (D2C) EWA providers offer access to amounts that they estimate to be below accrued wages, with the provider then generally debiting accessed amounts via automated withdrawal from the worker’s regular transaction account that receives their paycheck.⁶ Some D2C providers claim rights against the worker in the event that the amount that they are able to withdraw is insufficient. Some of the significant differences between these two types of earned wage products, however, are starting to erode. Some D2C providers now obtain payroll records to determine accrued wages, rather than estimate accrued wages by less direct means. Some also make deductions using the payroll process, rather than transferring from the consumer’s regular transaction account after the consumer is paid.⁷ In addition, some D2C providers limit their ability to seek recourse.

Both forms of EWA now exist at scale, reflecting significant consumer demand, dozens of EWA providers, and upwards of \$3.5 billion investment in the market

from venture capital firms over the past decade.⁸ A 2024 report from the CFPB estimated that the EP EWA market had grown from \$3.2 billion across 18.6 million transactions in 2018 to \$22.8 billion across 214 million transactions in 2022, with 7.2 million workers utilizing EP EWA transactions at least once.⁹ That same year, an estimated 3 million workers accessed roughly \$9.1 billion in D2C EWA funds; market analyses indicate that use of D2C products has also grown significantly over recent years.¹⁰ Recent estimates project that the U.S. EWA market is set to expand by about 300 percent between 2024 and 2034.¹¹

EP providers obtain revenue from one or more of several sources: direct payment from the employer; a share of interchange revenue from payment cards used by workers; fees paid by workers for expedited delivery of EWA funds; and, less frequently, from subscription charges for access to EWA, sometimes packaged with other employee benefits. D2C providers obtain revenue from one or more of some of these same sources as well: interchange revenue, expedited delivery fees, and subscription charges. Many D2C providers also solicit tips from the workers who use their products.¹²

B. Regulatory Background

In November 2020, the CFPB issued an advisory opinion (the 2020 AO)¹³ to respond to uncertainty about whether EWA providers offer or extend “credit” within the scope of the Truth in Lending Act (TILA) and its implementing Regulation Z.¹⁴ The 2020

AO noted that the CFPB had itself acknowledged some uncertainty on this point when it issued the 2017 Payday Rule.¹⁵ The 2020 AO was issued pursuant to the CFPB’s Advisory Opinions Policy, which is “intended to facilitate timely guidance by the Bureau that enables compliance by resolving outstanding regulatory uncertainty.”¹⁶

The 2020 AO clarified that a particular type of EWA—which it labeled as a “Covered EWA Program”—did not involve the offering or extension of “credit” as defined by section 1026.2(a)(14) of Regulation Z.¹⁷ As described further in the 2020 AO, a Covered EWA Program met all of the following criteria¹⁸: it is employer-partnered; the amount accessed by the employee does not exceed accrued wages; accessing EWA is free for the employee; the provider has no recourse against the employee if an employer-facilitated deduction from the next paycheck is insufficient, and engages in no debt collection or credit reporting activity; and the provider does not assess the credit risk of employees. The 2020 AO noted that Covered EWA Programs, being functionally equivalent to early wage payment, do not involve debt and, by extension, credit under Regulation Z. The 2020 AO did not state that other forms of EWA, such as direct-to-consumer EWA, are credit under Regulation Z. It did not reach that question, although it observed that EWA meeting all the listed criteria *except* being free to the consumer might not be credit under Regulation Z.¹⁹

On January 15, 2025, the CFPB issued another advisory opinion rescinding the 2020 AO (the 2025 Rescission).²⁰ The 2025 Rescission contended that the 2020 AO created, rather than reduced, regulatory uncertainty. It further claimed that the 2020 AO contained several legal flaws. Prior to the 2025

⁴ In some cases, deductions may include fees or other consumer payments associated with an EWA transaction.

⁵ For example, some EP providers instruct the payroll processor to divert a portion of the paycheck to the EP provider, with the remainder going straight to the worker. Others instruct the payroll processor to pay the entire paycheck to the EP provider, which then makes the relevant residual payment to the worker. Whatever the exact model of payroll process deduction used, EP providers generally do not take funds from the worker’s regular transaction account after that account’s receipt of wages; instead, they make use of the payroll process to facilitate deduction.

⁶ This includes, without limitation, prepaid and payroll card accounts. In some cases, the provider may partner with a bank to provide its EWA customers with a payroll card or other transaction account that the worker then uses to receive both early wage access and their regular paycheck.

⁷ For example, at least one D2C provider obtains consumer authorization to instruct payroll processors to divert a portion of the paycheck to a dedicated account opened “for the benefit” of the consumer, which is used solely for the purpose of enabling the D2C provider to obtain payment, with the remainder of the paycheck going straight to the consumer’s regular transaction account.

⁸ Lynne Marek, *EWA Chases Regulatory Clarity*, Payments Dive (Oct. 27, 2025), <https://www.paymentsdive.com/news/earned-wage-access-federal-state-legal-regulatory-clarity/803398/>.

⁹ See CFPB, Data Spotlight: Developments in the Paycheck Advance Market (July 18, 2024), <https://www.consumerfinance.gov/data-research/research-reports/data-spotlight-developments-in-the-paycheck-advance-market/> (hereinafter 2024 Data Spotlight).

¹⁰ See *id.* (“Combined with employer-partnered transactions, in 2022, roughly 10 million workers utilized earned wage product transactions to access over \$31.9 billion.”). Several providers of D2C products report significant recent growth. See, e.g., Dave, *3Q25 Earnings Presentation* (Nov. 4, 2025), <https://investors.dave.com/static-files/4971d257-0924-4d19-b35e-5d871e5136f8> (showing D2C origination volume increased 49 percent from 3Q24 to 3Q25); Chime, *Welcome to Chime*, at 24 (June 2025), <https://chime.gcs-web.com/static-files/ef823261-71ae-4183-bd16-a76f0cf8b6ff> (showing \$8.8 billion in D2C EWA transactions in the first nine months since product launch in 2024).

¹¹ See Market.U.S., *North America Earned Wage Access Market Size, Share, Industry Analysis Report By Model* (Nov. 2025), <https://market.us/report/north-america-earned-wage-access-market/>.

¹² The CFPB is not aware of EP providers that solicit tips.

¹³ See 2020 AO, 85 FR 79404 (Dec. 10, 2020).

¹⁴ 15 U.S.C. 1602(f); 12 CFR 1026.2(a)(14).

¹⁵ See 2020 AO, 85 FR 79404, 79407 (Dec. 10, 2020) (citing 82 FR 54472 at 54547).

¹⁶ 85 FR 77987, 77987 (Dec. 3, 2020).

¹⁷ The definition of “credit” in TILA is virtually identical to Regulation Z’s definition of the term. See 15 U.S.C. 1602(f). Accordingly, the 2020 AO also stated that Covered EWA does not involve the offering or extension of “credit” under TILA.

¹⁸ See 2020 AO, 85 FR 79404 at 79405–06.

¹⁹ The 2020 AO invited providers of EWA programs that charge fees to request clarification from the CFPB about their programs through, for example, applying for a compliance assistance sandbox (CAS) approval. See 2020 AO, 85 FR 79404 at 79405 (citing the CAS policy published at 84 FR 48246 (Sept. 13, 2019)). In December 2020, the CFPB granted one such application from Payactiv, stating that its EWA product—which charged a \$1 daily access fee for EWA—was not credit. See Approval Order (Dec. 30, 2020), https://files.consumerfinance.gov/f/documents/cfpb_payactiv_approval-order_2020-12.pdf. That approval was rescinded in June 2022.

²⁰ 2025 Rescission, 90 FR 3622 (Jan. 15, 2025).

Rescission, the CFPB considered replacing the 2020 AO with a contrary opinion. Specifically, in June 2024, the CFPB issued a proposed interpretive rule (the 2024 PIR) that, if finalized, would have identified *all* EWA as Regulation Z credit.²¹ In addition, the 2024 PIR would have identified expedited delivery fees and, at least in certain circumstances, tips as finance charges under Regulation Z. After soliciting public comment²² on the 2024 PIR, the CFPB never adopted the interpretive positions proposed in it, opting instead for the much narrower rescission of the 2020 AO.²³ Finally, in May 2025, the CFPB withdrew both the 2020 AO and the 2025 Rescission.²⁴

C. Legal Analysis

1. General

Part I.C.2 of this advisory opinion explains why Covered EWA is not credit under Regulation Z. Part I.C.3 explains why, to the extent that any EWA product is Regulation Z credit, expedited delivery fees and tips are not, in the normal course, finance charges under Regulation Z.

This advisory opinion does not state, and nothing in it should be understood to state, that EWA products that are *not* Covered EWA are credit under Regulation Z. In addition, nothing in this advisory opinion interprets provisions of law outside of Regulation Z. The CFPB continues to seek stakeholder feedback and evaluate whether it should take further legal steps with respect to EWA products, including steps that might encompass non-Covered EWA and/or other provisions of law besides Regulation Z.

2. Covered EWA Is Not Credit

a. Covered EWA

For purposes of this advisory opinion, the term “Covered EWA” means EWA that includes all of the following characteristics:

(1) Covered EWA transactions do not exceed the accrued cash value of the

wages²⁵ the worker has earned up to the date and time of the transaction, which amount is determined based upon payroll data²⁶ that evidence this amount.²⁷ A Covered EWA provider does not determine accrued wages based on other information, such as worker representations, or on estimates or predictions of accrued wages.

(2) The provider uses a payroll process deduction in connection with the worker's next payroll event.²⁸ In a payroll process deduction, payment instructions received and acted upon by the payroll processor (or by the employer itself if it does not use a processor) enable the EWA provider to receive accessed amounts without debiting the consumer's regular transaction account after the consumer is paid.²⁹ A transfer to the provider from

²⁵ The “accrued cash value of the wages” are wages that the worker is entitled to receive under State law in the event of separation from the employer for work performed for the employer, but for which the worker has yet to be paid.

²⁶ “Payroll data” are generally maintained by a payroll processor engaged by the employer to handle payroll; in some cases, however, the employer may handle payroll in-house and would be the source for payroll data.

²⁷ Providers should take note of the possibility that workers could take two or more EWA transactions, potentially from different providers, in the same pay period, and that these transactions could *cumulatively* exceed the accrued cash value of the worker's wages, even as each individual EWA transaction does not. A transaction that causes the cumulative amount to exceed the accrued cash value of the worker's wages is not a Covered EWA transaction; earlier EWA transactions may be. To meet this first criteria, therefore, providers may need to account for any earlier Covered EWA transactions in that same pay period.

²⁸ In the event of a technical or administrative error, Covered EWA encompasses one additional payroll process deduction at the *next* payroll event. Technical or administrative errors include, for instance, an API malfunction or a mistake in the employer's payroll process (e.g., miscalculation of a worker's base pay or overtime award). They do not include situations in which the employer has withheld a worker's garnished wages following a Covered EWA transaction. For example, a Covered EWA transaction may occur in week one of a worker's pay cycle, but the employer learns of and subjects the worker's paycheck to a required wage garnishment in week two of the pay cycle. As a result of the garnishment, the worker's paycheck is less than the amount of the Covered EWA transaction. That is not administrative or technical error of the kind identified in part I.C.2.a.(2).

²⁹ Examples of payroll process deduction include, without limitation: (a) the payroll processor sends the relevant amount to the EWA provider, and pays the remaining wages to the worker's regular transaction account; (b) the payroll processor sends the relevant amount to an account held “for the benefit” of the consumer and used only to make payments to the EWA provider, and the processor pays the remaining wages to the worker's regular transaction account; and (c) the payroll processor sends all wages to the EWA provider, with the EWA provider separately and directly paying the balance of the wages owed to the worker's regular transaction account. Providers seeking clarification from the CFPB about whether their practices constitute payroll process deduction may request clarification from the CFPB by, for instance,

any of the consumer's regular transaction accounts after the payment of wages into that account is not a payroll process deduction.³⁰

(3) Before providing Covered EWA, the provider clearly and conspicuously explains to the worker, and warrants to the worker as part of the contract between the parties, that it: (a) has no legal or contractual claim or remedy, direct or indirect, against the worker in the event the payroll process deduction is insufficient to cover the full amount of a Covered EWA transaction, including no right to take payment from any of the consumer's regular transaction accounts;³¹ and (b) will not engage in any debt collection activities related to Covered EWA, place a Covered EWA transaction amount as a debt with or sell it to a third party, or report to a consumer reporting agency concerning Covered EWA.

(4) The provider does not directly or indirectly assess the credit risk of individual workers, including through obtaining and reviewing credit reports or credit scores about the individual workers.

b. Analysis

Section 1026.2(a)(14) of Regulation Z defines “credit” as “the right to defer payment of debt or to incur debt and defer its payment.”³² Neither Regulation Z nor TILA define the term “debt.” Covered EWA does not provide workers with the right to defer payment of debt or to incur debt and defer its payment. As a result, Covered EWA is not credit.

As explained further in the 2020 AO, this is for several reasons.³³ The primary reason is that the common meaning of debt is “a sum of money due by certain and express agreement” or “a financial liability or obligation owed by one person, the debtor, to another, the creditor.”³⁴ In the context of Covered EWA, the worker incurs no such liability or obligation.³⁵ Covered EWA

applying for an Approval under the Policy on the Compliance Assistance Sandbox. See 84 FR 48246. Although the policy was rescinded in September 2022, the CFPB anticipates reissuing it shortly after this advisory opinion is published.

³⁰ As noted, a regular transaction account may include payroll or prepaid card accounts offered to the consumer by the EWA provider in partnership with a bank issuer. See *supra* note 6.

³¹ A provider may choose to refrain from offering the worker further EWA services and still meet this condition.

³² 12 CFR 1026.2(a)(14). TILA defines “credit” as “the right granted by a creditor to a debtor to defer payment of debt or to incur debt and defer its payment.” 15 U.S.C. 1602(f).

³³ See 2020 AO, 85 FR 79404 at 79406–07.

³⁴ *Debt*, Black's Law Dictionary (4th ed. 1968).

³⁵ See 2020 AO, 85 FR 79404 at 79406. Citing a later Black's definition of debt, the 2020 AO notes

Continued

²¹ See 2024 PIR, 89 FR 61358 (July 31, 2024).

²² In response to the 2024 PIR, the CFPB received 37 comments from industry stakeholders; 15 comments from consumer group stakeholders; 10 comments from Federal, State, and local government officials; and nearly 150,000 comments from individual consumers. In part because of the many comments received on the 2024 PIR, the CFPB is not seeking comment on this advisory opinion.

²³ The unfinalized and abandoned 2024 PIR is of no legal effect. However, the CFPB is hereby formally withdrawing the 2024 PIR for several reasons, including: the comments received on it; a number of Executive Orders, including E.O. 14219; and at least five Federal district court opinions, directly or indirectly, relying heavily on it. See cases cited in *infra* note 81.

²⁴ 90 FR 20084 (May 12, 2025).

facilitates workers' access to wage amounts that they have already earned, and to which they are already entitled.³⁶ Using payroll data, either at the employer or its payroll processor, the provider knows the accrued cash value of the worker's wages at the point that the worker requests a Covered EWA transaction. Using the payroll process, the provider makes a deduction for the amount of the Covered EWA transaction at the next scheduled payroll event, which corresponds to the pay period in which the worker accrued the wages on which the Covered EWA was based.³⁷ Covered EWA offers workers access to money that *they are owed by virtue of work that they have already performed*. Rather than the consumer's repayment of a debt, the provider's payroll process deduction from the payroll event associated with that work serves to ensure the consumer is not effectively compensated twice for the same work.³⁸ They have had earlier-than-normal access to wage amounts accrued, so they are owed less at payday. Fundamentally, Covered EWA resembles early wage payment and does not resemble an extension of credit.

The 2020 AO also drew support from two prior regulatory statements.³⁹ Comment 2(a)(14)-1.v to Regulation Z states that "[b]orrowing against the accrued cash value of an insurance policy or a pension account if there is no independent obligation to repay" is "not considered credit for purposes of the regulation."⁴⁰ When it issued this

the absence of a "liability" in this context. However, the 2020 AO did not intend to differentiate "liability" from "obligation" in this context. The present AO relies on the 1968 Black's definition of debt, which was current when TILA became law, and which also draws no such distinction.

³⁶ Covered EWA transactions cannot be more than this amount, which reduces the risk that EWA funds do not correspond to funds the worker has actually earned and is entitled to receive on payday.

³⁷ Payroll process deductions may not be attempted in any other pay period in the event that the initial payroll process deduction is insufficient to cover the full amount of the Covered EWA transaction. However, in the event of a technical or administrative error, one additional payroll process deduction may be attempted at the next payroll event.

³⁸ In proposing an interpretation of credit that would cover all EWA, the 2024 PIR noted that "it is not uncommon for credit providers to compel repayment of debt using wage garnishment automatically deducted from consumer paychecks." 2024 PIR, 89 FR 61358, 61361 n.26 (July 31, 2024). But the fact that some creditors sometimes obtain repayment of debts via payroll does not demonstrate that all payroll process deductions involve the repayment of debt. None of the examples cited in the 2024 PIR involve deductions to account for the consumer earlier accessing money that they were owed by virtue of work that they had already performed.

³⁹ See 2020 AO, 85 FR 79404 at 79406–07.

⁴⁰ 12 CFR 1026, supp. I, comment 2(a)(14)-1.

Regulation Z commentary, the Board of Governors of the Federal Reserve System (the Board) stated that in such instances, "credit has not been extended because the consumer is, in effect, only using the consumer's own money."⁴¹ As the 2020 AO explains, the accrued cash value of a worker's earned but unpaid wages is similarly the worker's own money. Accordingly, in a Covered EWA transaction, the worker is "in effect, only using the [worker's] own money" and is not incurring debt or deferring its payment. Similarly, Covered EWA involves "no independent obligation to repay" because the provider may only transfer funds via the allowed payroll process deduction for the pay period in which the wages were accrued; it has no claim direct or indirect against a worker for nonpayment in the event of a failed or partial deduction.⁴² The 2020 AO also cited the preamble to the 2017 Payday Rule in support of its interpretation of the application of § 1026.2(a)(14) to Covered EWA Programs. Recognizing that "some efforts to give consumers access to accrued wages may not be credit at all," that rule took specific steps to ensure that it had no application to several types of EWA products.⁴³

Finally, the 2020 AO noted that Covered EWA Programs lack typical substantive indicia of credit.⁴⁴ Covered EWA providers similarly reserve no recourse against the worker in the event a payroll process deduction for the period in which accessed wage amounts were accrued is insufficient to cover those amounts. A Covered EWA

⁴¹ 46 FR 20848, 20851 (Apr. 7, 1981) ("The regulatory definition [of 'credit'] may be difficult to apply in particular fact situations, and the Board therefore offers the following guidance, which will also be incorporated into the commentary."). In a footnote, the 2024 PIR asserts without support that because this exclusion was promulgated after notice and comment, products that are similar but not specifically covered by it "should therefore be presumed to be 'credit.'" See 2024 PIR, 89 FR 61358 at 61361 n.29. The 2024 PIR offers no citation or basis for this position. In fact, statements by the Board directly contradict that approach and instead explain that Regulation Z commentary is intended to serve as guidance for use in determining application to particular transactions. See, e.g., 46 FR 28560, 28560 (May 27, 1981) (proposing official Regulation Z commentary); 46 FR 50288, 50288 (Oct. 9, 1981) (adopting official Regulation Z commentary).

⁴² This could happen, for instance, if a worker's wages become subject to garnishment or an employer goes out of business after an EWA transaction but before the scheduled payday.

⁴³ 82 FR 54472 at 54547.

⁴⁴ See 2020 AO, 85 FR 79404 at 79407. As the 2020 AO noted, courts generally look at the totality of the circumstances—and weigh multiple factors in a fact-specific inquiry—to determine if a transaction's substance is credit. See *id.* (citing cases at note 20).

provider also cannot engage in debt collection, report to consumer reporting agencies, or sell or place the transaction as a debt with any third party. Providers also do not pull credit reports or credit scores on individual workers or otherwise assess their credit risk.

The 2020 AO limited its application to EP EWA, and more specifically to EP products where the provider transfers the amount of each EWA transaction "through an employer-facilitated payroll deduction from the employee's next paycheck." Upon reconsideration, however, the CFPB now believes that these specific limitations are not derived from the text of Regulation Z (or TILA). Section 1026.2(a)(14) of Regulation Z defines "credit" as "the right to defer payment of debt or to incur debt and defer its payment"; pursuant to this definition, the defining element of "credit" is a consumer's repayment—at some point in the future—of the amount owed. When an EWA provider makes arrangements to ensure that the appropriate amount of the consumer's paycheck is directed to it through a payroll process deduction, the funds never touch the consumer's regular transaction account, and accordingly the consumer makes no deferred payment.

Indeed, as noted above, the EWA market has evolved such that EP providers now use a variety of methods for effecting transfers through the payroll process, which include, but are no longer limited to, "employer-facilitated payroll deductions." For purposes of interpreting the application of "credit" to EWA, there is no reason to preference one such method over others. Similarly, D2C providers that transfer EWA amounts through the payroll process, rather than from a worker's regular transaction account after receipt of wages, are Covered EWA if they meet the other criteria.

The 2020 AO also limited its application to EWA products that were free to the consumer. That limitation, too, is not required by the text of Regulation Z (or TILA) and is not maintained in the present advisory opinion. Under existing law, consumer cost is relevant to the question of whether consumers incur Regulation Z finance charges in connection with products that extend credit—but has no bearing on whether or not a product amounts to Regulation Z credit in the first place. As noted, whether a product constitutes credit depends on whether it implicates a debt. For the reasons explained above, Covered EWA does not. Credit can be free to the consumer or it can cost the consumer. Non-credit products, too, can be free or they can

cost. The difference between the two is not cost.

Not only is this point clear from looking at the text of the statute and regulation, but it is a point of wide interpretive consensus, as demonstrated by stakeholder feedback on the 2020 AO. For example, in an October 12, 2021 letter, some 96 consumer, labor, civil rights, legal services, faith, community and financial organizations, and academics state that the 2020 AO was flawed in part because “the definition of ‘credit’ under TILA is not related to price.”⁴⁵ A contemporaneous letter from the National Consumer Law Center and the Center for Responsible Lending expands on the point: “Whether there is a charge for credit has absolutely no bearing on whether ‘debt’ has been incurred. The cost is only relevant to whether the lender is a ‘creditor’: one who ‘regularly extends consumer credit that is subject to a finance charge or is payable by written agreement in more than four installments.’”⁴⁶ Moreover, the 2020 AO did not position cost as critical to its interpretation. Rather, it simply limited its interpretive scope to products that were free.⁴⁷

It is important to note that obligations under Regulation Z and TILA generally only arise when a provider is a Regulation Z creditor. Regardless of whether a product counts as Regulation Z credit, if its provider is not a Regulation Z creditor, then as a general matter, the product is not subject to regulatory obligations under Regulation Z or TILA. And cost is relevant to the question of whether or not a provider is a creditor, as discussed in part I.C.3 below. In the normal course, providers of EWA products that are free and thus carry no finance charges will not be creditors under Regulation Z, and accordingly such EWA products will

not be subject to credit regulation under Regulation Z.⁴⁸

While the 2025 Rescission took no position on whether Regulation Z applies to any forms of EWA, it criticized the reasoning of the 2020 AO in four respects. Upon reconsideration, the CFPB now believes that none of these criticisms are persuasive. First, it faulted the 2020 AO for not drawing on State law definitions of debt, even as it did not claim that CFPB interpretations of Regulation Z debt *must* rely on State law.⁴⁹ However, the 2020 AO, like this advisory opinion, relied on the ordinary meaning of the term “debt,” which is found in numerous State laws. In addition, most States to have specifically considered EWA legislatively do not regulate EWA as credit.⁵⁰ And two States offering regulatory guidance on EWA

⁴⁸ A provider is a creditor under Regulation Z if the product is repayable in more than four installments or subject to finance charges. 12 CFR 1026.2(a)(17)(i). In the normal course, free EWA products will not meet either condition and thus their providers will not be Regulation Z creditors. Regulation Z also includes definitions of “creditor” that apply specifically to credit card issuers. See 12 CFR 1026(a)(17)(iii), (iv). The CFPB is unaware of any EWA providers that issue credit cards in connection with the provision of EWA.

⁴⁹ Regulation Z provides that undefined terms “have the meanings given to them by state law or contract” (12 CFR 1026.2(b)(3)), but the regulation offers no guidance about how to apply this provision, and there is little applicable case law. Some cases have interpreted the provision as an instruction to consult the “ordinary usage” of the undefined term in question. See, e.g., *Fernandes v. JPMorgan Chase Bank, N.A.*, 818 F. Supp. 2d 1086, 1090–91 (N.D. Ill. 2011) (consulting Black’s Law Dictionary for the meaning of the undefined term in question); *Wilbourn v. Advantage Fin. Partners*, 2010 WL 1194950, at *6 (N.D. Ill. 2010). This advisory opinion, like the 2020 AO, relies on exactly this kind of ordinary usage of the term “debt.”

⁵⁰ See, e.g., Kan. Stat. Ann. § 9–2407(a)(1) (“Earned wage access services provided by a registrant in accordance with this chapter shall not be considered to be: (A) A loan or other form of credit or the registrant a creditor or lender with respect thereto”); Mo. Ann. Stat. § 361.749(6)(1) (“Earned wage access services offered and provided by a registered provider shall not be considered to be any of the following: . . . (b) A loan or other form of credit”); S.C. Code Ann. § 39–5–860 (“Proceeds provided to a consumer by the [EWA] provider shall not be considered a consumer loan for purposes of Section 37–3–104 [defining consumer loan] or a loan for purposes of Section 37–3–106 [defining loan].”); Utah Code Ann. § 13–78–106(1) (“A provider offering or providing earned wage access services in this state: . . . (b) is not offering a loan or other form of credit or debt, if the provider is not a creditor, a debt collector, or a lender.”). The 2024 PIR cites State law definitions of “debt” (many of which happen to appear in State FDCA statutes) that it claims support its broad “any obligation” interpretation of “debt,” but it avoids discussing State law’s treatment of whether EWA is credit, which predominantly supports the interpretation offered here and in the 2020 AO. 2024 PIR, 89 FR 61358 at 61360.

determined that it does not count as a loan under State law.⁵¹

Second, the 2025 Rescission targeted what it characterized as the main rationale for the 2020 AO’s assertion that Covered EWA Programs do not involve the consumer incurring a liability: the claim that EWA “functionally operates like” an employer that pays its workers earlier than the scheduled payday. The 2025 Rescission took issue with this rationale for insufficiently explaining why “functional operation” supports the 2020 AO’s conclusion. The point intended by that language is the same point made above: for all the reasons stated in the 2020 AO and restated here, EWA resembles the early payment of wages and does not resemble the extension of credit. With Covered EWA, there is no liability or obligation sufficient to create a debt because the provider, by engaging with the consumer’s employer or its payroll processor, makes a payroll process deduction for the pay period in which the wages have been accrued, and reserves no recourse against the consumer if that deduction falls short of the amount of the EWA transaction—just as an employer directly advancing wages to a worker would use the payroll process to deduct that amount from the worker’s paycheck and take no further recourse against the worker. The deduction operates to ensure that the consumer is not effectively paid twice for the same work. The presence of a third-party intermediary—the EWA provider—facilitating access to accrued earnings does not change the nature of the transaction.

Third, while the 2025 Rescission did not dispute that Covered EWA lacks certain significant indicia that are common in credit transactions (such as underwriting, debt collection, recourse, credit reporting, and so on), it asserted that the 2020 AO failed to consider EWA features “commonly found in credit transactions, including a consumer’s receipt of funds, consumer repayment of those funds, and the wage garnishment tool used to effectuate repayment.”⁵² The CFPB does not

⁵¹ See Ariz. Op. Att’y Gen., No. I22–005 (Dec. 16, 2022); Mont. Op. Att’y Gen., Vol. 59, Op. 2 (Dec. 22, 2023).

⁵² See 2025 Rescission, 90 FR 3622, 3623 (Jan. 15, 2025). As part of this criticism, the 2025 Rescission faulted the 2020 AO for failing to “explain how its ‘totality of the circumstances’ approach derived from the definition of ‘credit.’” *Id.* But as the 2020 AO explained, courts commonly conduct a fact-specific inquiry—using the types of factors articulated in the 2020 AO—to determine whether a transaction is “credit.” The logic of the 2025 Rescission would prohibit an agency from interpreting terms using well-established precedent.

⁴⁵ See Nat’l Consumer L. Ctr., et al., Letter to CFPB (Oct. 12, 2021), <https://www.nclc.org/wp-content/uploads/2022/10/CFPB-EWA-letter-coalition-FINAL2.pdf>. The same letter also notes that the question of fees relates to finance charge issues, rather than to the definition of credit: “Free programs might be exempt from TILA for other reasons (i.e., if the provider is not a ‘creditor’ as defined by TILA).”

⁴⁶ See Nat’l Consumer L. Ctr. & Ctr. for Responsible Lending, Letter to CFPB (Oct. 12, 2021), https://www.nclc.org/wp-content/uploads/2022/10/EWA-letter-to-CFPB_Oct-4-2021.pdf.

⁴⁷ The 2020 AO noted that both wages and free EWA cost the consumer nothing, but that observation was not central to its core claim that the consumer does not incur a liability when using EWA. The 2020 AO focused on a class of EWA products that is the most akin to early wage payment—because wages are free to the consumer. But that does not mean that other forms of EWA—including Covered EWA as defined in this advisory opinion—are not more akin to early wage payment than to credit extension.

believe those factors are necessary to the analysis, but considering them further, it does not believe they would require a different result. Receipt of funds is common to many kinds of transactions—a sale or investment, for example, not to mention receipt of wages directly from an employer—and thus is not a meaningful indicium of credit. Further, covered EWA products do not garnish wages, and they do not involve consumer repayment. As noted above, the payroll process deduction that the EWA provider uses at the next payroll event works to ensure that the consumer is not effectively paid twice for the same work—and accordingly is not consumer repayment for credit advanced.

Fourth, the 2025 Rescission criticized the 2020 AO for drawing support from the 2017 Payday Rule's exclusion of certain EWA products. It suggested that these exclusions have no bearing on the Regulation Z credit status of EWA because the Payday Rule was based on the CFPB's UDAAP authority, not its TILA authority, and the exclusions would only operate to the extent that EWA was credit under Regulation Z. It is true that the 2017 Payday Rule did not conclusively determine that EWA was not Regulation Z credit. But when it considered and then finalized the Payday Rule, the CFPB recognized that EWA products might well not be credit. As a result, it took formal regulatory steps to ensure that the Payday Rule's regulation of short-term credit would not have application to EWA.⁵³ Upon reconsideration, the CFPB now believes that it was appropriate for the 2020 AO to cite this recognition as additional support for its conclusion.⁵⁴

⁵³ To the extent the 2025 Rescission contended that the Payday Rule's exclusion of certain "wage advance products" demonstrates that such products must be Regulation Z credit (because the rule only applies to such credit), that contention is false. The Payday Rule made clear that its wage advance exclusion was limited to "advances that constitute credit," indicating that some such advances might not in fact be credit for the various reasons that it noted, including that EWA lets consumers "draw on the accrued cash value of wages they have earned but not yet been paid," and does so "without recourse beyond deduction from the next paycheck," and without "collection or debt reporting activities." 82 FR 54472 at 54547 (emphasis added).

⁵⁴ The 2024 PIR contends that because the Payday Rule's exclusions for "wage advance products" only operate to the extent that such products are TILA credit, "the decision to exclude" such products "has no impact on the credit status of EWA products under TILA or Regulation Z." What this misses is that the CFPB was clear that it was providing these exclusions precisely because it recognized that such products might not be TILA credit. Absent a final determination of EWA's credit status, the CFPB needed to provide the exclusions to ensure that the Payday Rule would not apply to these products.

3. Expedited Delivery Fees and Tips Associated With EWA Are Not Finance Charges

As explained in part I.C.2 above, Covered EWA is not credit. Thus, given that a finance charge is the cost of credit, any fees charged in connection with Covered EWA cannot be finance charges. To the extent any EWA products other than Covered EWA are credit, fees associated with them can be finance charges. This is not to imply that any EWA products other than Covered EWA are credit. As noted, the CFPB continues to seek stakeholder feedback and evaluate whether it should provide additional clarity about whether (and when) other EWA products, which are not Covered EWA as described here, are also not credit under Regulation Z.

The question addressed in part I.C.3.b is whether expedited delivery fees associated with EWA are finance charges. Part I.C.3.c addresses the question of whether tips associated with EWA are finance charges.⁵⁵ For the reasons set forth below, the CFPB concludes that, in the normal course, fees for expedited delivery of earned wages and tips for the receipt of earned wages are *not* finance charges because they are not imposed directly or indirectly by the provider. That said, in certain factual scenarios discussed below, each could be a finance charge.

a. General

In general, the obligations of Regulation Z apply to any credit provider that regularly offers or extends consumer credit subject to a finance charge.⁵⁶ The finance charge is "the cost of consumer credit as a dollar amount."⁵⁷ Unless specifically excluded by the regulation, this includes "any charge payable directly or indirectly by the consumer and imposed directly or indirectly by the creditor as an incident to or a condition of the extension of credit."⁵⁸ Thus, to qualify as a finance charge, a charge must be either "an incident to" or "a condition of" an extension of credit *and* be "imposed directly or indirectly" by the creditor. Providers are required to disclose finance charges in the manner prescribed by Regulation Z.⁵⁹

Neither Regulation Z nor TILA defines the key terms in the definition of "finance charge": "imposed by,"

⁵⁵ This advisory opinion does not address the question of whether EWA subscription fees are finance charges because Regulation Z already clarifies that this type of "participation" fee is not a finance charge. See 12 CFR 1026.4(c)(4).

⁵⁶ See 12 CFR 1026.1(c)(1)(iii).

⁵⁷ 12 CFR 1026.4(a).

⁵⁸ *Id.*

⁵⁹ See, e.g., 12 CFR 1026.18(d).

"incident to," and "condition of."⁶⁰ The 1968 edition of Black's Law Dictionary defines "impose" to mean "to levy or exact as by authority; to lay as a burden, tax, duty, or charge."⁶¹ It defines "incident" to mean "anything which is usually connected with another, or connected for some purposes, though not inseparably."⁶² The meaning of "condition" is "an uncertain future act or event whose occurrence or nonoccurrence determines the rights or obligations of a party under a legal instrument and especially a contract."⁶³ On their own, however, these highly general definitions do not provide a clear answer to the questions at hand, *i.e.*, whether expedited delivery fees and tips are finance charges.⁶⁴ Rather, it is well established that determining whether a fee qualifies as a finance charge requires a case-by-case approach.⁶⁵

b. Expedited Delivery Fees

Most EWA providers offer consumers the option of receiving their earned wages via regular ACH and/or by instant transfer to the *provider's* debit, prepaid,

⁶⁰ Regulation Z provides that undefined terms "have the meanings given to them by state law or contract." 12 CFR 1026.2(b)(3). However, the regulation itself does not provide any guidance about how to apply this provision.

⁶¹ *Impose*, Black's Law Dictionary (4th ed. 1968); see also *Impose*, Merriam-Webster, <https://www.merriam-webster.com/dictionary/impose> (last updated Oct. 28, 2025) ("to establish or apply by authority").

⁶² *Incident*, Black's Law Dictionary (4th ed. 1968); see also *Incident*, Merriam-Webster, <https://www.merriam-webster.com/dictionary/incident> (last updated Oct. 30, 2025) ("dependent on or relating to another thing in law").

⁶³ *Condition*, Black's Law Dictionary (12th ed. 2024); see also *Condition*, Merriam-Webster, <https://www.merriam-webster.com/dictionary/condition> (last updated Oct. 30, 2025) ("a premise upon which the fulfillment of an agreement depends[;] . . . a provision making the effect of a legal instrument contingent upon an uncertain event").

⁶⁴ Nor does case law clarify their meaning. A good example is *Household Credit Servs., Inc. v. Pfennig*, 541 U.S. 232 (2004). In *Pfennig*, the Supreme Court overturned the Sixth Circuit's determination that a credit card over-limit fee was a finance charge, in part, on the ground that "the phrase 'incident to' does not make clear whether a substantial (as opposed to remote) connection is required." *Id.* at 241. As such, it is not possible "to conclude that the term 'finance charge' unambiguously includes over-limit fees." *Id.* Thus, the opinion provides little if any assistance in determining whether expedited delivery fees and tips associated with EWA are finance charges. The 2024 PIR implausibly interpreted *Pfennig* to hold that only a remote connection is required and then used this interpretation to buttress the view that expedited delivery fees and tips are "incident to" the provision of EWA.

⁶⁵ 61 FR 49237, 49239 (Sept. 19, 1996) ("The Board has generally taken a case-by-case approach in determining whether particular fees are 'finance charges.'").

or payroll card for free.⁶⁶ ACH delivery typically takes one to three days.⁶⁷ Most also offer one form or another of expedited delivery to an account of the consumer's choice. To effectuate such delivery, EWA providers incur charges from expedited delivery services which they then pass on to consumers. Consumers that choose this option pay fees typically ranging from \$2.50 to \$5.99.⁶⁸ *Prima facie*, these fees are charges for expedited delivery rather than for receiving a certain amount of earned wages. But are they actually finance charges?

There is no need for the CFPB to write on a clean slate when answering this question. In a 2003 rule, the Board considered whether two types of expedited fees in connection with credit cards accessing home equity lines of credit are finance charges: a fee for expediting a consumer's payment, and a fee expediting delivery of the physical card. As regards the former, the Board determined that "expedited payment fees . . . are not finance charges under TILA and Regulation Z because the consumer has a reasonable means for making payment on the account without paying a fee to the creditor."⁶⁹ As regards the latter, the Board likewise determined that "a fee for expedited delivery of a credit card is not incidental to the extension of credit and thus is not a finance charge where the consumer requests the service and the card is also available by standard mail service (or another means that is at least as fast) without a fee."⁷⁰ Fees that EWA providers charge for expedited delivery of EWA fit squarely into this mold, since consumers can receive exactly the same service without paying the fee.

Somewhat earlier, the Eleventh Circuit in *Veale v. Citibank* addressed the application of "finance charge" to an expedited delivery fee very similar to the expedited delivery fees charged by EWA providers: a \$21 Federal Express

fee for expedited delivery of *loan proceeds*. The court noted that "[i]f the borrower can choose to avoid the Federal Express fee by having the documents sent via regular mail, then the fee is not imposed as an incident to the extension of credit."⁷¹ And the court held that "[s]ince the [borrowers] could have chosen not to pay the Federal Express fee and the bank did not require it, then the fee was not imposed as an incident to the extension of credit and need not be included in the Finance Charge [disclosure]."⁷²

The 2024 PIR made essentially no effort to distinguish *Veale*. Instead, it attempted to place the entire weight of its novel proposed interpretation on a 1996 Board rule about a very different fact pattern: fees charged for debt cancellation agreements. Under such an agreement, "the creditor agrees to cancel all or part of any remaining debt in the event of an occurrence, such as the death, disability or unemployment of the borrower."⁷³ The Board reasoned that fees for such agreements are finance charges because the agreement "alters the fundamental nature of the borrower's repayment obligation."⁷⁴ More specifically, it potentially reduces the principal amount the consumer owes the creditor. Such fees bear little, if any, resemblance to fees for expedited delivery of earned wages. The *earned wage amount* the provider deducts is unaffected by the consumer's opting for expedited delivery; the provider deducts the same earned wage amount if the consumer opts instead for free ACH delivery.

Ignoring this fundamental difference between debt cancellation fees and expedited delivery fees, the 2024 PIR highlighted more general language in the 1996 rule, namely, "even though a lender may not require a particular loan feature, the feature may become a term of the credit if it is included."⁷⁵ Relying on this formulation, the 2024 PIR proposed the facially implausible interpretation that fees for expedited delivery of earned wages are finance charges because earned-wages-plus-expedited-delivery is one credit product, and earned-wages-without-expedited-delivery is an entirely different credit product. That interpretation conflicts with the longstanding interpretation of "finance charge" by the Board itself in its 2003 rule and by the Eleventh Circuit in

Veale, detailed above. In addition, the 2024 PIR's reading of the Board's 1996 rule would have created a principle without any limitation under which any fee for anything connected to a credit transaction can be transformed into a finance charge. All one needs to do is create a separate credit product for each "feature."⁷⁶

The preceding determination that, in the normal course, expedited delivery fees associated with EWA are not finance charges is not intended to mean that expedited delivery fees can never be finance charges. The key issue is whether such fees are "directly or indirectly imposed" on the consumer. In the normal course, expedited delivery fees are the cost of obtaining earned wages more quickly than via ACH, and are triggered by the consumer's opting for expedited delivery; they are not "directly or indirectly imposed" by the provider. However, to the extent that an EWA provider does impose expedited delivery fees on a consumer's receipt of earned wages, those fees could qualify as finance charges. Determining whether such imposition is occurring is a matter that depends on the facts and circumstances of a provider's practices. For example, if an EWA provider makes it too difficult for consumers to select the un-expedited delivery of EWA funds, the resulting expedited delivery fees may effectively be imposed. Providers seeking clarification from the CFPB about whether their practices concerning expedited delivery fees do not amount to the imposition of a finance charge may request clarification from the CFPB by, for instance, applying for an Approval under the Policy on the Compliance Assistance Sandbox.⁷⁷

c. Tips

Tipping is a longstanding, familiar aspect of the retail services economy, but it has only relatively recently appeared in the context of consumer financial services. The practice of seeking tips, gratuities, and the like is

⁶⁶ Other free options include, for instance, "visiting a specified retail store to obtain funds; taking the funds on a designated retailer's gift card; or employer-subsidized funding of some or all of transfers." 2024 Data Spotlight, *supra* note 9.

⁶⁷ *Id.*

⁶⁸ *Id.* (summarizing fees charged by a sample of EP and D2C providers obtained from publicly available websites).

⁶⁹ 68 FR 16185, 16186 (Apr. 3, 2003).

⁷⁰ *Id.* at 16187. The Board's determination about the two types of "expedited" fees is codified at 12 CFR 1026, comments 6(a)(2)–2(ix) and (x). The 2024 PIR sought to distinguish the Board's interpretation on the ground that neither of those expedited services "are as closely and integrally connected to the extension of credit as faster funds access is to obtaining an earned wage product." 2024 PIR, 89 FR 61358 at 61362 n.42. But this reasoning is off point because the Board based its determinations on whether there were options other than the expedited option, even if slower.

⁷¹ *Veale v. Citibank*, 85 F.3d 577, 579 (11th Cir. 1996).

⁷² *Id.*

⁷³ 61 FR 49237, 49240 (Sep. 19, 1996).

⁷⁴ *Id.*

⁷⁵ 2024 PIR, 89 FR 61358 at 61362 (citing 61 FR 49237 at 49239).

⁷⁶ The 2024 PIR also failed to mention that the Board's 1996 Rule did not simply determine that debt cancellation fees are finance charges. It also determined that debt cancellation fees are not finance charges where the lender provides certain disclosures about the debt cancellation agreement. See 61 FR 49237 at 49240–41. Thus, even if the Board's rule were factually on point, it would provide support only for a more limited interpretation that expedited delivery fees are finance charges only if the expedited delivery feature is not sufficiently disclosed. Moreover, even if it is assumed that fees for debt cancellation agreements are factually on point, the Seventh Circuit has held that fees for such agreements (specifically GAP agreements) are not finance charges. See *McGee v. Kerr-Hickman*, 93 F.3d 380, 383–85 (7th Cir. 1996).

⁷⁷ See *supra* note 29 (discussing the Policy on the Compliance Assistance Sandbox).

relatively common among D2C EWA providers, which raises the question of whether tips in this context qualify as finance charges. In general dictionaries, a tip is defined as a gratuity, and a gratuity is defined as “something given voluntarily or beyond obligation usually for some service.”⁷⁸ To the extent that any EWA products are credit, if a provider seeks tips in connection with the provision of EWA, the tip is arguably “incident to” the extension of credit. However, it is inherent in the meaning of “tip” that it is not imposed, even if providing one is considered customary. Accordingly, a bona fide tip provided by the consumer for EWA services cannot be a finance charge.

To the extent tipping for EWA services is not voluntary, however, tips can be “directly or indirectly imposed” by providers and thus qualify as finance charges. The determination of when a tip crosses the line from voluntary to imposed depends on the facts and circumstances of a provider’s practices.⁷⁹ For example, if the provider makes it too difficult to avoid tipping, the resulting consumer payment may be imposed, at least in part.⁸⁰ Providers seeking clarification from the CFPB about whether their particular practices concerning tipping do not rise to the level of imposing finance charges may request clarification from the CFPB by, for instance, applying for an Approval under its Policy on the Compliance Assistance Sandbox.⁸¹

⁷⁸ Tip, Merriam-Webster, <https://www.merriam-webster.com/dictionary/tip> (last updated Oct. 31, 2025); Gratuity, Merriam-Webster, <https://www.merriam-webster.com/dictionary/gratuity> (last updated Oct. 29, 2025). These terms are not defined in Black’s Law Dictionary.

⁷⁹ The 2024 PIR likewise indicated that determining when a tip is imposed depends on the facts and circumstances. But it also employed various devices designed to stack the deck in favor of a determination that tips are finance charges. For example, it used quotes for each and every mention of the word tip. It identified numerous considerations it deemed relevant to making this determination. Many of these, however, have no basis in the ordinary meaning of the term “tip” and the familiar practice of tipping. For example, the 2024 PIR states that the consumer’s “reasonable understanding that the provider expects a ‘tip’” is evidence that it is imposed. 2024 PIR, 89 FR 61358 at 61363 n.48. Consumers who are served at a restaurant have a “reasonable understanding” that the server expects a tip, but that doesn’t mean that the server imposes the tip. Another “relevant consideration” identified by the 2024 PIR is “suggesting ‘tip’ amounts or percentages to the consumer.” This is now a common practice on POS checkout platforms, but no reasonable consumer believes this makes any tips selected mandatory.

⁸⁰ Depending on the facts and circumstances, a provider’s tipping practices could instead or also be unlawfully deceptive under 12 U.S.C. 5531, 5536.

⁸¹ See *supra* note 29 (discussing the Policy on the Compliance Assistance Sandbox). Subsequent to the issuance of the 2024 PIR, at least five district court opinions have appeared that concern products

II. Regulatory Matters

This advisory opinion is an interpretive rule issued under the CFPB’s authority to interpret the Truth in Lending Act and Regulation Z, including under section 1022(b)(1) of the Consumer Financial Protection Act of 2010, which authorizes guidance as may be necessary or appropriate to enable the CFPB to administer and carry out the purposes and objectives of Federal consumer financial laws.⁸²

As guidance, this interpretive rule does not have the force or effect of law. It has no legally binding effect, including on persons or entities outside the Federal government.

By operation of TILA section 130(f), no provision of TILA sections 130, 108(b), 108(c), 108(e), or 112 imposing any liability applies to any act done or omitted in good faith in conformity with this interpretive rule, notwithstanding that after such act or omission has occurred, the interpretive rule is amended, rescinded, or determined by judicial or other authority.

The Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) has determined that this action is not a “significant regulatory action” under E.O. 12866, as amended.

Pursuant to the Congressional Review Act,⁸³ the CFPB will submit a report containing this advisory opinion and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to the interpretive rule taking effect. OIRA has designated this advisory opinion as not

that could be classified as EWA, and that hold that those products are credit and that expedited delivery fees and/or tips associated with those products are finance charges. See *Orubo v. Activehours, Inc.*, 780 F. Supp. 3d 927, 938 (N.D. Cal. Apr. 30, 2025) (motion to dismiss); *Johnson v. Activehours, Inc.*, 2025 WL 2299425, at *9 (D. Md. Aug. 8, 2025) (motion to dismiss); *Golubiewski v. Activehours, Inc.*, 2025 WL 2484192, at *1 (M.D. Pa. Aug. 28, 2025) (motion to dismiss); *Moss v. Cleo AI Inc.*, 2025 WL 2592265, at *4 (W.D. Wash. Sept. 8, 2025) (motion to dismiss); *Vickery v. Empower Finance Inc.*, 2025 WL 2841686, at *9 (N.D. Cal. Oct. 7, 2025) (motion to compel arbitration). All rely heavily, directly or indirectly, on the application of “credit” to EWA and the application of “finance charge” to EWA-related express delivery fees and tips in the 2024 PIR, despite the fact that the 2024 PIR was merely a *proposed* interpretive rule. The first of the cases, *Orubo v. Activehours*, quotes liberally from the 2024 PIR. Each of the four subsequent cases then relies heavily on *Orubo*. Now that the CFPB has not only formally withdrawn the 2024 PIR but officially rejected the interpretations advanced in it, these opinions have no real bearing on this advisory opinion.

⁸² 12 U.S.C. 5512(b)(1).

⁸³ 5 U.S.C. 801 *et seq.*

a “major rule” as defined by 5 U.S.C. 804(2).

The CFPB has determined that this advisory opinion does not contain any new or substantively revised information collection requirements that would require approval by OMB under the Paperwork Reduction Act.⁸⁴

Russell Vought,

Acting Director, Consumer Financial Protection Bureau.

[FR Doc. 2025–23735 Filed 12–22–25; 8:45 am]

BILLING CODE 4810-AM-P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Comment Request; AmeriCorps National Civilian Community Corps (NCCC) Project Sponsor Survey

AGENCY: Corporation for National and Community Service.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Corporation for National and Community Service (operating as AmeriCorps) is proposing to revise an information collection.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by February 20, 2026.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) Electronically through www.regulations.gov (preferred method).

(2) By mail sent to: AmeriCorps, Ken Goodson, 250 E Street SW, Washington, DC 20525.

(3) By hand delivery or by courier to the AmeriCorps mailroom at the mail address given in paragraph (2) above, between 9 a.m. and 4 p.m. Eastern Time, Monday through Friday, except Federal holidays.

Comments submitted in response to this notice may be made available to the public through regulations.gov. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public

⁸⁴ 44 U.S.C. 3501 *et seq.*

docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comment that may be made available to the public, notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Ken Goodson, Director, AmeriCorps NCCC, 202-489-5766, kgoodson@americorps.gov.

SUPPLEMENTARY INFORMATION:

Title of Collection: AmeriCorps NCCC Project Sponsor Survey.

OMB Control Number: 3045-0190.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public:

Current/prospective AmeriCorps NCCC Project Sponsors.

Total Estimated Number of Annual Responses: 300.

Total Estimated Number of Annual Burden Hours: 100 hours.

Abstract: The AmeriCorps NCCC Project Sponsor Survey is completed by organizations that have sponsored an AmeriCorps NCCC team. Each year, AmeriCorps NCCC engages teams of members in projects in communities across the United States. Service projects, which typically last from six to eight weeks, address critical needs in natural and other disasters, infrastructure improvement, environmental stewardship and conservation, energy conservation, and urban and rural development. Members construct and rehabilitate low-income housing, respond to natural disasters, clean up streams, help communities develop emergency plans, and address other local needs.

AmeriCorps seeks to revise the current survey to remove information that we no longer need to collect. The current survey is due to expire on March 31, 2026.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology;

and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. All written comments will be available for public inspection on [regulations.gov](http://www.regulations.gov).

Walter Goodson,

Director, AmeriCorps NCCC.

[FR Doc. 2025-23633 Filed 12-22-25; 8:45 am]

BILLING CODE 6050-28-P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Inland Waterways Users Board Third Request for Nominations

AGENCY: Department of the Army, U.S. Army Corps of Engineers, Department of Defense (DoD).

ACTION: Notice of open Federal advisory committee third request for nominations.

SUMMARY: The Department of the Army is publishing this third notice to request nominations to serve as representatives on the Inland Waterways Users Board ("Board"), sponsored by the U.S. Army Corps of Engineers. The Board provides independent advice and recommendations to the Secretary of the Army and the Congress. The Secretary of the Army recommends its 11 (eleven) representative organizations to the Secretary of Defense for approval. This notice is to solicit nominations for eleven (11) appointments for terms that will begin by May 29, 2026. For additional information about the Board, please visit the committee's website at <http://www.iwr.usace.army.mil/Missions/Navigation/Inland-Waterways-Users-Board/>.

ADDRESSES: Institute for Water Resources, U.S. Army Corps of Engineers, ATTN: Mr. Paul D. Clouse,

Designated Federal Officer (DFO) for the Inland Waterways Users Board, CEIWR-NDC, 7701 Telegraph Road, Casey Building (Room 1-204), Alexandria, Virginia 22315-3868; by telephone at 202-768-3157; and by email at Paul.D.Clouse@usace.army.mil.

FOR FURTHER INFORMATION CONTACT:

Alternatively, contact Mr. Steven D. Riley, the Alternate Designated Federal Officer (ADFO), in writing at the Institute for Water Resources, U.S. Army Corps of Engineers, ATTN: CEIWR-GW, 7701 Telegraph Road, Casey Building, Alexandria, VA 22315-3868; by telephone at 703-659-3097; and by email at Steven.D.Riley@usace.army.mil.

SUPPLEMENTARY INFORMATION: The selection, service, and appointment of representative organizations to the Board are covered by provisions of section 302 of Public Law 99-662, as amended (33 U.S.C. 2251). The substance of those provisions is as follows:

a. Selection. Representative organizations are to be selected from the spectrum of commercial carriers and shippers using the inland and intracoastal waterways, to represent geographical regions, and to be representative of waterborne commerce as determined by commodity ton-mile statistics.

b. Service. The Board is required to meet at least semi-annually to develop and make recommendations to the Secretary of the Army on waterways construction and major rehabilitation priorities and spending levels for commercial navigation improvements; advise and make recommendations to Congress regarding any feasibility report for a project on the inland waterways that has been submitted to Congress; advise and make recommendations to Congress regarding an increase in the authorized cost of inland waterways features and components; advise and make recommendations to Congress regarding construction, rehabilitation, and spending levels after submission of the budget proposal of the President to Congress; and report its recommendations annually to the Secretary and Congress. Additionally, the Board provides advice and recommendations on the development of a twenty (20) year capital improvement program submitted to Congress every five (5) years.

c. Appointment. The operation of the Board and appointment of representative organizations are subject to chapter 10, 5 U.S.C. (commonly known as the Federal Advisory Committee Act) and departmental implementing regulations. Individuals

invited or appointed to serve on the Board, or its subcommittees must be U.S. citizens and are appointed pursuant to 33 U.S.C. 2251(f)(2). The members of the Board serve as representative members and shall be appointed pursuant to 41 CFR 102–3.130(a), and in accordance with DoD policy and procedures. Representative organizations serve without compensation but their expenses due to Board activities are reimbursable pursuant to 33 U.S.C. 2251(f)(3). The considerations specified in 33 U.S.C. 2251 for the selection of representative organizations to the Board, and certain terms used therein, have been interpreted, supplemented, or otherwise clarified as follows:

(1) *Carriers and Shippers.* 33 U.S.C. 2251 uses the terms “primary users and shippers.” Primary users have been interpreted to mean the providers of transportation services on inland waterways such as barge or towboat operators. Shippers have been interpreted to mean the purchasers of such services for the movement of commodities they own or control. Representative companies are appointed to the Board, and they must be either a carrier or shipper or both. For that purpose, a trade or regional association is neither a shipper nor primary user.

(2) *Geographical Representation.* The law specifies “various” regions. For the purposes of the Board, the waterways subjected to fuel taxes and described in Public Law 95–502, as amended, have been aggregated into six regions. They are (1) the Upper Mississippi River and its tributaries above the mouth of the Ohio; (2) the Lower Mississippi River and its tributaries below the mouth of the Ohio and above Baton Rouge; (3) the Ohio River and its tributaries; (4) the Gulf Intracoastal Waterway in Louisiana and Texas; (5) the Gulf Intracoastal Waterway east of New Orleans and associated fuel-taxed waterways including the Tennessee-Tombigbee, plus the Atlantic Intracoastal Waterway below Norfolk; and (6) the Columbia-Snake Rivers System and Upper Willamette. The intent is that each region shall be represented by at least one representative organization, with that representation determined by the regional concentration of the firm’s traffic on the waterways.

(3) *Commodity Representation.* Waterway commerce has been aggregated into six commodity categories based on “inland” ton-miles shown in Waterborne Commerce of the United States. These categories are (1) Farm and Food Products; (2) Coal and Coke; (3) Petroleum, Crude and Products; (4) Minerals, Ores, and

Primary Metals and Mineral Products; (5) Chemicals and Allied Products; and (6) All Other. A consideration in the selection of representative organizations to the Board will be that the commodities carried or shipped by those firms will be reasonably representative of the above commodity categories.

d. *Nomination.* Individuals, firms, or associations may nominate representative organizations to serve on the Board. Nominations will:

(1) Include the commercial operations of the carrier and/or shipper representative organization being nominated. This commercial operations information will show the actual or estimated ton-miles of each commodity carried or shipped on the inland waterways system in the most recent year (or years), using the waterway regions and commodity categories previously listed. Only ton-miles will be accepted.

(2) State the region(s) to be represented.

(3) State whether the nominated representative organization is a carrier, shipper or both.

(4) Provide the name of an individual to be the principal person representing the organization and information pertaining to their personal qualifications, to include a current within six months biography or resume.

Previous nominations received in responses to the published documents 2025–07787 (90 FR 18971) in the **Federal Register** filed on May 2, 2025, and 2025–13844 (90 FR 34645) in the **Federal Register** filed on July 23, 2025, will be retained for consideration. Previous nominations received prior to May 2, 2025, will not be retained for consideration.

e. *Deadline for Nominations.* All nominations must be received at the address shown above no later than January 9, 2025.

Stephen L. Hill,

Director, Operations and Regulatory Programs.

[FR Doc. 2025–23687 Filed 12–22–25; 8:45 am]

BILLING CODE 3720–58–P

ACTION: Approval of a limitation of the Randolph-Sheppard priority for the Department of the Army.

SUMMARY: The Secretary has found that the placement and operation of dining facilities (DFACs), through the Randolph-Sheppard priority, on Department of the Army installations adversely affects the interests of the United States. As such, the Secretary has approved a limitation of the Randolph-Sheppard priority for the Department of the Army’s DFAC contracts.

DATES: The limitation of the priority is approved on December 23, 2025. This limitation applies prospectively to DFAC contracts entered into by Department of the Army after the date of publication of this notice.

FOR FURTHER INFORMATION CONTACT: Christopher Pope, U.S. Department of Education, 400 Maryland Ave. SW, Room 4B104, Washington, DC 20202. Telephone: (202) 245–7375. Email: Christopher.Pope@ed.gov.

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Background

The Randolph-Sheppard Vending Facility Program provides entrepreneurs who are blind with opportunities to operate a business in competitive integrated employment consistent with the Rehabilitation Act of 1973, as amended by title IV of the Workforce Innovation and Opportunity Act. In 1936, Congress established the program, through the Randolph-Sheppard Act, to enhance employment opportunities for trained, licensed blind persons to operate vending facilities on federal and other properties. Blind vendors are licensed by State licensing agencies (SLAs); SLAs are typically State Vocational Rehabilitation (VR) agencies. Each state (except Wyoming), Puerto Rico, and the District of Columbia operate a Randolph-Sheppard Vending Facility Program. In FFY 2024, there were approximately 1,200 licensed blind vendors. For the Department of the Army specifically, 24 DFAC contracts, across 22 installations in the United States, are currently awarded to SLAs through the Randolph-Sheppard priority.

Authority

The Randolph-Sheppard Act, 20 U.S.C. 107 *et seq.*, and the Department’s regulations implementing it at 34 CFR part 395, establish a priority for

DEPARTMENT OF EDUCATION

34 CFR Part 395 Limitation of the Randolph-Sheppard Vending Facility Program Priority for the Department of the Army

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

operation of vending facilities and cafeterias on Federal properties by blind vendors licensed by SLAs, where such operation is feasible and would not adversely affect the interests of the United States. Upon justification provided by a Federal department or agency to the Secretary, and the Secretary's determination that placement or operation of a vending facility or cafeteria adversely affects the interests of the United States and thus justifies a limitation on such placement or operation, the limitation becomes effective upon publication by the Secretary in the **Federal Register**. 34 CFR 395.30(a) and (b).

Justification of Limitation

Based on information provided by the Department of the Army, the Secretary has determined that a limitation of the Randolph-Sheppard priority is justified for the Department of the Army's DFAC contracts. The Secretary acknowledges that the Randolph-Sheppard Vending Facility program, as applied to the Department of the Army's DFAC contracts, adversely affects the interests of the United States. Specifically, the Department of the Army's critical role in national security and the paramount importance of maintaining operational mission readiness of its service members necessitates removal of barriers that prevent the Department of the Army from being in the best position possible to conduct its procurements and manage its DFAC contracts. Based on the Department of the Army's representations, it is clear that the Randolph-Sheppard priority hinders the Department of the Army's ability to act swiftly, efficiently, and cost-effectively in procuring and managing DFAC contracts, which negatively impacts the availability and quality of food options for the nation's warfighters.

Higher Costs

Randolph-Sheppard regulations at 34 CFR 395.33(b) stipulate that when a proposal submitted by an SLA for the operation of a DFAC is determined to be within the competitive range, the agency shall consult with the Secretary as described in 34 CFR 395.33(a). The Secretary considered that the Department of the Army reported an instance where a DFAC contract had a 33 percent higher price differential and a cumulative difference of \$164 million more when comparing lowest price technically acceptable proposals with some proposals made by SLAs over a five-year period. The higher costs from applying the Randolph-Sheppard priority may also have the adverse effect of decreasing funds available for other

investments critical to ensuring service member readiness. According to the Department of the Army, this requirement has stifled its ability to select a vendor proposing innovative approaches and process improvements, better service, and cost savings. The Secretary thus has determined, after consultation with the Department of the Army, that operation of DFACs subject to a Randolph-Sheppard priority cannot be provided at a reasonable cost.

Arbitration Delays

SLAs are afforded the right to arbitration in the Randolph-Sheppard Act. On average, the Department of the Army has faced arbitrations that last 801 days resulting in significant delays in awarding DFAC contracts. The Secretary considers it unreasonable to expect the Department of the Army to be entangled in any DFAC contract arbitration that could last for more than two years. The Secretary believes this is an unreasonable burden to place on the Department of the Army, thus a limitation on applicability of the Act for Department of the Army DFAC contracts is justified.

Performance Issues

The Department of the Army conveyed various examples of performance issues with Randolph-Sheppard DFAC contracts including nutrition (e.g., not including nutritional menu standards and serving meals that do not meet requirements) and sanitation (e.g., cross-contamination of food and improper labeling). Other reported performance issues include food safety (e.g., foreign objects in food) and lack of documented employee training related to safety and sanitation.

Conclusion

For these reasons, the Secretary has concluded that a limitation of the Randolph-Sheppard priority is justified for future DFAC contracts competed by the Department of the Army. The Secretary notes that blind vendors may still bid for DFAC contracts even if there is no Randolph-Sheppard priority in place.

Accessible Format: On request to the program contact listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is

the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at www.govinfo.gov. At this site you can view this document, as well as all other Department documents published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access Department documents published in the **Federal Register** by using the article search feature at www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Linda McMahon,

Secretary of Education.

[FR Doc. 2025-23761 Filed 12-22-25; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2025-SCC-0548]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Foreign Schools Eligibility Criteria Apply To Participate in Title IV HEA Programs

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an extension without change of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before January 22, 2026.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link www.reginfo.gov/public/do/PRAMain to access the site. Find this information collection request (ICR) by selecting "Department of Education" under "Currently Under Review," then check the "Only Show ICR for Public Comment" checkbox. Reginfo.gov provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the "View Information Collection (IC) List" link. Supporting statements and other supporting

documentation may be found by clicking on the “View Supporting Statement and Other Documents” link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Carolyn Rose, (202) 453–5967.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Foreign Schools Eligibility Criteria Apply to Participate in Title IV HEA Programs.

OMB Control Number: 1845–0105.

Type of Review: Extension without change of a currently approved ICR.

Respondents/Affected Public: Individual and Households; Private Sector.

Total Estimated Number of Annual Responses: 27,578.

Total Estimated Number of Annual Burden Hours: 8,023.

Abstract: This request is for an extension of the information collection of the requirements in the policies and procedures related to the eligibility of foreign schools to apply to participate in Title IV, HEA programs that were added by the Higher Education Opportunity Act of 2008 (HEOA). The information in 34 CFR 600.54, 600.55, 600.56, and 600.57 is used by the Department during the initial review for eligibility certification, recertification and annual evaluations. These regulations help to ensure that all foreign institutions participating in the Title IV, HEA programs are meeting the minimum participation standards.

Ross Santy,

Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2025–23733 Filed 12–22–25; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket ID ED–2025–FSA–0811]

Privacy Act of 1974; Matching Program

AGENCY: Federal Student Aid, U.S. Department of Education.

ACTION: Notice of a new matching program.

SUMMARY: Pursuant to the Privacy Act of 1974, as amended by the Computer Matching and Privacy Protection Act of 1988 and the Computer Matching and Privacy Protection Amendments of 1990 (Privacy Act), and Office of Management and Budget (OMB) guidance on the conduct of matching programs, notice is hereby given of the re-establishment of the matching program between the U.S. Department of Education (Department), as the recipient agency, and the U.S. Department of the Treasury (Treasury), Internal Revenue Service (IRS), as the source agency, for the purpose of determining eligibility for, or the amount of repayments of obligations under, Income-Driven Repayment (IDR) plans, the Direct Loan Program, and determining eligibility for and the amount of Federal student financial aid under the Pell Grant Program, Federal Work-Study (FWS) Program, and the Federal Supplemental Educational Opportunity Grant (FSEOG) Program, under the authority of the Fostering Undergraduate Talent by Unlocking Resources for Education Act (FUTURE Act), Public Law 116–91, 133 Stat. 1189–1197 (2019), as amended by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116–136, 134 Stat. 281–615 (2020), and the FAFSA Simplification Act, title VII of division FF of Public Law 116–260, 134 Stat. 3137–3201 (2020) (which is part of the Consolidated Appropriations Act, 2021), as amended by the FAFSA Simplification Act Technical Corrections Act, division R of Public Law 117–103, 136 Stat. 819–821 (2022) (which is part of the Consolidated Appropriations Act, 2022).

DATES: The period of this matching program is estimated to cover the 18-month period from January 30, 2026 through July 29, 2027. However, the matching program will become applicable at the later of the following two dates: January 30, 2026, or 30 days after the publication of this notice, on December 23, 2025, unless comments have been received from interested members of the public requiring modification and republication of the notice. The matching program will continue for 18 months after the applicable date and may be extended for

up to an additional 12 months, if the Data Integrity Boards (DIBs) of ED and Treasury determine that the conditions specified in 5 U.S.C. 552a(o)(2)(D) have been met.

ADDRESSES: Comments must be submitted via the Federal eRulemaking Portal at [regulations.gov](https://www.regulations.gov). However, if you require an accommodation or cannot otherwise submit your comments via [regulations.gov](https://www.regulations.gov), please contact the program contact person listed under **FOR FURTHER INFORMATION CONTACT**. The Department will not accept comments submitted by fax or by email, or comments submitted after the comment period. To ensure that the Department does not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

■ *Federal eRulemaking Portal:* Go to www.regulations.gov to submit your comments electronically. Information on using [Regulations.gov](https://www.regulations.gov), including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under “FAQ”.

Privacy Note: The Department’s policy is generally to make comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at <http://www.regulations.gov>. Therefore, commenters should include in their comments only information about themselves that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Corinne Sauri, Program Analyst, U.S. Department of Education, Federal Student Aid, 400 Maryland Ave. SW, Washington, DC 20024. Telephone: (202) 245–6412.

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION: In accordance with the Privacy Act, OMB “Final Guidance Interpreting the Provisions of Public Law 100–503, the Computer Matching and Privacy Protection Act of 1988,” published in the **Federal Register** on June 19, 1989 (54 FR 25818–25829), and OMB Circular No. A–108, notice is hereby provided of the re-establishment of a matching program between the IRS and the Department pursuant to which the IRS will disclose to the Department certain FTI of an individual, upon approval being provided by the individual to the Department, for the purpose of determining eligibility for, or repayment obligations under, IDR plans under title

IV of the HEA with respect to loans under part D of title IV of the HEA; and determining eligibility for, and amount of, Federal student financial aid under the Pell Grant Program authorized under subpart 1 of part A of Title IV of the HEA, FWS Program, and the FSEOG Program authorized under part C of title IV of the HEA or the Direct Loan Program, as set forth in IRC 6103(l)(13)(A) and (C).

The FTI that the IRS discloses to the Department under sections 6103(l)(13)(A) and (C) of the IRC may also be used by ED for the purposes of: (a) reducing the net cost of improper payments: (i) under IDR plans and (ii) relating to awards of Federal student financial aid under the Pell Grant, FWS and Direct Loan programs; (b) oversight by the Department's OIG as authorized by chapter 4 of title 5 of the United States Code, except for the purpose of conducting criminal investigations or prosecutions; and (c) conducting analyses and forecasts for estimating costs related to: (i) IDR plans and (ii) awards of Federal student financial aid under a program authorized under the Pell Grant, FWS and Direct Loan programs, as set forth in IRC § 6103(l)(13)(D). The FTI will not be duplicated or redisclosed for these uses.

Participating Agencies

U.S. Department of Education (Department) and the U.S. Department of the Treasury, Internal Revenue Service (IRS).

Authority for Conducting the Matching Program

This matching program is authorized by the FUTURE Act, as amended. The FUTURE Act amended section 6103(l)(13) of the IRC to authorize the IRS to disclose to ED certain FTI for the purposes set forth in the **SUPPLEMENTARY INFORMATION** section of this Notice provided certain conditions are satisfied. In addition, 5 U.S.C. 552a(b)(3) provides authority for the IRS to disclose Privacy Act-protected records to the Department pursuant to a published routine use in an applicable system of records notice for a purpose that is compatible with the purposes for which the IRS collected the records. Further, the Department is authorized to participate in the matching program pursuant to the HEA, including sections 483 and 494(a) and (b) of the HEA (20 U.S.C. 1090 and 1098h(a) and (b)) and the FUTURE Act.

Purpose(s)

The purpose of this matching program between the IRS and the Department is for the IRS to disclose to the Department

certain FTI of an individual, upon approval being provided by the individual to the Department, for determining eligibility for, or repayment obligations under, IDR plans under title IV of the HEA with respect to loans under part D of title IV of the HEA; and determining eligibility for, and amount of, Federal student financial aid under a program authorized under subpart 1 of part A, part C, or part D of title IV of the HEA.

The FTI that the IRS discloses to ED under sections 6103(l)(13)(A) and (C) of the IRC may also be used by the Department for the purposes of: (a) reducing the net cost of improper payments: (i) under IDR plans and (ii) relating to awards of Federal student financial aid under the Pell Grant, FWS and Direct Loan programs; (b) oversight by ED's OIG as authorized by chapter 4 of title 5 of the United States Code, except for the purpose of conducting criminal investigations or prosecutions; and (c) conducting analyses and forecasts for estimating costs related to: (i) IDR plans and (ii) awards of Federal student financial aid under a program authorized under the Pell Grant, FWS and Direct Loan programs, as set forth in IRC § 6103(l)(13)(D). The FTI will not be duplicated or redisclosed for these uses.

The FTI information that the Department will obtain as a result of this matching program effectuates the purpose of the HEA because it provides an efficient and comprehensive match to determine eligibility for, and the amount of, Federal student financial aid under a program authorized under subpart 1 of part A, part C, or part D of title IV of the HEA, and eligibility for, or repayment obligations under, IDR plans for loans under the Federal Direct Loan Program.

Categories of Individuals

This matching program covers students (including a student's spouse for an independent student and a student's parent(s) for dependent student) who apply for Federal student financial assistance under title IV of the HEA through the Free Application for Federal Student Aid (FAFSA®) and borrowers (including spouses of borrowers who are independent students) who have had a loan disbursed and are fully responsible to pay the loan and interest back to the loan holder under applicable Federal student loan programs administered under the authority of title IV of the HEA, or who have such a loan written off due to default. This matching program also includes as a "borrower" an individual who is responsible for

completing a service obligation and fails to complete the service obligation in exchange for having received a grant under the Teacher Education Assistance for College and Higher Education (TEACH) Grant Program authorized under subpart 9 of part A of title IV of the HEA.

Categories of Records

This matching program covers the following categories of records:

(1) An applicant's information submitted to the Department to determine the applicant's eligibility for Federal student financial assistance under a program authorized under subpart 1 of part A, part C, or part D of title IV of the HEA;

(2) A borrower's information submitted to ED to determine the borrower's eligibility for, or repayment obligations under, IDR plans under title IV of the HEA with respect to loans under part D of title IV of the HEA;

(3) An applicant's approval and consent submitted to ED to process an application for determining eligibility for Federal student financial assistance under a program authorized under subpart 1 of part A, part C, or part D of aid under title IV of the HEA;

(4) A borrower's approval and consent submitted to ED to process an application for determining eligibility for, or repayment obligations under, IDR plans under title IV of the HEA with respect to loans under part D of title IV of the HEA; and

(5) FTI on individuals from the IRS' Customer Account Data Engine (CADE) Individual Master File.

More specifically, the Department will transmit the following specific data elements to the IRS under the matching program:

(1) Social Security Number (SSN)/Taxpayer Identification Number (TIN);
(2) Tax year for which FTI is required;
(3) Last name;
(4) Date of birth (DOB);
(5) Unique identifier; and
(6) Date/time stamp of the individual's approval for use of FTI in determining eligibility by ED.

In addition, in response to a valid request submitted by ED to the IRS pursuant to section 6103(l)(13)(A) of the IRC (IDR request) that matches a tax record for the requested SSN/TIN and tax year, the IRS will return the following specific data elements to ED:

(1) SSN/TIN (provided in the request);
(2) Tax year (associated with FTI provided);
(3) Last name;
(4) Filing status code;
(5) Adjusted gross income (AGI) amount;

- (6) Total number of exemptions; and
- (7) Total number of dependents.

Further, in response to a valid request submitted by ED to the IRS pursuant to section 6103(l)(13)(C) of the IRC (FAFSA request) that matches a tax record for the requested SSN/TIN and tax year, the IRS will return the following specific data elements to ED:

- (1) SSN/TIN (provided in the request);
- (2) Tax year (provided in the request);
- (3) Last name (provided in the request);
- (4) Filing status code;
- (5) AGI amount;
- (6) Total number of exemptions;
- (7) Total number of dependents;
- (8) Income earned from work (sum of wages, farm income, Schedule C income);
- (9) Total amount of income tax paid;
- (10) Total allowable education credits;
- (11) Sum of untaxed IRA contributions and other payments to qualified plans;
- (12) Total amount of untaxed IRA distributions;
- (13) Tax exempt interest;
- (14) Sum of untaxed pensions and annuities;
- (15) Net profit/loss from Schedule C; and
- (16) Indicator of filing for Schedules A, B, D, E, F, and H.

System(s) of Records

The Department will disclose, with written consent, to the IRS information under this matching program from the Department's systems of records notice entitled "FUTURE Act System (FAS)" (18-11-23), published in the **Federal Register** on June 29, 2023 (88 FR 42220-42226).

The IRS will disclose to the Department FTI under this matching program from the IRS's system of records notice entitled "Customer Account Data Engine (CADE) Individual Master File (IMF)—Treasury/IRS" (Treasury/IRS 24.030), published in the **Federal Register** on September 8, 2015 (80 FR 54082-54083).

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

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You may also access documents of the Department published in the **Federal Register** by using the article search feature at www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Richard Lucas,

Acting Chief Operating Officer, Federal Student Aid.

[FR Doc. 2025-23632 Filed 12-22-25; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2025-SCC-0581]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Guaranty Agencies Security Self-Assessment and Attestation

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a revision of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before January 22, 2026.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link www.reginfo.gov/public/do/PRAMain to access the site. Find this information collection request (ICR) by selecting "Department of Education" under "Currently Under Review," then check the "Only Show ICR for Public Comment" checkbox. Reginfo.gov provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the "View Information

Collection (IC) List" link. Supporting statements and other supporting documentation may be found by clicking on the "View Supporting Statement and Other Documents" link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Carolyn Rose, 202-453-5967.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Guaranty Agencies Security Self-assessment and Attestation.

OMB Control Number: 1845-0134.

Type of Review: A revision of a currently approved ICR.

Respondents/Affected Public: Private Sector.

Total Estimated Number of Annual Responses: 11.

Total Estimated Number of Annual Burden Hours: 6,226.

Abstract: This is a request for a revision of the approved information collection used by Federal Student Aid (FSA) to ensure that all data collected and managed by Guaranty Agencies (GAs) in support federal student financial aid programs is secure. FSA continues to use a formal assessment program that ensures the GAs have security protocols in place to protect the confidentiality and integrity of data entrusted to FSA by students and families. This assessment will identify security deficiencies based on the federal standards described in the National Institute of Standards and Technology (NIST) publications.

Ross Santy,

Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2025-23734 Filed 12-22-25; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY**[Docket No. 25–155–LNG]****ST LNG, LLC; Application for Long-Term Authorization To Export Liquefied Natural Gas to Non-Free Trade Agreement Nations****AGENCY:** Office of Fossil Energy and Carbon Management, Department of Energy.**ACTION:** Notice of application.

SUMMARY: The Office of Fossil Energy and Carbon Management (FECM) of the Department of Energy (DOE) gives notice (Notice) of receipt of an application (Application), filed by ST LNG, LLC (ST LNG) on December 10, 2025. ST LNG requests long-term, multi-contract authorization to export domestically produced liquefied natural gas (LNG) in a volume equivalent to approximately 460 billion cubic feet (Bcf) of natural gas per year (Bcf/yr). ST LNG seeks to export this LNG from its proposed deepwater port (DWP) export terminal project, the ST LNG DWP Development Project (Project), to be located off the southeast coast of Matagorda, Texas, in the Gulf of America. ST LNG filed the Application under the Natural Gas Act (NGA).

DATES: Protests, motions to intervene, or notices of intervention, as applicable, and written comments are to be filed electronically as detailed in the Public Comment Procedures section no later than 4:30 p.m., Eastern time, February 23, 2026.

ADDRESSES:

Electronic Filing by email (Strongly encouraged): fergas@hq.doe.gov.

Postal Mail, Hand Delivery, or Private Delivery Services (e.g., FedEx, UPS, etc.): U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Fossil Energy and Carbon Management, Forrestal Building, Room 3E–056, 1000 Independence Avenue SW, Washington, DC 20585.

Due to potential delays in DOE's receipt and processing of mail sent through the U.S. Postal Service, we encourage respondents to submit filings electronically to ensure timely receipt.

FOR FURTHER INFORMATION CONTACT:

Jennifer Wade or Peri Ulrey, U.S. Department of Energy (FE–34) Office of Regulation, Analysis, and Engagement, Office of Resource Sustainability, Office of Fossil Energy and Carbon Management, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–4749 or (202) 586–7893, jennifer.wade@hq.doe.gov or peri.ulrey@hq.doe.gov.

Cassandra Bernstein, U.S. Department of Energy (GC–76) Office of the Assistant General Counsel for Energy Delivery and Resilience, Forrestal Building, Room 6D–033, 1000 Independence Avenue SW, Washington, DC 20585, (240) 780–1691, cassandra.bernstein@hq.doe.gov.

SUPPLEMENTARY INFORMATION: ST LNG requests authorization to export domestically produced LNG from its proposed Project to be located at Brazos Block BA–476 in Federal waters in the Gulf of America, offshore of Matagorda, Texas. ST LNG states that the Project will be a deepwater port under the Deepwater Port Act of 1974, as amended. ST LNG seeks to export LNG in a volume equivalent to 460 Bcf/yr of natural gas (equivalent to approximately 8.4 million metric tons per annum) by ocean-going vessel on a non-additive basis to: (i) any country with which the United States has entered into a free trade agreement (FTA) requiring national treatment for trade in natural gas (FTA countries), and (ii) any other country with which trade is not prohibited by U.S. law or policy (non-FTA countries). This Notice applies only to the portion of the Application requesting authority to export LNG to non-FTA countries pursuant to section 3(a) of the NGA.¹ DOE will review ST LNG's request for authorization to export LNG to FTA countries separately pursuant to NGA section 3(c).²

ST LNG seeks this authorization on its own behalf and as agent for other entities that will hold title to the LNG at the time of export. ST LNG requests the authorization for a term to commence on the date of first export following the commencement of commercial operation of the Project, and to extend through December 31, 2050, plus a three-year Make-Up Period extending through December 31, 2053, consistent with recent DOE practice.

Additional details can be found in ST LNG's Application, posted on the DOE website at https://www.energy.gov/sites/default/files/2025-12/12-05-25_ST%20LNG_DOE%20FTA-NFTA%20Application%20-Executed.pdf.

DOE Evaluation

In reviewing the Application, DOE will consider any issues required by law or policy under NGA section 3(a), DOE's regulations, and any other documents deemed appropriate.

Parties that may oppose the Application should address these issues and documents in their comments and/

or protests, as well as other issues deemed relevant to the Application.

The National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.*, requires DOE to give appropriate consideration to the environmental effects of its proposed decisions. No final decision will be issued in this proceeding until DOE has met its NEPA responsibilities.

Public Comment Procedures

In response to this Notice, any person may file a protest, comments, or a motion to intervene or notice of intervention, as applicable, addressing the Application. Interested parties will be provided 60 days from the date of publication of this Notice in the **Federal Register** in which to submit comments, protests, motions to intervene, or notices of intervention.

Any person wishing to become a party to this proceeding evaluating the Application must file a motion to intervene or notice of intervention.³ The filing of comments or a protest with respect to the Application will not serve to make the commenter or protestant a party to this proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the Application. All protests, comments, motions to intervene, or notices of intervention must meet the requirements specified by DOE's regulations in 10 CFR part 590, including the service requirements.

Filings may be submitted using one of the following methods:

(1) Submitting the filing electronically at fergas@hq.doe.gov;

(2) Mailing the filing to the Office of Regulation, Analysis, and Engagement at the address listed in the **ADDRESSES** section; or

(3) Hand delivering the filing to the Office of Regulation, Analysis, and Engagement at the address listed in the **ADDRESSES** section.

For administrative efficiency, DOE prefers filings to be filed electronically. All filings must include a reference to “Docket No. 25–155–LNG” or “ST LNG, LLC Application” in the title line. Filings must be submitted in English to be considered.⁴

For electronic submissions: Please include all related documents and attachments (e.g., exhibits) in the original email correspondence. Please do not include any active hyperlinks or

³ 10 CFR 590.303.

⁴ Executive Order 14224 of March 1, 2025, *Designating English as the Official Language of the United States*, 90 FR 11363 (Mar. 6, 2025).

¹ 15 U.S.C. 717b(a).

² *Id.* 717b(c).

password protection in any of the documents or attachments related to the filing. All electronic filings submitted to DOE must follow these guidelines to ensure that all documents are filed in a timely manner.

The Application, and any filed protests, motions to intervene, notices of intervention, and comments will be available electronically on the DOE website at www.energy.gov/fecm/regulation.

A decisional record on the Application will be developed through responses to this Notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final Order may be issued based on the official record, including the Application and responses filed by parties pursuant to this Notice, in accordance with 10 CFR 590.316.

Signed in Washington, DC, on December 19, 2025.

Amy Sweeney,

Director, Office of Regulation, Analysis, and Engagement, Office of Resource Sustainability.

[FR Doc. 2025-23763 Filed 12-22-25; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

National Coal Council Meeting

AGENCY: Office of Fossil Energy and Carbon Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the National Coal Council. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Thursday, January 15, 2026; 11 a.m. to no later than 12 noon (EST).

ADDRESSES: White House Executive Studios and Conference Centers (ESCC), Indian Treaty Room, Room 474, Eisenhower Executive Office Building, 1650 17th Street NW, Washington, DC 20500. In-person meeting. Information to access a live stream of the meeting proceedings will be available at: <https://nationalcoalcouncil.energy.gov/ncc>.

FOR FURTHER INFORMATION CONTACT: Tom Sarkus, U.S. Department of Energy, National Energy Technology Laboratory; telephone: (412) 386-5981 or email:

thomas.sarkus@netl.doe.gov or telephone (412) 386-5981.

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: To provide advice, information, and recommendations to the Secretary of Energy on matters relating to coal and the coal industry.

Purpose of the Meeting: The National Coal Council will hold a meeting on January 12, 2026, to present government representatives and members.

Tentative Agenda:

- Welcome from the White House and Meeting Room Logistics;
- Welcome and Congratulatory Remarks from the Secretary of Energy;
- Remarks from the Assistant Secretary of Fossil Energy and Carbon Management;
- Introduction of National Coal Council Members;
- Public Statements, if any; and
- Dismissal.

Public Participation: The meeting is accessible to the public via live stream. The Chair of the Council will conduct the meeting to facilitate the orderly conduct of business. Members of the public who wish to make oral statements pertaining to agenda items should contact Mr. Tom Sarkus at the email address or telephone number listed above. Approximately 10 minutes will be reserved for public comments. The time allocated per speaker will depend on the number of requests received but will not exceed five minutes. Requests for oral statements must be received at least seven days prior to the meeting. Those not able to attend the meeting or having insufficient time to address the Council are invited to send a written statement to thomas.sarkus@netl.doe.gov. Any member of the public who wishes to file a written statement to the Council will be permitted to do so, either before or after the meeting.

Minutes: The minutes of the meeting will be available at <https://nationalcoalcouncil.energy.gov/ncc> or by contacting Mr. Sarkus. He may be reached at the email address or telephone number listed previously.

Signing Authority: This document of the Department of Energy was signed on December 19, 2025, by David Borak, Committee Management Officer, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the

document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on December 19, 2025.

Jennifer Hartzell,

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

[FR Doc. 2025-23766 Filed 12-22-25; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

[Docket No. 20-31-LNG]

Epsilon LNG LLC; Request for Extension of Export Commencement Deadline

AGENCY: Office of Fossil Energy and Carbon Management, Department of Energy.

ACTION: Notice of request.

SUMMARY: The Office of Fossil Energy and Carbon Management (FECM) (formerly the Office of Fossil Energy (FE)) of the Department of Energy (DOE) gives notice (Notice) of receipt of a request (Request), filed on December 15, 2025, by Epsilon LNG LLC (Epsilon). Epsilon asks DOE to amend its existing authorization to re-export U.S.-sourced natural gas in the form of liquefied natural gas (LNG) from the proposed Amigo LNG export terminal project (Project), to be located in Guaymas, Sonora, Mexico, to non-free trade agreement countries set forth in DOE/FE Order No. 4629 (as amended)—specifically, to extend its current export commencement deadline. Epsilon filed the Request under the Natural Gas Act (NGA).

DATES: Protests, motions to intervene, or notices of intervention, as applicable, and written comments are to be filed electronically as detailed in the Public Comment Procedures section no later than 4:30 p.m., Eastern time, January 22, 2026.

ADDRESSES:

Electronic Filing by email (Strongly encouraged): fergas@hq.doe.gov.

Postal Mail, Hand Delivery, or Private Delivery Services (e.g., FedEx, UPS, etc.), U.S. Department of Energy (FE-34), Office of Regulation, Analysis, and Engagement, Office of Fossil Energy and Carbon Management, Forrestal Building, Room 3E-056, 1000 Independence Avenue SW, Washington, DC 20585.

Due to potential delays in DOE's receipt and processing of mail sent through the U.S. Postal Service, we

encourage respondents to submit filings electronically to ensure timely receipt.

FOR FURTHER INFORMATION CONTACT:

Jennifer Wade or Peri Ulrey, U.S.

Department of Energy (FE–34) Office of Regulation, Analysis, and Engagement, Office of Resource Sustainability, Office of Fossil Energy and Carbon Management, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–4749 or (202) 586–7893, jennifer.wade@hq.doe.gov or peri.ulrey@hq.doe.gov.

Cassandra Bernstein, U.S. Department of Energy (GC–76) Office of the Assistant General Counsel for Energy Delivery and Resilience, Forrestal Building, Room 6D–033, 1000 Independence Avenue SW, Washington, DC 20585, (240) 780–1691, cassandra.bernstein@hq.doe.gov.

SUPPLEMENTARY INFORMATION: On

December 8, 2020, in Order No. 4629, as amended (and as relevant here),¹ DOE authorized Epsilon to re-export U.S.-sourced natural gas in the form of LNG in a volume equivalent to 395 billion cubic feet (Bcf) per year (Bcf/yr) of natural gas by vessel from the proposed Project, to be located in the State of Sonora, Mexico, to any country with which the United States has not entered into a free trade agreement (FTA) requiring national treatment for trade in natural gas, and with which trade is not prohibited by U.S. law or policy (non-FTA countries), pursuant to NGA section 3(a).² Epsilon is authorized to re-export this LNG for a term of 20 years.³

Under Order No. 4629, Epsilon is required to “commence . . . re-export operations using the planned LNG Facility no later than seven years from the date of issuance of this Order”—*i.e.*, by December 8, 2027.⁴ In the Request, Epsilon asks DOE to grant a 24-month extension of the export commencement deadline set forth in Order No. 4629, thus “extending the current deadline from December 8, 2027 to December 8, 2029.”⁵

In support of this Request, Epsilon states that it “continues to make substantial progress in advancing the project, but [that] in the past, it has encountered significant and unforeseen delays due to global macroeconomic and geopolitical disruptions.”⁶ Epsilon asserts that these delays have been fully resolved, and Epsilon “intends to take FID (Final Investment Decision) in early Q1 2026” for the Project.⁷ Therefore, according to Epsilon, the requested commencement extension will enable the Project to reach FID and proceed to the construction phase.⁸ Epsilon adds that the Request is limited solely to an extension of time and does not seek any modification to the scope, configuration, or nature of the Project.⁹

Additional details can be found in the Request, posted on the DOE website at https://www.energy.gov/sites/default/files/2025-12/Epsilon%20LNG%20LLC%20%28FE%20DOCKET%20NO%20%2020_31_LNG%29%20Request%20for%20Extension%2012122025%20%28003%29.pdf.

DOE Evaluation

In reviewing the Request, DOE will consider any issues required by law or policy under NGA section 3(a), DOE’s regulations, and any other documents deemed appropriate.

Parties that may oppose the Request should address these issues and documents in their comments and/or protests, as well as other issues deemed relevant to the Request.

The National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.*, requires DOE to give appropriate consideration to the environmental effects of its proposed decisions. No final decision will be issued in this proceeding until DOE has met its NEPA responsibilities.

Public Comment Procedures

In response to this Notice, any person may file a protest, comments, or a motion to intervene or notice of intervention, as applicable, addressing the Request. Interested parties will be

provided 30 days from the date of publication of this Notice in the **Federal Register** in which to submit comments, protests, motions to intervene, or notices of intervention. The public previously was given an opportunity to intervene in, protest, and comment on Epsilon’s long-term non-FTA application in this docket. Therefore, DOE will not consider comments or protests that do not bear directly on this Request.

Any person wishing to become a party to this proceeding evaluating Epsilon’s Request must file a motion to intervene or notice of intervention.¹⁰ The filing of comments or a protest with respect to the Request will not serve to make the commenter or protestant a party to this proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the Request. All protests, comments, motions to intervene, or notices of intervention must meet the requirements specified by DOE’s regulations in 10 CFR part 590, including the service requirements.

Filings may be submitted using one of the following methods:

(1) Submitting the filing electronically at fergas@hq.doe.gov;

(2) Mailing the filing to the Office of Regulation, Analysis, and Engagement at the address listed in the **ADDRESSES** section; or

(3) Hand delivering the filing to the Office of Regulation, Analysis, and Engagement at the address listed in the **ADDRESSES** section.

For administrative efficiency, DOE prefers filings to be filed electronically. All filings must include a reference to “Docket No. 20–31–LNG” or “Epsilon Request for Extension” in the title line. Filings must be submitted in English to be considered.¹¹

For electronic submissions: Please include all related documents and attachments (*e.g.*, exhibits) in the original email correspondence. Please do not include any active hyperlinks or password protection in any of the documents or attachments related to the filing. All electronic filings submitted to DOE must follow these guidelines to ensure that all documents are filed in a timely manner.

¹ *Epsilon LNG LLC*, DOE/FE Order No. 4629, Docket No. 20–31–LNG, Opinion and Order Granting Long-Term Authorization to Export Natural Gas to Mexico for Liquefaction, and to Re-Export U.S.-Sourced Natural Gas in the Form of Liquefied Natural Gas from Mexico to Free Trade Agreement and Non-Free Trade Agreement Countries (Dec. 8, 2020), *amended* by DOE/FE Order No. 4629–A (May 6, 2021) (amending order to correct monthly reporting obligations).

² 15 U.S.C. 717b(a).

³ See *Epsilon LNG LLC*, DOE/FE Order No. 4629, at 55 (Ordering Para. A).

⁴ *Id.* at 56 (Ordering Para. F).

⁵ *Epsilon LNG LLC*, Request for Amendment of Long-Term Authorizations to Export Liquefied

Natural Gas to FTA and Non-FTA Countries and for Extension of Time to Commence Exports, Docket No. 20–31–LNG, at 6 (Dec. 15, 2025) [hereinafter Request]; see also *id.* at 1–2, 9. The Request also applies to Epsilon’s FTA authorization in the same docket, but DOE will address the FTA portion of the Application separately pursuant to NGA section 3(c), 15 U.S.C. 717b(c).

⁶ Request at 1.

⁷ *Id.*

⁸ *Id.* at 9.

⁹ *Id.* Epsilon also requests that DOE amend its authorization “to reflect the updated project development and construction schedule.” Request at 6.

¹⁰ Status as an intervenor in prior proceeding(s) in this docket does not continue to this proceeding evaluating Epsilon’s Request, and therefore any person interested in intervening to address the Request must file a new motion to intervene (or notice of intervention, as applicable). 10 CFR 590.303.

¹¹ Executive Order 14224 of March 1, 2025, *Designating English as the Official Language of the United States*, 90 FR 11363 (Mar. 6, 2025).

The Request, and any filed protests, motions to intervene, notices of intervention, and comments will be available electronically on the DOE website at www.energy.gov/fecm/regulation.

A decisional record on the Request will be developed through responses to this Notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final Order may be issued based on the official record, including the Request and responses filed by parties pursuant to this Notice, in accordance with 10 CFR 590.316.

Signed in Washington, DC, on December 18, 2025.

Amy Sweeney,

Director, Office of Regulation, Analysis, and Engagement, Office of Resource Sustainability.

[FR Doc. 2025–23764 Filed 12–22–25; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: PR26–21–000.

Applicants: Northwest Natural Gas Company.

Description: 284.123 Rate Filing: Revised Statement of Operating Conditions to be effective 1/16/2026.

Filed Date: 12/17/25.

Accession Number: 20251217–5293.

Comment Date: 5 p.m. ET 1/7/26.

Docket Numbers: RP26–306–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: Compliance filing: Rate Schedule S–2 OFO Refund Report October 2025 to be effective N/A.

Filed Date: 12/18/25.

Accession Number: 20251218–5122.

Comment Date: 5 p.m. ET 12/30/25.

Docket Numbers: RP26–307–000.

Applicants: Ovintiv Marketing Inc., NuVista Energy Ltd.

Description: Joint Petition for Limited Waiver of Capacity Release Regulations, et al. of Ovintiv Marketing Inc., et al.

Filed Date: 12/18/25.

Accession Number: 20251218–5167.

Comment Date: 5 p.m. ET 12/30/25.

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.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercensearch.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.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

Dated: December 18, 2025.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2025–23703 Filed 12–22–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1988–105]

Pacific Gas & Electric Company; Notice of Application for a Flow Variance Under Article 401 Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Application for Temporary Variance of Minimum Flow Releases into Helms Creek.

b. *Project No:* 1988–105.

c. *Date Filed:* October 14, 2025; supplemented on October 22, 2025, and November 26, 2025.

d. *Applicant:* Pacific Gas & Electric Company.

e. *Name of Project:* Haas-Kings River Hydroelectric Project.

f. *Location:* The project is located on the North Fork Kings River in Fresno County, California. The project occupies

federal lands managed by the U.S. Forest Service, U.S. Corps of Engineers, and Bureau of Land Management.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Tiffany Begaye; P.O. Box 28209, Oakland, California 94604; T9BC@pge.com; and (559) 955–7135.

i. *FERC Contact:* Katherine Schmidt; (415) 369–3348; and katherine.schmidt@ferc.gov.

j. *Cooperating agencies:* With this notice, the Commission is inviting federal, state, local, and Tribal agencies with jurisdiction and/or special expertise with respect to environmental issues affected by the proposal, that wish to cooperate in the preparation of any environmental document, if applicable, to follow the instructions for filing such requests described in item k below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of any environmental document cannot also intervene. See 94 FERC ¶ 61,076 (2001).

k. *Deadline for filing comments, motions to intervene, and protests:* January 16, 2026, 5:00 p.m. Eastern Time.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. 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, MD 20852. The first page of any filing should include the docket number P–1988–105. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project.

Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

l. *Description of Request:* The licensee requests a temporary variance of the release requirements under Article 401 that require it, in part, to release from Courtright Dam into Helms Creek a minimum flow of 4 cubic feet per second (cfs) from June 1 through November 30, as measured at gaging station downstream of the dam (KI-17). With the variance, the licensee proposes to reduce flow released into Helms Creek to 2.5 cfs September 1 through November 30, 2026, with compliance assessed by a 24-hour average of measurements taken by KI-17. In addition, though Courtright Reservoir does not have a license-required minimum elevation, the licensee advises they will draw down the reservoir to an elevation of 8,000 feet, with an impoundment of 2,283 acre-feet, from September 1 through December 31, 2026. The licensee states that the requested variance and reservoir drawdown is necessary to complete repair and replacement projects related to maintaining Courtright Dam, its low-level outlet bypass valve, and the KI-17 weir.

m. *Locations of the Application:* This filing may be viewed on the Commission's website at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1-866-208-3676 or email FEROnlineSupport@ferc.gov, for TTY, call (202) 502-8659. Agencies may obtain copies of the application directly from the applicant.

n. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

o. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's

Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

p. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

q. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502-6595 or OPP@ferc.gov.

(Authority: 18 CFR 2.1)

Dated: December 17, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025-23642 Filed 12-22-25; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RD25-10-000]

Commission Information Collection Activities (FERC-725T, 725Z, 725L, 725G, 725A and 725X); Comment Request; Revision

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC-725T_BAL-001-TRE (Primary Frequency Response in the ERCOT Region), FERC-725Z_IRO-010-5 (Reliability Coordinator Data and

information Specification and Collection), FERC-725L_MOD-032-1 (Data for Power System Modeling and Analysis), FERC-725G_PRC-012-2 (Remedial Action Schemes), FERC-725G_PRC-017-1 (Remedial Action Scheme Maintenance and Testing), FERC-725A_TOP-003-6.1 (Transmission Operator and Balancing Authority Data and Information Specification and Collection), FERC-725X_VAR-001-5 (Voltage and Reactive Control), FERC-725X_VAR-002-4.1 (Generator Operation for Maintaining Network Voltage Schedules) (Mandatory Reliability Standards for category 2 generator owners and generator operators). There are anticipated changes in the reporting requirements for this information collection for each of the eight standards.

DATES: Comments on the collection of information are due February 23, 2026.

ADDRESSES: Please submit comments via email to DataClearance@FERC.gov. You must specify the Docket No. (RD25-10-000) and the FERC Information Collection number (FERC-725T, 725Z, 725L, 725G, 725A and 725X) in your email. If you are unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery:

- *Mail via U.S. Postal Service only, addressed to:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

- *Hand (including courier) delivery to:* Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Docket: To view comments and issuances in this docket, please visit <https://elibrary.ferc.gov/eLibrary/search>. Once there, you can also sign-up for automatic notification of activity in this docket.

FOR FURTHER INFORMATION CONTACT:

Kayla Williams, (202) 502-6468.

DataClearance@FERC.gov.

SUPPLEMENTARY INFORMATION:

Title: FERC-725T, 725Z, 725L, 725G, 725A, 725X—FERC-725T_BAL-001-TRE (Primary Frequency Response in the ERCOT Region), FERC-725Z_IRO-010-5 (Reliability Coordinator Data and information Specification and Collection), FERC-725L_MOD-032-1 (Data for Power System Modeling and Analysis), FERC-725G_PRC-012-2 (Remedial Action Schemes), FERC-725G_PRC-017-1 (Remedial Action Scheme Maintenance and Testing), FERC-725A_TOP-003-6.1 (Transmission Operator and Balancing Authority Data and Information Specification and Collection), FERC-

725X_VAR-001-5 (Voltage and Reactive Control), FERC-725X_VAR-002-4.1 (Generator Operation for Maintaining Network Voltage Schedules) OMB Control No.: 1902-0273 (725T), 1902-0276 (725Z), 1902-0261 (725L), 1902-0252 (725G), 1902-0244 (725A), 1902-0278 (725X).

Type of Request: Update information collection requirements with changes to the current reporting requirements.

Abstract: Section 215 of the FPA provides that the Commission may certify an Electric Reliability Organization (ERO), the purpose of which is to develop mandatory and enforceable Reliability Standards, subject to Commission review and approval.¹ Reliability Standards may be enforced by the ERO, subject to Commission oversight, or by the Commission independently.² Pursuant to section 215 of the FPA, the Commission established a process to select and certify an ERO,³ and subsequently certified NERC.⁴

On October 1, 2025, in Docket No. RD25-10, the Commission approved NERC's filing of a petition seeking approval of two revised NERC definitions, generator owner and generator operator as "to align the definitions of the Generator Owner and Generator Operator terms in the NERC Glossary with the recently revised Generator Owner and Generator Operator registration functions in the NERC Rules of Procedure Statement of Compliance Registry Criteria,"⁵ approved by the Commission in Docket No. RR24-2-000 on June 27, 2024.⁶ The terms generator owner and generator operator now include non-bulk electric system (BES) inverter-based resources (IBR) that either have or contribute to an aggregate nameplate capacity of greater than or equal to 20 MVA, connected through a system designed primarily for delivering such capacity to a common point of connection at a voltage greater than or equal to 60 kV (category 2). Consequently, the new definitions in the Glossary of Terms Used in NERC

Reliability Standards (NERC Glossary) will impose paperwork burdens on category 2 generator owners and generator operators that will now need to comply with applicable Reliability Standards.

The approved revision to the definition of generator owner in the NERC Glossary is:⁷

The entity that: (1) owns and maintains generating Facility(ies) (Category 1 GO); or (2) owns and maintains non-BES Inverter-Based Resource(s) that either have or contribute to an aggregate nameplate capacity of greater than or equal to 20 MVA, connected through a system designed primarily for delivering such capacity to a common point of connection at a voltage greater than or equal to 60 kV (Category 2 GO).

The approved revision to the definition of generator operator in the NERC Glossary is:⁸

The entity that: (1) operates generating Facility(ies) and performs the functions of supplying energy and Interconnected Operations Services (Category 1 GOP); or (2) operates non-BES Inverter-Based Resource(s) that either have or contribute to an aggregate nameplate capacity of greater than or equal to 20 MVA, connected through a system designed primarily for delivering such capacity to a common point of connection at a voltage greater than or equal to 60 kV (Category 2 GOP).

As a result of the inclusion of category 2 resources in the NERC Glossary, applicable responsible entities will have to comply with reporting requirements for this information collection for each of the eight reliability standards included in NERC's implementation plan associated with Docket No. RD25-10. The eight applicable Reliability Standards are: BAL-001-TRE-2; IRO-010-5; MOD-032-1; PRC-012-2; PRC-017-1; TOP-003-6.1; VAR-001-5; and VAR-002-4.1.

Reliability Standard BAL-001-TRE-2 is currently located in the FERC-725T (OMB Control No. 1902-0273) collection. The purpose of Reliability Standard BAL-001-TRE-2 is to maintain interconnection steady-state frequency within defined limits. The category 2 generator owners and generator operators will now have to follow Requirements R6 through R10. Requirements R6, R7, R9, and R10 require the generator owner to set their governor parameters to be responsive to frequency obligations and provide notification to other entities when their governor is unavailable. Requirement R8

requires generator operators notify their balancing authority of service status changes.

Reliability Standard IRO-010-5 is currently located in the FERC-725Z (OMB Control No. 1902-0276) collection. The purpose of the standard is to prevent instability, uncontrolled separation, or cascading outages that adversely impact reliability by ensuring each reliability coordinator has the data and information it needs to plan, monitor and assess the operation of its reliability coordinator area. The category 2 generator owners and operators will now have to meet Requirement R3 that requires the generator owners and generator operators to satisfy the obligations of the documented specifications from the reliability coordinator on data and information needed for the operational planning analyses, real-time monitoring, and real-time assessments. Reliability Standard MOD-032-1 is currently located in the FERC-725L (OMB Control No. 1902-0261) collection. The purpose of the standard is to establish consistent modeling data requirements and reporting procedures for development of planning horizon cases necessary to support analysis of the reliability of the interconnected transmission system. The category 2 generator owners will now have to follow Requirements R2 and R3 that require generator owners provide modeling data to and address any concerns raised by the planning coordinator or transmission planner.

Reliability Standards PRC-012-2 and PRC-017-1 are currently located in the FERC-725G (OMB Control No. 1902-0252) collection. The purpose of PRC-012-2 is to ensure that remedial action schemes (RAS) do not introduce unintentional or unacceptable reliability risks to the BES. The stated purpose of Reliability Standard PRC-017-1 is to ensure that all RAS are properly designed, meet performance requirements, and are coordinated with other protection systems and to ensure that maintenance and testing programs are developed and misoperations are analyzed and corrected. The category 2 generator owners, that are part of a RAS, will now have to follow Requirements R1, R3, and R5 through R8 in Reliability Standard PRC-012-2 and Requirements R1 and R2 in Reliability Standard PRC-017-1. Specifically, Reliability Standard PRC-012-2 requires that generator owners that own all or part of a RAS to review and provide information to their reliability coordinator in R1 and R3; and to test, analyze performance, and take corrective action, if needed, in Requirements R5 through R8. Requirements R1 and R2 of Reliability

¹ 16 U.S.C. 824o(c).

² *Id.* 824o(e).

³ *Rules Concerning Certification of the Elec. Reliability Org.; & Procs. for the Establishment, Approval, & Enft 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).

⁴ *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) (Certification Order).

⁵ NERC Petition at 4.

⁶ *Order on Approving Revisions to N. Am. Elec. Reliability Corp. Rules of Proc. & Requiring Compliance Filing*, 187 FERC ¶ 61,196 (June 27, 2024).

⁷ NERC Petition at 3.

⁸ NERC Petition at 3-4.

Standard PRC-017-1 require generator owners that own a RAS to maintain and document a system maintenance and testing program.

Reliability Standard TOP-003-6.1 is currently located in the FERC-725A (OMB Control No. 1902-0244) collection. The purpose of this standard is to ensure that each transmission operator and balancing authority has the data and information it needs to plan, monitor, and assess the operation of its transmission operator area or balancing authority area. The category 2 generator owners and generator operators will now have to follow Requirement R5, which requires generator owners and generator operators to satisfy the obligations of the documented specifications of data and information related to operational planning analyses, real-time monitoring, and real-time assessments provided by the transmission operator or balancing authority.

Reliability Standards VAR-001-5 and VAR-002-4.1 are currently located in the FERC-725X (OMB Control No. 1902-0278) collection. The purpose of Reliability Standard VAR-001-5 is to ensure that voltage levels, reactive flows, and reactive resources are

monitored, controlled, and maintained within limits in real-time to protect equipment and the reliable operation of the interconnection. The purpose of Reliability Standard VAR-002-4.1 is to ensure generators provide reactive support and voltage control, within generating facility capabilities, in order to protect equipment and maintain reliable operation of the interconnection. The category 2 generator owners in Western Electricity Coordinating Council (WECC) will now have to follow Requirements E.A.15 and E.A.17 in Reliability Standard VAR-001-5. The category 2 generator operators will now have to follow Reliability Standard VAR-002-4.1, Requirements R1 through 4 and the category 2 generator owners will now have to follow Requirements R5 and R6. Specifically, Requirements E.A.15 and E.A. 17 require generator operators in WECC to provide voltage set point conversion methodologies to its transmission operator and to meet control loop specifications. Requirements R1 through 4 of Reliability Standard VAR-002-4.1 require the generator operators to operate their generators in automatic voltage control mode, maintain voltage

schedules, and to notify their transmission operator in the event of a change. Requirements R5 and R6 require the generator owner to provide data and tap settings information to their transmission operator and transmission planner and to ensure transformer tap positions are changed according to the specifications provided by the transmission operator.

Type of Respondents: Generator owners and generator operator entities registered with NERC that own or operate category 2 resources.

*Estimate of Annual Burden:*⁹ The applicable requirements from the eight applicable Reliability Standards largely consist of sharing and communicating readily available data and information for category 2 resources. Thus, Commission staff anticipates that the paperwork burden should be minimal for category 2 resources. The number of respondents, in the tables below, are based on good faith estimates provided by NERC, in August 2025, to Commission staff for the number of entities that either own or operate category 2 resources.

The Commission estimates the annual reporting burden and cost for the information collection as:

FERC-725T—MANDATORY RELIABILITY STANDARD FOR THE TRE-BAL

	Number of respondents ¹⁰	Annual number of responses per respondent	Total number of responses	Average burden & cost per response ¹¹	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
BAL-001-TRE-2 Annual Review and Record Retention.	30 (GO) 23 (GOP)	1 1	30 23	8 hrs.; \$508.16 4 hrs.; \$254.08	240 hrs.; \$15,244.80 92 hrs.; \$5,843.84	508.16 254.08
Total			53		332 hrs.; \$21,088.64	762.24

FERC-725Z—MANDATORY RELIABILITY STANDARD FOR THE IRO

	Number of respondents ¹²	Annual number of responses per respondent	Total number of responses	Average burden & cost per response ¹³	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
IRO-010-5 Annual Review and Record Retention.	491(GO) 310 (GOP)	1 1	491 310	8 hrs.; \$508.16 8 hrs.; \$508.16	3,928 hrs.; \$249,506.56 2,480 hrs.; \$157,529.60	508.16 508.16
Total			801		6,408 hrs.; \$407,036.10	1,016.32

⁹ "Burden" is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, see 5 CFR 1320.3.

¹⁰ The numbers for respondents were derived from the NERC's identification of category 2

generator owners and generator operators registered entities in the United States to Commission staff in August 2025.

¹¹ The estimated hourly cost (salary plus benefits) is a combination of the following categories from the Bureau of Labor Statistics (BLS) website, May 2024 http://www.bls.gov/oes/current/naics2_22.htm: 75% of the average of an Electrical Engineer

(17-2071) \$71.19/hr., × .75 = 53.3925 (\$53.39-rounded) (\$53.39/hour); and 25% of an Information and Record Clerk (43-4199) \$40.51/hr., \$40.51 × .25 = 10.1275 (\$10.13 rounded) (\$10.13/hour), for a total (\$53.39 + \$10.13 = \$63.52/hour).

¹² See note 10.

¹³ See note 11.

FERC-725L—MANDATORY RELIABILITY STANDARD FOR THE MOD

	Number of respondents ¹⁴	Annual number of responses per respondent	Total number of responses	Average burden & cost per response ¹⁵	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
MOD-032-1 Annual Review and Record Retention.	491 (GO)	1	491	20 hrs.; \$1,270.40	9,820 hrs.; \$623,766.40	1,270.40
Total			491		9,820 hrs.; \$623,766.40	1,270.40

FERC-725G—MANDATORY RELIABILITY STANDARD FOR THE PRC

	Number of respondents ¹⁶	Annual number of responses per respondent	Total number of responses	Average burden & cost per response ¹⁷	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
PRC-012-2 Annual Review and Record Retention.	491 (GO)	1	491	40 hrs.; \$2,540.80	19,640 hrs.; \$1,247,532.80	2,540.80
PRC-017-1 Annual Review and Record Retention.	491 (GO)	1	491	40 hrs.; \$2,540.80	19,640 hrs.; \$1,247,532.80	2,540.80
Total			982		39,280 hrs.; \$2,495,065.60	5,081.60

FERC-725A—MANDATORY RELIABILITY STANDARD FOR THE TOP

	Number of respondents ¹⁸	Annual number of responses per respondent	Total number of responses	Average burden & cost per response ¹⁹	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
TOP-003-6.1 Annual Review and Record Retention.	491 (GO) 310 (GOP)	1 1	491 310	8 hrs.; \$508.16 8 hrs.; \$508.16	3,928 hrs.; \$249,506.56 2,480 hrs.; \$157,529.6	508.16 508.16
Total			801		6,408 hrs.; \$407,036.16	1,016.32

FERC-725X—MANDATORY RELIABILITY STANDARD FOR THE VAR

	Number of respondents ²⁰	Annual number of responses per respondent	Total number of responses	Average burden & cost per response ²¹	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
VAR-001-5 Annual Review and Record Retention.	491 (GO)	1	491	8 hrs.; \$508.16	3,928 hrs.; \$249,506.56	508.16
VAR-002-4.1 Annual Review and Record Retention.	310 (GOP)	1	310	8 hrs.; \$508.16	2,480 hrs.; \$157,529.60	508.16
	491 (GO)	1	391	8 hrs.; \$508.16	3,928 hrs.; \$249,506.56	508.16
	310 (GOP)	1	310	8 hrs.; \$508.16	2,480 hrs.; \$157,529.60	508.16
Total					12,816 hrs.; \$814,072.32	2,032.64

Comments: Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of

the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: December 18, 2025.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025-23710 Filed 12-22-25; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP26-11-000]

**Columbia Gulf Transmission, LLC;
Notice of Scoping Period Requesting
Comments on Environmental Issues
for the Proposed Pulaski Project**

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental document that will discuss the environmental impacts of the Pulaski Project involving construction and operation of facilities

¹⁴ See note 10.

¹⁵ See note 11.

¹⁶ See note 10.

¹⁷ See note 11.

¹⁸ See note 10.

¹⁹ See note 11.

²⁰ See note 10.

²¹ See note 11.

by Columbia Gulf Transmission, LLC (Columbia) in Lincoln County and Pulaski County, Kentucky. The Commission will use this environmental document in its decision-making process to determine whether the project is in the public convenience and necessity.

On November 24, 2025, FERC staff issued a *Notice of Scoping Period Requesting Comments on Environmental Issues for the Pulaski Project and Notice of Public Scoping Session*. It was brought to FERC staff attention that the notice may not have been mailed properly to the environmental mailing list. This notice is being sent to an updated environmental mailing list and extends the scoping period for the project.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies regarding the project. As part of the National Environmental Policy Act (NEPA) review process, the Commission takes into account concerns the public may have about proposals and the environmental impacts that could result from its action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. This gathering of public input is referred to as “scoping.” The main goal of the scoping process is to focus the analysis in the environmental document on the important environmental issues. Additional information about the Commission’s NEPA process is described below in the *NEPA Process and Environmental Document* section of this notice.

By this notice, the Commission requests public comments on the scope of issues to address in the environmental document. To ensure that your comments are timely and properly recorded, please submit your comments so that the Commission receives them in Washington, DC on or before 5:00 p.m. Eastern Time on January 20, 2025. Comments may be submitted in written. Further details on how to submit comments are provided in the *Public Participation* section of this notice.

Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the environmental document. Commission staff will consider all comments during the preparation of the environmental document.

If you submitted comments on this project to the Commission before the opening of this docket on October 15, 2025, you will need to file those comments in Docket No. CP26–11–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission’s current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable easement agreement. You are not required to enter into an agreement. However, if the Commission approves the project, the Natural Gas Act conveys the right of eminent domain to the company. Therefore, if you and the company do not reach an easement agreement, the pipeline company could initiate condemnation proceedings in court. In such instances, compensation would be determined by a judge in accordance with state law. The Commission does not subsequently grant, exercise, or oversee the exercise of that eminent domain authority. The courts have exclusive authority to handle eminent domain cases; the Commission has no jurisdiction over these matters.

Columbia provided landowners with a fact sheet prepared by the FERC entitled “An Interstate Natural Gas Facility On My Land? What Do I Need To Know?” which addresses typically asked questions, including the use of eminent domain and how to participate in the Commission’s proceedings. This fact sheet along with other landowner topics of interest are available for viewing on the FERC website (www.ferc.gov) under the Natural Gas, Landowner Topics link.

Public Participation

Please carefully follow these instructions so that your comments are properly recorded. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or FercOnlineSupport@ferc.gov.

(1) You can file your comments electronically using the eComment feature, which is located on the Commission’s website (www.ferc.gov) under the link to FERC Online. Using eComment is an easy method for

submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the eFiling feature, which is located on the Commission’s website (www.ferc.gov) under the link to FERC Online. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on “eRegister.” You will be asked to select the type of filing you are making; a comment on a particular project is considered a “Comment on a Filing”; or

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the project docket number (CP26–11–000) on your letter. 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, MD 20852.

It is important to note that the Commission provides equal consideration to all comments received.

Additionally, the Commission offers a free service called eSubscription which makes it easy to stay informed of all issuances and submittals regarding the dockets/projects to which you subscribe. These instant email notifications are the fastest way to receive notification and provide a link to the document files which can reduce the amount of time you spend researching proceedings. Go to <https://www.ferc.gov/ferc-online/overview> to register for eSubscription.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

Summary of the Proposed Project

Columbia proposes to install and operate 41.3 miles of new 30-inch-diameter greenfield natural gas pipeline from Lincoln County Kentucky to the new South Somerset Delivery Meter Station located in Pulaski County, Kentucky, with additional aboveground facilities. The Pulaski Project would provide about 253 million standard cubic feet of natural gas per day to the John S. Cooper Power Station in Pulaski County, Kentucky. According to Columbia, its project would service its new and existing generation resources.

The Pulaski Project would consist of the following facilities:

- 41.3 miles of new 30-inch-diameter greenfield natural gas pipeline;
- a proposed tie-in to the Columbia Mainline in Lincoln County, Kentucky, including a new launcher/receiver and bidirectional pig¹ trap;
- a new meter and regulator station designated as the South Somerset Delivery Meter Station in Pulaski County, Kentucky, including a tie-in to East Kentucky Power Cooperative's (EKPC's) John S. Cooper Power Station, a new launcher/receiver, and a bidirectional pig trap; and
- four new mainline valves.

The general location of the project facilities is shown in appendix 1.

Land Requirements for Construction

Construction of the proposed facilities would disturb about 657.2 acres of land for the aboveground facilities and the pipeline. Following construction, Columbia would maintain about 254.0 acres for permanent operation of the project's facilities; the remaining acreage would be restored and revert to former uses. About 27 percent of the proposed pipeline route parallels existing EKPC and/or Kentucky Utilities Company rights-of-way.

NEPA Process and the Environmental Document

Any environmental document issued by the Commission will discuss impacts that could occur as a result of the construction and operation of the proposed project under the relevant general resource areas:

- geology and soils;
- water resources and wetlands;
- vegetation and wildlife;
- threatened and endangered species;
- cultural resources;
- land use;
- socioeconomic;
- air quality and noise; and
- reliability and safety.

Commission staff will also evaluate reasonable alternatives to the proposed project or portions of the project and make recommendations on how to lessen or avoid impacts on the various resource areas. Your comments will help Commission staff identify and focus on the issues that might have an effect on the human environment and potentially eliminate others from further study and discussion in the environmental document.

Following this scoping period, Commission staff will determine

whether to prepare an Environmental Assessment (EA) or an Environmental Impact Statement (EIS). The EA or the EIS will present Commission staff's independent analysis of the issues. If Commission staff prepares an EA, a *Notice of Schedule for the Preparation of an Environmental Assessment* will be issued. The EA may be issued for an allotted public comment period. The Commission would consider timely comments on the EA before making its decision regarding the proposed project. If Commission staff prepares an EIS, a *Notice of Intent to Prepare an EIS/ Notice of Schedule* will be issued, which will open up an additional comment period. Staff will then prepare a draft EIS which will be issued for public comment. Commission staff will consider all timely comments received during the comment period on the draft EIS and revise the document, as necessary, before issuing a final EIS. Any EA or draft and final EIS will be available in electronic format in the public record through eLibrary² and the Commission's natural gas environmental documents web page (<https://www.ferc.gov/industries-data/natural-gas/environment/environmental-documents>). If eSubscribed, you will receive instant email notification when the environmental document is issued.

With this notice, the Commission is asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate in the preparation of the environmental document.³ Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the *Public Participation* section of this notice.

Consultation Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, the Commission is using this notice to initiate consultation with the applicable State Historic Preservation Office(s), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.⁴

² For instructions on connecting to eLibrary, refer to the last page of this notice.

³ Cooperating agency responsibilities are addressed in Section 107(a)(3) of NEPA (42 U.S.C. 4336(a)(3)).

⁴ The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define

The environmental document for this project will document findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project and includes a mailing address with their comments. Commission staff will update the environmental mailing list as the analysis proceeds to ensure that Commission notices related to this environmental review are sent to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

If you need to make changes to your name/address, or if you would like to remove your name from the mailing list, please complete one of the following steps:

(1) Send an email to GasProjectAddressChange@ferc.gov stating your request. You must include the docket number CP26-11-000 in your request. If you are requesting a change to your address, please be sure to include your name and the correct address. If you are requesting to delete your address from the mailing list, please include your name and address as it appeared on this notice. This email address is unable to accept comments.

OR

(2) Return the attached "Mailing List Update Form" (appendix 2).

Additional Information

Additional information about the project is available from the FERC website at www.ferc.gov using the eLibrary link. Click on the eLibrary link, click on "General Search" and enter the docket number in the "Docket Number" field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at FercOnlineSupport@ferc.gov or (866)

historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

¹ A "pig" is a tool that the pipeline company inserts into and pushes through the pipeline for cleaning the pipeline, conducting internal inspections, or other purposes.

208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

Public sessions or site visits will be posted on the Commission's calendar located at <https://www.ferc.gov/news-events/events> along with other related information.

Authority: 18 CFR 2.1.

Dated: December 18, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025–23711 Filed 12–22–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2545–205]

Avista Corporation; Notice of Intent To Prepare an Environmental Assessment

On July 3, 2024, Avista Corporation filed an application for non-capacity amendment at the Spokane River Hydroelectric Project No. 2545. The dam is located on the Spokane River in Spokane, Lincoln, and Stevens counties, Washington, and in Kootenai and Benewah counties, Idaho.

To rehabilitate the spillway at the North Channel Dam, the licensee proposed to replace all existing gates. The North Channel Dam is L-shaped, and its primary spillway structure currently consists of one 100-foot-long rolling sector gate, seven 21-foot-long Tainter gates, and one 12-foot-long Tainter gate. The proposed rehabilitation involves replacing the existing spillway gates within the same footprint without any significant change in elevation, surface area, or capacity. The project would not alter the project boundary, reservoir levels, down-ramping rate, or minimum flow requirements. The project would also continue to operate under the terms of its current license and applicable Water Quality Certification. The licensee states that no resource agencies have objected to the proposed rehabilitation, and no long-term effects to project operations or environmental resources are anticipated. Temporary impacts would be limited to ground disturbance in construction areas and a temporary suspension of aesthetic spills during construction.

On June 18, 2025, Commission staff issued a public notice for the proposed amendment, accepted the application

for filing, and solicited comments, motions to intervene, and protests. The public comment period closed on July 18, 2025. On July 17, 2025, the Idaho Governor's Office of Energy & Mineral Resources filed a response to the Commission's notice.

This notice identifies Commission staff's intention to prepare an environmental assessment (EA) under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) for the project.¹ Commission staff plans to issue an EA by April 10, 2026. Revisions to the schedule may be made as appropriate. The EA will be issued for a 30-day comment period. All comments filed on the EA will be reviewed by staff and considered in the Commission's final decision on the proceeding.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or *OPP@ferc.gov*.

Any questions regarding this notice may be directed to Woohee Choi at 202–502–6336 or *Woohee.Choi@ferc.gov*.
(Authority: 18 CFR 2.1.)

Dated: December 18, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025–23709 Filed 12–22–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2731–045; Project No. 2737–028]

Green Mountain Power Corporation; Notice of Application Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

- a. *Application Type:* Extension of License Terms and Non-capacity Amendment of License.
- b. *Project Nos:* 2731–045 and 2737–028.
- c. *Date Filed:* July 1, 2025.
- d. *Applicant:* Green Mountain Power Corporation.
- e. *Name of Project:* Weybridge and Middlebury Lower Hydroelectric Projects.

¹ The unique identification number for documents relating to this environmental review is EAXX–019–20–000–1762338353.

f. *Location:* The Weybridge Project is located on the Otter Creek in the towns of Weybridge and New Heaven, Addison County, Vermont, and the Middlebury Lower Project is located on the Otter Creek in the towns of Middlebury and Weybridge, Addison County, Vermont. The projects do not occupy federal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* John Tedesco, Green Mountain Power, 163 Acorn Lane Colchester, VT 05446, (802) 655–8753, *John.Tedesco@greenmountainpower.com*.

i. *FERC Contact:* Aneela Mousam, (202) 502–8357, *aneela.mousam@ferc.gov*.

j. *Cooperating agencies:* With this notice, the Commission is inviting federal, state, local, and Tribal agencies with jurisdiction and/or special expertise with respect to environmental issues affected by the proposal, that wish to cooperate in the preparation of any environmental document, if applicable, to follow the instructions for filing such requests described in item k below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of any environmental document cannot also intervene. See 94 FERC ¶ 61,076 (2001).

k. *Deadline for filing comments, motions to intervene, and protests:* January 20, 2026 5:00 p.m. Eastern Time.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. 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, MD 20852. The first page of any filing should include the docket numbers P–2731–045 and P–2737–028. Comments emailed to

Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

l. *Description of Request:* On August 1, 2001, the Commission issued 30-year licenses for the Weybridge (Project No. 2731) and Middlebury Lower (Project No. 2737) hydroelectric projects that expire on July 31, 2031. The licensee requests the Commission extend the term of both licenses to July 31, 2041. The extension would allow the licensee to recoup rehabilitation costs associated with planned turbine runner replacement programs at each project.¹

The licensee also proposes to replace the turbine runner at the Weybridge Project. The proposed upgrade would maintain the project's authorized installed capacity of 3.0 megawatts and decrease the maximum hydraulic capacity of the powerhouse from 1,600 cubic feet per second (cfs) to 1,590 cfs. The licensee states all construction activities associated with the proposed amendment would occur within the Weybridge powerhouse and would be isolated from the river. Access to the powerhouse area during the mobilization and demobilization phases would be via the existing access road, and would not require any ground disturbance. The licensee does not propose any changes to the licensed project operations during or after turbine runner replacement.

m. *Locations of the Application:* This filing may be viewed on the Commission's website at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1-866-208-3676 or email FERCOnlineSupport@ferc.gov, for TTY, call (202) 502-8659. Agencies may

obtain copies of the application directly from the applicant.

n. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

o. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

p. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

q. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502-6595 or OPP@ferc.gov.

(Authority: 18 CFR 2.1)

Dated: December 18, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025-23706 Filed 12-22-25; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM26-3-000]

Authorizations for Certain Post-Licensing Activities at Hydroelectric Projects Notice Granting Extension of Time

On December 15, 2025, the National Hydropower Association (NHA) filed a motion requesting an extension of time from January 26, 2026, to February 25, 2026, to submit comments in response to the Notice of Inquiry (NOI) in this proceeding. NHA states that, given the significance of the NOI's questions to the hydropower industry, number of questions in the NOI, and the comment period falling over the holiday season, a 30-day extension will allow commenters to evaluate the questions posed by the Commission and provide comprehensive comments.¹ NHA asserts that the extension will not prejudice any interested party.

Given the request and importance of the issues raised by the NOI, upon consideration, notice is hereby given that the date for submitting comments on the NOI is hereby extended to and including February 10, 2026.

(Authority: 18 CFR 2.1.)

Dated: December 17, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025-23643 Filed 12-22-25; 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 accounting Request filings:

Docket Numbers: AC26-16-000.

Applicants: American Electric Power Service Corporation.

Description: American Electric Power Service Corporation submits Proposed Accounting Entries re Public Service Company of Oklahoma's acquisition of Green Country Energy, LLC.

Filed Date: 12/18/25.

Accession Number: 20251218-5128.

Comment Date: 5 p.m. ET 1/8/26.

Take notice that the Commission received the following electric corporate filings:

¹ On July 3, 2024, Commission staff issued an order approving the licensee's request to replace the Unit 3 turbine runner at the Middlebury Lower Project.

¹ Motion for Extension of Time at 2.

Docket Numbers: EC26–40–000.
Applicants: Adams Solar LLC, Caden Energix Axton LLC, Caden Energix Endless Caverns LLC, Caden Energix Hickory LLC, Northumberland Solar, LLC, Waverly Solar, LLC.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Adams Solar LLC, et al. under.

Filed Date: 12/17/25.

Accession Number: 20251217–5319.

Comment Date: 5 p.m. ET 1/7/26.

Docket Numbers: EC26–41–000.

Applicants: NextEra Energy Duane Arnold, LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act of NextEra Energy Duane Arnold, LLC.

Filed Date: 12/18/25.

Accession Number: 20251218–5223.

Comment Date: 5 p.m. ET 1/8/26.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG26–106–000.

Applicants: IP Aramis, LLC.

Description: IP Aramis, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 12/17/25.

Accession Number: 20251217–5250.

Comment Date: 5 p.m. ET 1/7/26.

Docket Numbers: EG26–107–000.

Applicants: IP Easley, LLC.

Description: IP Easley, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 12/17/25.

Accession Number: 20251217–5278.

Comment Date: 5 p.m. ET 1/7/26.

Docket Numbers: EG26–108–000.

Applicants: IP Easley II, LLC.

Description: IP Easley II, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 12/17/25.

Accession Number: 20251217–5281.

Comment Date: 5 p.m. ET 1/7/26.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1789–011; ER10–1768–010; ER10–1771–010; ER16–2725–008.

Applicants: PSEG Energy Solutions LLC, PSEG Nuclear LLC, Public Service Electric and Gas Company, PSEG Energy Resources & Trade LLC.

Description: Triennial Market Power Analysis for Northeast Region of PSEG Energy Resources & Trade LLC, et al.

Filed Date: 12/17/25.

Accession Number: 20251217–5366.

Comment Date: 5 p.m. ET 2/16/26.

Docket Numbers: ER10–2727–014; ER10–2688–019; ER10–2728–018;

ER10–1469–017; ER10–1467–017;

ER11–3907–010; ER10–1451–016;

ER10–2687–016; ER24–172–008.

Applicants: FirstEnergy Pennsylvania Electric Company, Monongahela Power Company, Jersey Central Power & Light, The Toledo Edison Company, Ohio Edison Company, The Cleveland Electric Illuminating Company, Green Valley Hydro, LLC, The Potomac Edison Company, Allegheny Energy Supply Company, LLC.

Description: Updated Triennial Market Power Analysis for Northeast Region of Allegheny Energy Supply Company, LLC, et al.

Filed Date: 12/16/25.

Accession Number: 20251216–5339.

Docket Numbers: ER19–1217–007.

Applicants: Montana-Dakota Utilities Co.

Description: Updated Triennial Market Power Analysis for Northwest Region of Montana-Dakota Utilities Co. under ER19–1217.

Filed Date: 12/17/25.

Accession Number: 20251217–5365.

Comment Date: 5 p.m. ET 2/16/26.

Docket Numbers: ER23–1928–003; ER19–2259–004; ER20–2722–002; ER22–874–003; ER22–2689–003; ER22–2850–003; ER24–1660–001; ER24–1661–001; ER24–1662–001; ER24–1665–002.

Applicants: Oak Leaf Solar 56 LLC, Oak Leaf Solar XXVI LLC, Oak Leaf Solar XXII LLC, Oak Leaf Solar XVIII LLC, Fall River Solar, LLC, MTSun LLC, Graphite Solar 1, LLC, CO Buffalo Flats, LLC, Turquoise Nevada LLC, Appaloosa Solar I, LLC.

Description: Triennial Updated Market Power Analysis for Northwest Region of Appaloosa Solar I, LLC, et al.

Filed Date: 12/16/25.

Accession Number: 20251216–5338.

Comment Date: 5 p.m. ET 2/16/26.

Docket Numbers: ER25–3431–001.

Applicants: Mammoth Central LLC.

Description: Tariff Amendment: Deficiency Filing to 2 to be effective 2/17/2026.

Filed Date: 12/18/25.

Accession Number: 20251218–5141.

Comment Date: 5 p.m. ET 1/8/26.

Docket Numbers: ER25–3432–001.

Applicants: Mammoth Central II LLC.

Description: Tariff Amendment: Deficiency Filing to 2 to be effective 2/17/2026.

Filed Date: 12/18/25.

Accession Number: 20251218–5143.

Comment Date: 5 p.m. ET 1/8/26.

Docket Numbers: ER25–3434–001.

Applicants: Mammoth South LLC.

Description: Tariff Amendment: Deficiency Filing to 1 to be effective 2/17/2026.

Filed Date: 12/18/25.

Accession Number: 20251218–5152.

Comment Date: 5 p.m. ET 1/8/26.

Docket Numbers: ER26–806–000.

Applicants: Upper Missouri G. & T. Electric Cooperative, Inc.

Description: 205(d) Rate Filing: Revised Wholesale Power Contracts to be effective 10/22/2025.

Filed Date: 12/17/25.

Accession Number: 20251217–5283.

Comment Date: 5 p.m. ET 1/7/26.

Docket Numbers: ER26–807–000.

Applicants: Southwest Power Pool, Inc.

Description: 205(d) Rate Filing: 4543 Rabbit's Foot Solar GIA to be effective 11/18/2025.

Filed Date: 12/18/25.

Accession Number: 20251218–5059.

Comment Date: 5 p.m. ET 1/8/26.

Docket Numbers: ER26–808–000.

Applicants: PacifiCorp.

Description: 205(d) Rate Filing: TransWest Engineering Services Agreement (RS No. 804) to be effective 2/17/2026.

Filed Date: 12/18/25.

Accession Number: 20251218–5104.

Comment Date: 5 p.m. ET 1/8/26.

Docket Numbers: ER26–809–000.

Applicants: Southwest Power Pool, Inc.

Description: 205(d) Rate Filing: 4545 Welcome Way Solar Energy GIA to be effective 11/20/2025.

Filed Date: 12/18/25.

Accession Number: 20251218–5106.

Comment Date: 5 p.m. ET 1/8/26.

Docket Numbers: ER26–810–000.

Applicants: AEP Texas Inc.

Description: 205(d) Rate Filing: AEPTX-Rolling Plains Solar LLC Interconnection Agreement to be effective 12/8/2025.

Filed Date: 12/18/25.

Accession Number: 20251218–5125.

Comment Date: 5 p.m. ET 1/8/26.

Docket Numbers: ER26–811–000.

Applicants: Midcontinent

Independent System Operator, Inc.

Description: 205(d) Rate Filing: 2025–12–18_SA 4627 ITC Midwest-Interstate Power & Light GIA (E0010) to be effective 12/12/2025.

Filed Date: 12/18/25.

Accession Number: 20251218–5176.

Comment Date: 5 p.m. ET 1/8/26.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES26–16–000.

Applicants: Portland General Electric Company.

Description: Amendment to Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Portland General Electric Company.

Filed Date: 12/16/25.

Accession Number: 20251216–5337.

Comment Date: 5 p.m. ET 12/26/25.

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.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

Dated: December 18, 2025.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2025–23701 Filed 12–22–25; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreement to the Secretary by email at Secretary@fmc.gov, or by mail, Federal Maritime Commission, 800 North Capitol Street, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**, and the Commission requests that comments be submitted within 7 days on agreements that request expedited review. Copies of agreements are available through the Commission's website (www.fmc.gov) or by contacting the Office of General Counsel at (202)–523–5740 or GeneralCounsel@fmc.gov.
Agreement No.: 201447–001.

Agreement Name: CMA CGM/COSCO/ONE/OOCL MED–USEC Vessel Sharing Agreement.

Parties: CMA CGM S.A.; COSCO SHIPPING Lines Co. Ltd.; Ocean Network Express Pte. Ltd.; and Orient Overseas Container Line Limited and OOCL (Europe) Limited (acting as a single party).

Filing Party: Joshua Stein, Cozen O'Connor.

Synopsis: The Amendment would add France and Canada to the geographic scope of the agreement.

Proposed Effective Date: 1/26/2026.

Location: <https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/88593>.

Agreement No.: 201461.

Agreement Name: Maersk/CMA Space Charter Agreement.

Parties: CMA CGM S.A.; Maersk A/S.

Filing Party: Wayne Rohde, Cozen O'Connor.

Synopsis: The Agreement would authorize Maersk to charter space to CMA CGM in the trades between the U.S. East Coast, on the one hand, and Australia, New Zealand, Colombia and Panama, on the other hand.

Proposed Effective Date: 2/1/2026.

Location: <https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/89637>.

Dated: December 19, 2025.

Jennifer Everling,

Assistant Secretary.

[FR Doc. 2025–23714 Filed 12–22–25; 8:45 am]

BILLING CODE 6730–02–P

FEDERAL RESERVE SYSTEM

[Docket No. OP–1877]

Request for Information and Comment on Reserve Bank Payment Account Prototype

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Request for information and comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) seeks public input on a special purpose Reserve Bank account prototype (a Payment Account) tailored to the risks and needs of institutions focused on payments innovation. A Payment Account holder would be expected to use its account for the express purpose of clearing and settling the institution's payment activity. Payment Accounts would be designed to pose limited risk to the Federal Reserve Banks (Reserve Banks) and the overall payment system, and Reserve Banks would generally conduct a streamlined review of requests for these accounts. Any institution that is legally eligible for

Federal Reserve accounts or services (accounts and services) under the Federal Reserve Act would be eligible to request a Payment Account from a Reserve Bank. The Payment Account prototype does not seek to expand or otherwise change legal eligibility for access to accounts and services.

DATES: Comments must be received on or before February 6, 2026.

ADDRESSES: You may submit comments, identified by Docket No. OP–1877 by any of the following methods:

- *Agency Website:* <https://www.federalreserve.gov/apps/proposals/>. Follow the instructions for submitting comments, including attachments. *Preferred Method.*

- *Mail:* Benjamin W. McDonough, Deputy Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

- *Hand Delivery/Courier:* Same as mailing address.

- *Other Means:* publiccomments@frb.gov. You must include the docket number in the subject line of the message.

Comments received are subject to public disclosure. In general, comments received will be made available on the Board's website at <https://www.federalreserve.gov/apps/proposals/> 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 be not appropriate for public disclosure. Public comments may also be viewed electronically or in person in Room M–4365A, 2001 C St. NW, Washington, DC 20551, between 9 a.m. and 5 p.m. during Federal business weekdays.

FOR FURTHER INFORMATION CONTACT:

Jason Hinkle, Associate Director, Zineb York, Manager, or Maggie Bota, Senior Financial Institution Policy Analyst, Division of Reserve Bank Operations and Payment Systems; Matthew Malloy, Chief, Division of Monetary Affairs, or Corinne Milliken Van Ness, Senior Counsel, Legal Division, Board of the Federal Reserve System: (202) 452–3000. For users of text telephone systems (TTY) or any TTY-based Telecommunications Relay Services, please call 711 from any telephone, anywhere in the United States.

SUPPLEMENTARY INFORMATION:

I. Background

The payments landscape continues to evolve rapidly as technological progress,

statutory developments, and other factors drive the introduction of innovative approaches to banking functions. These innovations necessitate adaptation throughout the financial sector, including the institutions and infrastructure that support a safe and efficient payment system.

On August 15, 2022, after a public comment process, the Board adopted guidelines (Account Access Guidelines or Guidelines) for Reserve Banks to utilize in evaluating requests for access to accounts and services (access requests). The Guidelines establish a transparent, risk-based, and consistent set of factors for Reserve Banks to use in reviewing access requests from legally-eligible institutions.^{1 2 3} The Guidelines incorporate a tiering framework under which access requests from certain types of entities (e.g., non-federally insured institutions) are subject to greater due diligence and scrutiny than access requests from other types of entities (e.g., federally-insured institutions).

Over the last three years, the business models of institutions submitting access requests have continued to evolve. For example, several institutions have explained that they are interested in access to accounts and services in order to reduce costs to their customers while increasing payment processing speed, often through new technologies. Some of these institutions have requested either a state or federal banking charter and a few have initiated requests for Reserve Bank accounts and services.

Over the same period, many eligible uninsured institutions have requested or expressed interest in requesting a master account and have expressed concern about the length of time that Reserve Banks take to review their access requests and the likelihood of denial. Institutions focused primarily on payment activities may only desire access to a subset of Federal Reserve services through a Reserve Bank account. While recognizing that decisions on access requests are made at the discretion of the individual Reserve Banks, the Board is exploring whether a tailored, special purpose Payment Account could meet these institutions'

needs while mitigating material risks identified in the Guidelines.

II. Payment Account Prototype

The Board is requesting feedback on a Payment Account prototype. In designing the Payment Account prototype, the Board has considered the risks identified in the Guidelines (*i.e.*, risks to the Reserve Banks, to the overall payment system, to financial stability, to the overall economy as a result of illicit activities, and to the implementation of monetary policy). In addition, the Board considered features that could limit Payment Accounts' impact on the Federal Reserve's balance sheet. As explained further below, Payment Accounts would be subject to a common set of risk-mitigating features. For example, to reduce credit risk to the Reserve Banks, a Payment Account holder would only have access to Federal Reserve payment services that have automated controls to prevent the account holder from incurring an overdraft. In addition, a Payment Account holder would not be eligible for discount window access. The Reserve Banks would retain their discretion to impose additional restrictions and risk controls on a Payment Account on a case-by-case basis.

A Payment Account would be separate and distinct from a full-service Reserve Bank master account (Master Account).⁴ If the Federal Reserve decides that the Reserve Banks will offer a Payment Account, the Board would propose necessary changes to existing guidance and regulations, including the Guidelines and Regulation D.

III. Payment Account Term Sheet

A. Account Description

a. A Payment Account would be a special purpose account with a Reserve Bank that holds limited overnight balances of a legally-eligible institution for the express purpose of clearing and settling the institution's payments.⁵ The Reserve Bank would permit a Payment Account holder to maintain only a limited balance in the account at the close of business; these end-of-day balances would be intended only to provide liquidity for payment activity at the beginning of the next business day. A Payment Account would be a separate and distinct type of account from a Reserve Bank master account (a Master

Account), which generally does not have a limit imposed on overnight balances.^{6 7} The Board would explore reporting the balances maintained in Payment Accounts separate from balances maintained in Master Accounts on the Reserve Banks' financial reporting. The Reserve Banks would retain their discretion to impose additional restrictions and risk controls on a Payment Account on a case-by-case basis.

B. Eligibility

a. Any institution that satisfies the legal eligibility requirements for an account under the Federal Reserve Act would be eligible to request a Payment Account. Generally, institutions would be limited to maintaining one account with a Reserve Bank, either a Payment Account or a Master Account.⁸ The Payment Account prototype would not make any changes to legal eligibility for access to accounts and services.

C. Overnight Balance Limit

a. A Payment Account would be subject to an overnight balance limit, meaning that a Payment Account holder would need to reduce the balance of the account below a specified limit at the Federal Reserve's close of business.⁹ During the Federal Reserve business day, a Payment Account holder would be allowed to maintain a balance in a Payment Account above the overnight limit to fund payments settling in the account. The Reserve Banks would establish a compliance program to enforce the overnight balance limit, which could include, among other options, counseling, penalty fees, and service restrictions.

i. The Board is considering setting the overnight balance limit at the lesser of \$500 million or 10% of the Payment Account holder's total assets.¹⁰

ii. The Reserve Bank could have the ability to adjust the overnight balance limit, temporarily or permanently, on a

⁶ As with existing Master Accounts, overnight overdrafts would not be permitted in Payment Accounts.

⁷ A Payment Account would be a separate and distinct type of account from a Reserve Bank Joint Account.

⁸ A Payment Account holder would not be eligible to be a participant in an Excess Balance Account.

⁹ The business day of Federal Reserve Financial Services is defined in the Federal Reserve Policy on Payment System Risk and begins immediately after the close of business of the Fedwire Funds Service on days when the Fedwire Funds Service is open and the close of the FedNow Service on all other days (which, in both cases, is generally 7:00 p.m. ET).

¹⁰ The institution's total assets would be determined by its most recent report to its primary banking regulator or equivalent.

¹ 87 FR 51099 (Aug. 19, 2022).

² Information on the Federal Reserve Banks' financial services, including a list of such services, can be found at <https://www.frbsservices.org>.

³ The Guidelines do not apply to accounts provided under fiscal agency authority or to accounts authorized pursuant to the Board's Regulation N (12 CFR part 214), joint account requests, or account requests from designated financial market utilities, since existing rules or policies already set out the considerations involved in granting these types of accounts.

⁴ Some of the Payment Account features and risk controls could be the same as utilized for a Master Account and are included in this document for completeness.

⁵ A Payment Account would be technology-agnostic and would not be designed to promote any particular payment product or service.

case-by-case basis. In some cases, the Reserve Bank would be expected to consult with the Board on such an adjustment.

b. As noted above, a Payment Account would be designed only to facilitate the clearing and settlement of the Payment Account holder's payment activity, and this feature would be intended to encourage a Payment Account holder to limit overnight balances in their account.

D. No Interest on Overnight Balances

a. A Payment Account holder would not receive interest on balances held at a Reserve Bank.

b. As noted above, a Payment Account would be designed only to facilitate the clearing and settlement of the Payment Account holder's payment activity. This feature, along with the overnight balance limit, would be intended to encourage a Payment Account holder to limit overnight balances in their account.

E. No Access to the Discount Window

a. A Payment Account holder would not be permitted to access credit from the discount window.

b. This feature would be intended to reduce the credit risk that a Payment Account holder could pose to the Reserve Bank.

F. No Access to Reserve Bank Intraday Credit

a. A Reserve Bank provides intraday credit, also known as a daylight overdraft, when an institution's Federal Reserve account is in a negative position during the business day. An institution with a Payment Account would not be permitted to incur daylight overdrafts. Payments would need to be prefunded and as noted below, payments that would cause an overdraft in a Payment Account would be rejected.

b. This feature would be intended to reduce the credit risk that a Payment Account could pose to the Reserve Bank.

G. Services Available

a. The following services (collectively, the permitted services) would be available for an institution to request to settle in a Payment Account:¹¹

- i. The Fedwire® Funds Service;
- ii. The National Settlement Service;
- iii. The FedNow® Service; and
- iv. The Fedwire® Securities Service for Free Transfers only.^{12 13}

¹¹ A description of the Federal Reserve payment services is available at www.frbsservices.org.

¹² Free Transfers, as defined in the Reserve Banks' Operating Circular 7 (Fedwire Securities Service), are transfers of securities that do not result in a

b. This feature would be intended to reduce the credit risk that a Payment Account could pose to the Reserve Bank. Limiting Payment Accounts to these services would reduce credit risk to the Reserve Banks since each of these services have automated solutions that can reject transactions that would cause daylight overdrafts. As noted above, Payment Account holders would not be permitted to incur daylight overdrafts.

H. Services Not Available

a. Any services not listed above (collectively, the excluded services) would not be available in connection with a Payment Account, including:

- i. FedACH® Services;
- ii. Check Services;
- iii. FedCash®; and
- iv. The Fedwire® Securities Service for Transfer Against Payment.¹⁴

b. This feature would be intended to reduce the credit risk that a Payment Account could pose to the Reserve Bank. These services would not be available because they do not currently have automated solutions that can reject transactions that would cause daylight overdrafts. As noted above, Payment Account holders would not be permitted to incur daylight overdrafts.

I. Account Usage Restrictions

a. A Payment Account would be designed as a special purpose account for the express purpose of clearing and settling the institution's payment activity. Accordingly, a Payment Account holder would not be permitted to act as a correspondent bank, and a Payment Account could not be used to settle transactions for respondent institutions.¹⁵ This feature would be

debit or a credit to a Master Account other than a transaction fee. Free transfers are commonly referred to as transfers free of payment.

¹³ "Fedwire" and "FedNow" are service marks of the Federal Reserve Banks. A list of marks related to financial services products that are offered to financial institutions by the Federal Reserve Banks is available at <https://www.frbsservices.org>.

¹⁴ Transfer Against Payment, as defined in the Reserve Banks' Operating Circular 7 (Fedwire Securities Service), is a transfer that is affected with a credit to the account of the sender and a debit to the account of the receiver for the amount of the payment.

¹⁵ A Correspondent is a financial institution: (1) that has authorized a Reserve Bank to settle Debit and Credit Transaction Activity to its Master Account for a Respondent or for any financial institution for which the Respondent acts as Correspondent; or (2) that maintains required reserve balances for one or more financial institutions in its Master Account. See Section 2.2 of Operating Circular (OC) 1. A Respondent is: (1) a financial institution that settles Debit and Credit Transaction Activity for some or all its Reserve Bank transactions in the Master Account of a Correspondent; or (2) a financial institution that maintains its required reserve balances in the Master Account of a Correspondent. See Section 2.2 of OC 1.

intended to reduce the range of risks a Payment Account could pose to the Reserve Bank and the overall payment system.

b. In addition, consistent with the Reserve Banks' current practice for Master Accounts, the Reserve Banks would not recognize third-party interests in Payment Accounts. Like Master Account balances, the Reserve Banks would treat all balances in a Payment Account solely as obligations to the account holder.

J. Other Risk Controls

a. In addition to the foregoing risk mitigants, the Reserve Banks would apply the following risk controls to a Payment Account:¹⁶

i. Outgoing transactions that would result in an overdraft in the account would be rejected. This feature is intended to reduce the potential credit risk a Payment Account could pose to the Reserve Bank. As noted above, Payment Account holders would not be permitted to incur daylight overdrafts.

b. The Board is exploring additional risk controls and conditions for a Payment Account. These controls could take the form of, among other things, account agreement conditions, attestation requirements, consent to reviews, or periodic reporting requirements. These controls could cover areas of risks to the Reserve Bank and payment system (such as operational or cyber risks), or risks associated with illicit financing (such as Anti-Money Laundering (AML) risk mitigation).

K. Payment Account Request Process

a. An eligible institution would request a Payment Account from the relevant Reserve Bank. The relevant Reserve Bank would have the discretion to approve or deny the request. Similar to requests for Master Accounts, Reserve Banks would be expected to review a request for a Payment Account under the Guidelines.

b. Consistent with a Payment Account's lower risk profile, the Board anticipates that a request for a Payment Account would generally receive a more streamlined review than a request for a Master Account from a comparable institution. As a result, a Reserve Bank would generally be expected to complete its review of an institution's request for a Payment Account within 90 calendar days of receiving all documentation requested by the Reserve Bank.¹⁷

¹⁶ Some of these risk controls may also apply to Master Accounts.

¹⁷ Additional due diligence may be required in some circumstances, which could require a

c. As noted above, the Reserve Banks would retain their discretion to impose additional restrictions and risk controls on a Payment Account on a case-by-case basis.

IV. Request for Information

The Board requests public input on all aspects of the Payment Account prototype, and in particular the Board seeks responses to the following questions:

1. Would the design of the Payment Account prototype support payment activities of eligible institutions?
2. What payment activities or use cases would a Payment Account best facilitate (or be unable to facilitate)?
3. What barriers to innovation in payments would a Payment Account eliminate or alleviate?
4. Would the design of the Payment Account prototype potentially increase the range of risks to the payment system identified in the Guidelines? If so, in what ways?
5. What are the benefits and challenges of imposing an overnight balance limit on a Payment Account? Are there adjustments to the proposed formula for setting the balance limit that the Board should consider if it decides to establish a Payment Account?
6. What are the benefits and drawbacks of paying no interest on overnight balances in a Payment Account?
7. How might the Federal Reserve condition access to a Payment Account on the applicant having an acceptable AML, Bank Secrecy Act (BSA) and Countering the Financing of Terrorism (CFT) compliance programs and, more generally, how can the Federal Reserve best constrain AML/BSA/CFT risks associated with a Payment Account?
8. Are there additional features or limits that the Board should consider in the design of the Payment Account prototype?

By order of the Board of Governors of the Federal Reserve System.

Benjamin W. McDonough,
Deputy Secretary of the Board.

[FR Doc. 2025–23712 Filed 12–22–25; 8:45 am]

BILLING CODE 6210–01–P

moderate amount of additional time for the Reserve Bank to review the request, and the Reserve Bank would be expected to consult with the Board on such an adjustment. The Board may set a limit on the additional review time. Thus, the 90-day review might be extended in some cases.

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, Benjamin W. McDonough, Deputy Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than January 7, 2026.

A. Federal Reserve Bank of Atlanta (Erien O. Terry, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to Applications.Comments@atl.frb.org:

1. *Delmar A. Benton, Sharon Benton, Sara Jane Frerichs, and BD and Merle Benton Trust, Delmar A. Benton as trustee, all of Madisonville, Tennessee; Darrell A. Benton, Meghan N. Benton, Elizabeth Sharon Benton, Sally Suzanne Benton, and Nancy F. Garza, all of Maryville, Tennessee*; to form the Benton Family Control Group, a group acting in concert, to retain voting shares of Peoples Bancshares, of TN, Inc., and thereby indirectly retain voting shares of

Peoples Bank of East Tennessee, both of Madisonville, Tennessee.

B. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001. Comments can also be sent electronically to KCApplicationComments@kc.frb.org:

1. *Adam Duston Rainbolt Trust I; Jacob Patrick Rainbolt Trust I; and Samuel Johnson Rainbolt Trust I, all of Oklahoma City, Oklahoma; David E. Rainbolt as trustee and trust supervisor, and Dana Kim Rainbolt as trust supervisor, all of Oklahoma City, Oklahoma; Dana Kim Rainbolt Revocable Trust, Oklahoma City, Oklahoma, David E. Rainbolt and Dana Kim Rainbolt as co-trustees and trust supervisors, Samuel Johnson Rainbolt and Jacob Patrick Rainbolt as trust supervisors, all of Oklahoma City, Oklahoma*; to become members of the Rainbolt Family Control Group, a group acting in concert, to retain voting shares of BancFirst Corporation, Oklahoma City, Oklahoma, and thereby indirectly retain voting shares of BancFirst, Oklahoma City, Oklahoma; Pegasus Bank, Dallas, Texas; Worthington Bank, Arlington, Texas; and American Bank of Oklahoma, Collinsville, Oklahoma.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2025–23715 Filed 12–22–25; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

[File No. 241 0081]

Adamas Amenity Services LLC, et al.; Analysis of Agreement Containing Consent Order To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of Federal law prohibiting unfair methods of competition. The attached Analysis of Agreement Containing Consent Order to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before January 22, 2026.

ADDRESSES: Interested parties may file comments online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section

below. Please write: “Adamas Services; File No. 241 0081” on your comment and file your comment online at <https://www.regulations.gov> by following the instructions on the web-based form. If you prefer to file your comment on paper, please mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Mail Stop H-144 (Annex P), Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Mike Naranjo (415-848-5183), American Competition Enforcement Division, Federal Trade Commission, 90 7th Street, Suite 14-300, San Francisco, CA 94103.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of 30 days. The following Analysis of Agreement Containing Consent Order to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC website at this web address: <https://www.ftc.gov/news-events/commission-actions>.

The public is invited to submit comments on this document. We strongly encourage you to submit your comments online through the <https://www.regulations.gov> website. For the Commission to consider your comment, we must receive it on or before January 22, 2026.

If you prefer to file your comment on paper, write “Adamas Services; File No. 241 0081” on your comment and on the envelope, and mail your comment by overnight service to: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Mail Stop H-144 (Annex P), Washington, DC 20580. Because of the agency’s heightened security screening, postal mail addressed to the Commission will be delayed.

Your comment—including your name and your State—will be placed on the public record of this proceeding, including, to the extent practicable, on the <https://www.regulations.gov> website. Because your comment will be placed on the publicly accessible website at <https://www.regulations.gov>, you are solely responsible for making sure your comment does not include

any sensitive or confidential information. In particular, your comment should not include sensitive personal information, such as your or anyone else’s Social Security number; date of birth; driver’s license number or other State identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any “trade secret or any commercial or financial information which . . . is privileged or confidential”—as provided by section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled “Confidential,” and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on <https://www.regulations.gov>—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at <https://www.ftc.gov> to read this document and the news release describing this matter. The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments it receives on or before January 22, 2026. For information on the Commission’s privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

Analysis of Agreement Containing Consent Order To Aid Public Comment

I. Introduction

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) with Adamas Amenity Services LLC, Adamas Building Services LLC, Adamas Concierge LLC, Adamas Parking Services LLC, and Adamas Security LLC (collectively, “Respondents”). The proposed Decision and Order (“Order”), included in the Consent Agreement and subject to final Commission approval, is designed to remedy the anticompetitive effects that have resulted from Respondents’ use of restrictive covenants in some of their contracts with building owners and managers that limit the ability of those building owners and managers to solicit or hire Respondents’ employees (“No-Hire Agreements”). The term No-Hire Agreement refers to a term in an agreement between two or more companies that restricts, imposes conditions on, or otherwise limits a company’s ability to solicit, recruit, or hire another company’s employees, during employment or afterwards, directly or indirectly, including by imposing a fee or damages in connection with such conduct, or that otherwise inhibits competition between companies for each other’s employees’ services.

The Consent Agreement settles charges that Respondents have engaged in unfair methods of competition in violation of section 5 of the FTC Act, as amended, 15 U.S.C. 45 (“section 5 of the FTC Act”), by entering into No-Hire Agreements with customers. Respondents’ No-Hire Agreements constitute unreasonable restraints of trade that are unlawful under section 1 of the Sherman Act, 15 U.S.C. 1, and are thus unfair methods of competition in violation of section 5 of the FTC Act. Independent of the Sherman Act, Respondents’ use of the No-Hire Agreements constitutes an unfair method of competition with a tendency or likelihood to harm competition, consumers, and employees in the building services industry, in violation of section 5 of the FTC Act.

The proposed Order has been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Consent Agreement, and the comments received, and will decide whether it should withdraw from the Consent Agreement

and take appropriate action or make the proposed Order final.

II. The Respondents

Respondents are building services contractors headquartered in Rutherford, New Jersey that provide building maintenance, janitorial, concierge, valet, and security services. Respondent Adamas Amenity Services LLC provides services relating to residential building amenities such as pool and fitness facilities. Respondent Adamas Building Services LLC provides janitorial and maintenance services. Respondent Adamas Concierge LLC handles front desk, doorman, and lobby attendant services. Respondent Adamas Parking LLC provides parking garage and valet services. Respondent Adamas Security LLC handles unarmed security services. A substantial majority of Respondents' work relates to residential buildings.

III. The Complaint

The complaint alleges that Respondents sell building services to building owners and property management companies, primarily consisting of the labor of janitors, security guards, maintenance workers, and concierge desk workers who are directly employed by Respondents. These employees perform their work predominantly in New Jersey and New York City.

The complaint also alleges that Respondents and their building owner and property manager customers are direct competitors in labor markets for building services workers. These include the markets for workers to perform concierge, security, janitorial, maintenance, and related services.

As alleged in the complaint, Respondents use standard-form agreements with their customers that include No-Hire Agreements. The No-Hire Agreements restrict the ability of Respondents' customers to (1) directly hire workers employed by Respondents and (2) indirectly hire workers employed by Respondents through a competing building services contractor after the competitor wins the customers' business away from Respondents. These restrictions apply during the term of Respondents' contracts and for six months thereafter. The restrictions against hiring apply not just to Respondents' employees staffed to provide services for a particular customer, but to all of Respondents' building services employees.

The complaint alleges that Respondents' No-Hire Agreements are anticompetitive because they eliminate direct, horizontal, and significant forms

of competition to attract labor in the U.S. building services industry. These agreements deny employees access to job opportunities, restrict their mobility, and deprive them of competitively significant information that they could have used to negotiate for better terms of employment. The complaint further alleges that any legitimate objectives of Respondents' conduct could have been achieved through significantly less restrictive means. Among other terms, the scope and duration of the No-Hire Agreements are not reasonably necessary to achieve any claimed pro-competitive purpose of Respondents' building services contracts. For these reasons, the complaint alleges that the No-Hire Agreements constitute unreasonable restraints of trade that violate section 1 of the Sherman Act, 15 U.S.C. 1, and are thus unfair methods of competition in violation of section 5 of the FTC Act.

Independent of the Sherman Act, the complaint alleges that Respondents' conduct constitutes an unfair method of competition with a tendency or likelihood to harm competition, consumers, and employees in the building services industry, in violation of section 5 of the FTC Act. According to the complaint, the No-Hire Agreements limit the ability of building owners and competing building service contractors to hire Respondents' employees. This harms Respondents' employees because it limits their ability to negotiate for higher wages, better benefits, and improved working conditions. Employees may suffer further hardship if the building they work at changes management, because the No-Hire Agreements force them to leave their jobs in some circumstances. The complaint further alleges that the No-Hire Agreements harm building owners and managers because they may be foreclosed from seeking or accepting bids from Respondents' competitors due to the prospect of losing long-serving workers with extensive, building-specific experience.

IV. Proposed Order

The proposed Order seeks to remedy Respondents' unfair methods of competition. Section II of the proposed Order prohibits Respondents from entering or attempting to enter, maintaining or attempting to maintain, enforcing or attempting to enforce, or threatening to enforce a No-Hire Agreement, or communicating to a customer or any other person that any Adamas employee is subject to a No-Hire Agreement.

Paragraph III.A of the proposed Order requires Respondents to provide written

notice to customers that are subject to No-Hire Agreements that (i) the restriction is null and void, and (ii) any customer or a subsequent building services contractor for a customer is no longer subject to the restrictions or penalties related to the No-Hire Agreements in Respondents' contracts.

Paragraph III.B of the proposed Order requires Respondents to provide written notices to employees who are subject to a No-Hire Agreement. Paragraph III.C requires that Respondents post clear and conspicuous notice that employees are not subject to No-Hire Agreements and may seek or accept a job with the building directly, or any company that wins the building's business.

Paragraphs IV.A and IV.B of the proposed Order require that Respondents immediately cease enforcing No-Hire Agreements and, within 30 days after the Order is issued, provide key employees of Respondents with a copy of the Order and Complaint. Paragraphs IV.C–E set forth Respondents' ongoing compliance obligations.

Other paragraphs contain standard provisions regarding compliance reports, requirements for Respondents to provide notice to the FTC of material changes to their business, and access for the FTC to documents and personnel. The term of the proposed Order is ten years.

The purpose of this analysis is to facilitate public comment on the Consent Agreement and proposed Order to aid the Commission in determining whether it should make the proposed Order final. This analysis is not an official interpretation of the proposed Order and does not modify its terms in any way.

By direction of the Commission.

April J. Tabor,
Secretary.

[FR Doc. 2025–23716 Filed 12–22–25; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension

AGENCY: Federal Trade Commission.

ACTION: Notice.

SUMMARY: The Federal Trade Commission ("FTC" or "Commission") is seeking public comment on its proposal to extend for an additional three years the Office of Management and Budget clearance for information collection requirements of its Affiliate Marketing Rule, which applies to

certain motor vehicle dealers, and its shared enforcement with the Consumer Financial Protection Bureau (“CFPB”) of the provisions (subpart C) of the CFPB’s Regulation V regarding other entities (“CFPB Rule”). The current clearance expires on April 30, 2026.

DATES: Comments must be received on or before February 23, 2026.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comments part of the **SUPPLEMENTARY INFORMATION** section below. Write “Paperwork Reduction Act Comment: FTC File No. P072108” on your comment, and file your comment online at <https://www.regulations.gov> by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex J), Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: David Walko, Attorney, Division of Privacy and Identity Protection, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, (202) 326–2880.

SUPPLEMENTARY INFORMATION:

Title: Affiliate Marketing Rule (16 CFR part 680).

OMB Control Number: 3084–0131.

Type of Review: Extension of currently approved collection.

Affected Public: Businesses and other for-profit entities.

Estimated Annual Burden Hours: 7,880.

Estimated Annual Labor Costs: \$429,838.

Estimated Annual Non-Labor Costs: *de minimis*.

Abstract: As required by section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), the FTC is providing this opportunity for public comment before requesting that the Office of Management and Budget (“OMB”) extend the existing clearance for the information collection requirements contained in the Affiliate Marketing Rule.

The Dodd-Frank Wall Street Reform and Consumer Protection Act (“Dodd-Frank Act”) was enacted on July 21, 2010.¹ The Dodd-Frank Act transferred to the CFPB most of the FTC’s rulemaking authority for the Affiliate Marketing provisions of the Fair Credit Reporting Act (“FCRA”).² The FTC

retained rulemaking authority for its Affiliate Marketing Rule (16 CFR part 680) solely for motor vehicle dealers described in section 1029(a) of the Dodd-Frank Act as predominantly engaged in the sale and servicing of motor vehicles, the leasing and servicing of motor vehicles, or both.³ Additionally, the FTC shares enforcement authority with the CFPB and other agencies for provisions of Regulation V subpart C (12 CFR 1022.20–1022.27) that apply to entities other than those specified above.⁴

As mandated by section 214 of the Fair and Accurate Credit Transactions Act (“FACT Act”), Public Law 108–159 (Dec. 6, 2003), the Affiliate Marketing Rule (“Rule”) requires covered entities to provide consumers with notice and an opportunity to opt out of the use of certain information before sending marketing solicitations. The Rule generally provides that, if a company communicates certain information about a consumer (eligibility information) to an affiliate, the affiliate may not use it to make or send solicitations to the consumer unless the consumer is given notice and a reasonable opportunity to opt out of such use of the information and does not opt out.

To minimize compliance costs and burdens for entities, particularly any small businesses that may be affected, the Rule contains model disclosures and opt-out notices that may be used to satisfy the statutory requirements. The Rule also gives covered entities flexibility to satisfy the notice and opt-out requirement. Covered entities may send the consumer a free-standing opt-out notice to satisfy the Rule’s requirements or add the opt-out notice to privacy notices already provided to consumers, such as those provided in accordance with the provisions of Title V, subtitle A of the Gramm Leach Bliley Act (“GLBA”).⁵ As a result, the time necessary to prepare or incorporate an opt-out notice is likely to be minimal

³ See Dodd-Frank Act sec. 1029(a), (c).

⁴ While the FTC shares enforcement authority with the Federal Reserve System, Commodity Futures Trading Commission, National Credit Union Administration, Office of the Comptroller of the Currency, and the Federal Deposit Insurance Corporation for the CFPB’s counterpart affiliate sharing rule, Regulation V (Subpart C), 12 CFR 1022.20–1022.27, the CFPB has assumed 95% of the burden associated with its affiliate sharing rule. See Consumer Financial Protection Bureau, *Agency Information Collection Activities: Submission for OMB Review; Comment Request*, 85 FR 52559 (Aug. 26, 2020); CFPB Supporting Statement, *Fair Credit Reporting Act (Regulation V)* 12 CFR 1022, OMB Control Number: 3170–0002 (2020). In addition, the CFPB has estimated that the burden associated with Regulation V’s affiliate sharing provisions is *de minimis*.

⁵ 15 U.S.C. 6801 *et seq.*

because covered entities may either use the model disclosure verbatim or base their own disclosures upon it. Moreover, verbatim adoption of the model notice does not constitute a PRA “collection of information.”⁶ The Rule also provides that affiliated companies may send a joint disclosure to consumers, thereby eliminating the need for each affiliate to send a separate disclosure. Staff anticipates that affiliated entities will choose to send a joint notice, which will reduce the number of notices required under the Rule.

Burden Statement

Under the PRA, 44 U.S.C. 3501–3521, the FTC is requesting that OMB renew the clearance (OMB Control Number 3084–0131) for the information collection burden associated with the Rule. Staff estimates that there are approximately 47,057 franchise/new car and independent/used car dealers in the U.S.⁷ Applying an estimated rate of affiliation of 16.75%, staff estimates that there are approximately 7,882 motor vehicle dealerships in affiliated families that may be subject to the Rule’s affiliate sharing obligations. Staff further estimates an average of five businesses per family or affiliated relationship, and anticipates that affiliated entities will choose to send a joint notice as permitted by the Rule. Therefore, staff estimates that approximately 1,576 covered motor vehicle business families would be subject to the Rule.

Staff assumes that all or nearly all motor vehicles subject to the Rule’s provisions are also subject to the Commission’s Privacy of Consumer Financial Information Rule under the Gramm-Leach-Bliley Act (16 CFR part 313) (“Privacy Rule”). Entities that are subject to the Commission’s GLBA Privacy Rule already provide privacy notices to their customers. Absent an exception, financial institutions must provide an initial privacy notice at the time the customer relationship is established and then annually so long as

⁶ “The public disclosure of information originally supplied by the Federal government to the recipient for purpose of disclosure to the public is not included within [the definition of collection of information].” 5 CFR 1320.3(c)(2).

⁷ See Notice of Paperwork Reduction Act Clearance for Information Collection Requirements in the Used Motor Vehicle Trade Regulation Rule, 90 FR 56147, 56147 (Dec. 5, 2025). (This figure is based on estimates made by the U.S. Census Bureau. See 2023 U.S. Census Bureau Data, showing 25,147 establishments for “used car dealers,” NAICS code 44112 and 21,910 “new car dealers,” NAICS code 44111, available at https://data.census.gov/profile/44112_-_Used_Car_Dealers?codeset=naics-44112&g=010XX00US and https://data.census.gov/profile/44111_-_New_car_dealers?codeset=naics-44111&g=010XX00US.)

¹ Public Law 111–203, 124 Stat. 1376 (2010).

² 15 U.S.C. 1681 *et seq.*

the relationship continues. 15 U.S.C. 6803. Staff's estimates assume that in all or nearly all cases covered institutions will choose to incorporate the affiliate marketing opt-out notice into the initial and annual GLBA privacy notices. In 2015, Congress, as part of the FAST Act, amended the GLBA to provide an exception under which financial institutions that meet certain conditions are not required to provide annual notices to customers.⁸ Staff seeks comment on how the use of this exception by institutions that are required to provide an affiliate marketing notice will impact the burden estimates for these entities. Institutions that claim the FAST Act exemption and forego sending required annual privacy

notices in some years will nonetheless be required to send a separate affiliate marketing notice to comply with their obligations under the Rule.

Staff estimates that the 1,576 covered motor vehicle business families will spend on average about 5 hours per year to comply with the Affiliate Sharing Rule beyond their separate obligations under the Privacy Rule, yielding a total annual hours of burden of 7,880 hours. Staff's estimates take into account the time necessary to determine compliance obligations; create the notice and opt-out, in either paper or electronic form; and disseminate the notice and opt-out. Staff's estimates presume that the availability of model disclosures and opt-out notices will simplify the compliance review and implementation

processes, thereby significantly reducing the compliance burden.

Staff estimates the associated labor cost by adding the hourly mean private sector wages for managerial, technical, and clerical work and multiplying that sum by the estimated number of hours. The private sector hourly wages for these classifications are \$68.15, \$56.16, and \$24.12, respectively.⁹ Estimated hours spent for each category are 2, 2, and 1, respectively. Multiplying each occupation's hourly wage by the associated time estimate, yields the annual labor cost burden per respondent which is then multiplied by the estimated number of respondents to determine the cumulative annual labor cost burden: \$429,838 per year.

Hourly wage and labor category	Hours per respondent	Total hourly labor cost	Number of respondents	Approx. total annual labor costs
\$68.15 Management Employees	2	\$136.30	1,576	\$214,809
\$56.16 Technical Staff	2	112.32		177,016
\$24.12 Clerical Workers	1	24.12		38,013
Total				429,838

Because the FACT Act and the Rule contemplate that the affiliate marketing notice can be included in the GLBA notices, the capital and non-labor cost burden on regulated entities would be greatly reduced. Covered entities typically already provide notices to their customers so there are no new capital or non-labor costs, as the affiliate marketing notice may be consolidated into their annual privacy notice. Thus, staff estimates that any capital or non-labor costs associated with compliance for these entities are *de minimis*.

Request for Comments

Pursuant to section 3506(c)(2)(A) of the PRA, the FTC invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, 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 maintaining records and

providing disclosures to consumers. All comments must be received on or before February 23, 2026.

You can file a comment online or on paper. For the FTC to consider your comment, we must receive it on or before February 23, 2026. Write "Paperwork Reduction Act Comment: FTC File No. P072108" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including the <https://www.regulations.gov> website.

If you prefer to file your comment on paper, write "Paperwork Reduction Act Comment: FTC File No. P072108" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex J), Washington, DC 20580.

Because your comment will become publicly available at <https://www.regulations.gov>, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal

information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies

⁸ Fixing America's Surface Transportation Act ("FAST Act"), Public Law 114–94, 129 Stat. 1312, Section 75001 (Dec. 4, 2015) (amending 15 U.S.C. 6803 to exempt financial institutions from the annual notice requirement if they meet certain criteria, and if they have not changed their policies and practices with regard to disclosing nonpublic

personal information from the policies and practices that were disclosed in the most recent disclosure sent to consumers).

⁹ The classifications used are "Management Occupations" for managerial employees, "Computer and Mathematical Occupations" for technical staff, and "Office and Administrative

Support" for clerical workers. See National employment and wage data from the Occupational Employment and Wage Statistics survey by occupation, May 2024, U.S. Bureau of Labor Statistics, last modified April 2, 2025: <https://www.bls.gov/news.release/ocwage.t01.htm>.

the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at www.regulations.gov, we cannot redact or remove your comment unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before February 23, 2026. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

[FR Doc. 2025-23696 Filed 12-22-25; 8:45 am]

BILLING CODE 6750-01-P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090-0315; Docket No. 2025-0001; Sequence No. 20]

Information Collection; Ombudsman Inquiry/Request Instrument

AGENCY: Office of Acquisition Policy, Office of the Procurement Ombudsman (OPO), General Services Administration (GSA).

ACTION: Notice and request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the OMB a request to review and approve a reinstatement of an information collection requirement regarding OMB Control No. 3090-0315; Ombudsman Inquiry/Request Instrument.

DATES: Submit comments on or before February 23, 2026.

ADDRESSES: Submit comments regarding this collection via <http://www.regulations.gov> and follow the instructions on the site. Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link "Comment Now" that corresponds with

"Information Collection 3090-0315." Please include your name, company name (if any) and "Information Collection 3090-0315, Ombudsman Inquiry Request/Request Instrument" on your attached document.

Instructions: Please submit comments only and cite Information Collection 3090-0315; Ombudsman Inquiry/Request Instrument, in all correspondence related to this collection. Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two-to-three days after submission to verify posting. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at GSARegSec@gsa.gov.

FOR FURTHER INFORMATION CONTACT: Frederick Landry, GSA Procurement Ombudsman & Industry Liaison, at telephone 202-501-4755.

SUPPLEMENTARY INFORMATION:

A. Purpose

The online intake Instrument on the GSA Ombudsman's web page receives inquiries from vendors who are currently doing business with or interested in doing business with GSA. The inquiries are collected by the GSA Ombudsman and routed to the appropriate office for resolution and/or implementation in the case of recommendations for process or program improvements. Reporting of the data collected helps highlight thematic issues that vendors encounter with GSA acquisition programs, processes, or policies, and identify areas where training is needed. The information collected also assists in identifying and analyzing patterns and trends to help improve efficiencies and lead to improvements in current practices.

B. Annual Reporting Burden

Maximum Potential Respondents: 118.

Responses per Respondent: 1.

Total Maximum Potential Annual

Responses: 118.

Hours per Response: .25.

Total Burden Hours: 29.5.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary, whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the

information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division at GSARegSec@gsa.gov. Please cite OMB Control No. 3090-0315, Ombudsman Inquiry/Request Instrument, in all correspondence.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202-501-4755 or emailing GSARegSec@gsa.gov. Please cite "Information Collection 3090-0315, Ombudsman Inquiry/Request Instrument", in all correspondence.

Nicole Bynum,

Regulatory Program Specialist, General Services Administration.

[FR Doc. 2025-23718 Filed 12-22-25; 8:45 am]

BILLING CODE 6820-61-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-D-2204]

Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Federal Food, Drug, and Cosmetic Act." This guidance provides recommendations for industry and review staff on the formal dispute resolution (FDR) and administrative hearings procedures for resolving scientific and/or medical disputes between the Center for Drug Evaluation and Research (CDER) and requestors and sponsors of drugs that will be subject to a final administrative

order under section 505G of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ("Final Order"). This guidance finalizes the draft guidance of the same title issued on June 23, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on December 23, 2025.

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

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-D-2204 for "Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Federal Food, Drug, and Cosmetic Act." 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 this 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 guidance document.

FOR FURTHER INFORMATION CONTACT:

Suzanne Strayhorn, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6317, Silver Spring, MD 20993, 240-402-4247.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Federal Food, Drug, and Cosmetic Act." This guidance provides recommendations for industry and review staff on the FDR and administrative hearings procedures for resolving scientific and/or medical disputes between CDER and requestors and sponsors of drugs that will be subject to a Final Order under section 505G of the FD&C Act (21 U.S.C. 355h).

Section 505G of the FD&C Act was added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116-136), which was enacted on March 27, 2020. After FDA issues a Final Order in accordance with section 505G(b)(2) of the FD&C Act, FDA must afford eligible requestors or sponsors the opportunity for FDR and hearings on disputes over the Final Order. This guidance describes the FDR procedures for eligible requestors or sponsors that wish to appeal a scientific and/or medical issue related to a Final Order. This guidance also outlines the procedures for an administrative hearing related to a Final Order. Finally, as required by section 505G(l)(4) of the FD&C Act, this guidance describes the procedures for consolidated proceedings for FDR and hearings to resolve the scientific and/or medical disputes.

FDA agreed to specific performance goals and procedures described in the document "Over-the-Counter Monograph User Fee Program Performance Goals and Procedures—Fiscal Years 2018–2022," commonly referred to as the OMUFA commitment letter (the document can be accessed at <https://www.fda.gov/media/106407/download>, and the document with updated goal dates for fiscal years 2021–2025 can be accessed at <https://www.fda.gov/media/146283/download>). The OMUFA commitment letter specifies that FDA will revise the guidance for industry and review staff entitled "Formal Dispute Resolution: Sponsor Appeals Above the Division Level" (existing FDR guidance), available at <https://www.fda.gov/media/126910/download>, to include circumstances and procedures under which FDR may be used with respect to

Final Orders under section 505G of the FD&C Act. In addition, consistent with the statutory requirement under section 505G(l)(4), the OMUFA commitment letter explains that FDA will issue guidance on its views regarding best practices for consolidated proceedings for appeals.

For administrative efficiency, rather than amend the existing FDR guidance to include FDR procedures for Final Orders and issue a separate guidance for consolidated proceedings for appeals, FDA is issuing this single guidance. This guidance addresses the process for resolving scientific and/or medical disputes of Final Orders, including FDR, administrative hearings, and consolidated proceedings. FDA has incorporated recommendations from the existing FDR guidance as appropriate.

This guidance finalizes the draft guidance entitled “Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Federal Food, Drug, and Cosmetic Act” issued on June 23, 2023 (88 FR 41107). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft guidance to the final guidance include: (1) clarifying that the recommendations in this guidance are limited to FDR in accordance with section 505G(b)(2)(A)(iv)(III) and 505G(b)(4)(D)(iii) of the FD&C Act and to hearings in accordance with section 505G(b)(3) of the FD&C Act, and (2) removing language implying that new information could be submitted outside of, but at the same time or during, the FDR to avoid any suggestion that an eligible requestor or sponsor submitting a request for FDR should actively engage with other entities within FDA or pursue other regulatory or legal pathways on the same matter at the same time.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Federal Food, Drug, and Cosmetic Act.” 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. FDA considered the applicability of Executive Order 14192, per Office of Management and Budget (OMB) guidance in M–25–20, and finds this action to be deregulatory in nature.

II. Paperwork Reduction Act of 1995

Under section 505G(o) of the FD&C Act, the Paperwork Reduction Act of 1995 (PRA) does not apply to collections of information made under section 505G of the FD&C Act. The information collections made in this guidance implement the provisions of the following subsections of 505G:

(1) Section 505G(l)(4), which requires FDA to issue guidance that specifies the consolidated proceedings for appeal and the procedures for such proceedings where appropriate;

(2) Section 505G(b)(2)(A)(iv)(III), which requires that FDA afford requesters of drugs that will be subject to final administrative orders the opportunity for FDR up to the level of the Director of CDER;

(3) Section 505G(b)(3) and section 505G(b)(4)(E), which allow persons who participated in each stage of FDR with respect to a drug to request a hearing concerning a final administrative order with respect to such drug. Under section 505G(b)(3)(C)(ii), a single hearing may be conducted if more than one request is submitted with respect to the same administrative order; and

(4) Section 505G(j), which requires that all submissions be in electronic format.

Therefore, clearance by OMB under the PRA (44 U.S.C. 3501–3521) is not required for these collections of information.

In addition, this guidance refers to previously approved FDA collections of information. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information for over-the-counter (OTC) monograph products, OTC monograph order requests, and the OTC Monograph User Fee Program have been approved under OMB control number 0910–0340. The collections of information for FDR have been approved under OMB control number 0910–0001. The collections of information in 21 CFR 10.65 relating to meetings and correspondence have been approved under OMB control number 0910–0191.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, [https://www.fda.gov/regulatory-information/search-fda-](https://www.fda.gov/regulatory-information/search-fda-guidance-documents)

[guidance-documents](https://www.fda.gov/regulatory-information/search-fda-guidance-documents), or <https://www.regulations.gov>.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–23707 Filed 12–22–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1210]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarket Surveillance of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by January 21, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0449. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Postmarket Surveillance of Medical Devices—21 CFR Part 822

OMB Control Number 0910–0449—
Extension

This information collection supports FDA regulations. Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) authorizes FDA to require a manufacturer to conduct postmarket surveillance (PS) of any device that meets the criteria set forth in the statute. The PS regulation establishes procedures that FDA uses to approve and disapprove PS plans. The regulation provides instructions to manufacturers, so they know what

information is required in a PS plan submission. FDA reviews PS plan submissions in accordance with 21 CFR 822.15 through 822.19 of the regulation, which describe the grounds for approving or disapproving a PS plan. In addition, the PS regulation provides instructions to manufacturers to submit interim and final reports in accordance with 21 CFR 822.38. To assist respondents with understanding the applicable statutory and regulatory requirements, we also developed the interpretive agency guidance entitled, “Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and

Cosmetic Act” (October 2022) (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-surveillance-under-section-522-federal-food-drug-and-cosmetic-act>). Respondents to this collection of information are those manufacturers that require PS of their products.

In the **Federal Register** of June 6, 2025 (90 FR 25318) FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR part/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 822.9 and 822.10; PS submission	3	1	3	120	360
§ 822.21; Changes to PS plan after approval	8	1	8	40	320
§ 822.28; Changes to PS plan for a device that is no longer marketed	1	1	1	8	8
§ 822.29; Waiver	1	1	1	40	40
§ 822.30; Exemption request	1	1	1	40	40
§ 822.38; Periodic reports	35	3	105	40	4,200
Total					4,968

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR part/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
§ 822.31; Manufacturer records	3	1	3	20	60
§ 822.32; Investigator records	9	1	9	5	45
Total	105				

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an increase of 1,890 total burden hours and a corresponding increase 45 total annual responses. This increase is based on internal FDA tracking data. The number of respondents varies annually, subject to the number of original plans, plan changes, and interim and final reports (which are dependent on enrollment progress for each study) received by FDA.

Brian Fahey,

Associate Commissioner for Legislation.

[FR Doc. 2025–23630 Filed 12–22–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OS–0990–0488]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, Administration for Strategic Preparation and Response (ASPR), U.S. Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Administration for Strategic Preparation and Response (ASPR), HHS, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the information collection request (ICR) must be received on or before February 23, 2026.

ADDRESSES: Submit your comments to wayland.coker@hhs.gov or by calling (202) 875–1103.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier OS–0990–0488, and project title for reference, and send to Wayland Coker, the ASPR Center for Industrial Base Management and Supply Chain, Chief Supply Chain Strategist, wayland.coker@hhs.gov, or call (202) 875–1103.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and

utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Ensure a Strong Public Health Supply Chain Through Streamlined Oversight and American Priorities.

Type of Collection: Extension.
Office of Management and Budget (OMB) No. 0990-0488—Administration for Strategic Preparedness and Response—Center for Industrial Base Management and Supply Chain.

Abstract

HHS, Administration for Strategic Preparedness and Response (ASPR) is seeking approval by OMB on an extension of the existing clearance (OMB Control Number: 0990-0488, Expiration Date: March 31, 2026). HHS is working with the White House and across the federal interagency to launch

a multiyear implementation involving the identification and coordination of measurable activities across the United States government, state, local, tribal, and territorial (SLTT) jurisdictions, and private sector partners. Cross-sectoral engagement is the underpinning of many of the interdependent implementation activities. For example, one such activity involves information collection from SLTT partners on facility, local, and state stockpiling plans to ensure coordinated plans are in place for a future public health emergency. Potential engagements include, and are not limited to, surveys, stakeholder meetings, requests for information (RFI), town hall meetings, and workshops. With each of these different mechanisms of engagement, there is a varied frequency ranging from single engagements to regularly recurring meetings.

In 2025, the White House capacity and strengthening the public health supply chain through a series of executive actions focused on reducing foreign dependency, enhancing domestic manufacturing capacity, and

improving emergency preparedness. This includes the establishment of the Strategic Active Pharmaceutical Ingredients Reserve (SAPIR), directed by HHS and managed through ASPR, to ensure a secure, domestic supply of essential drug components. The administration has also invoked Section 232 of the *Trade Expansion Act* of 1962 to assess whether reliance on imports of materials such as processed critical minerals and copper poses a national security risk, including risks to the production of pharmaceuticals and other medical countermeasures. These coordinated efforts reflect a broader federal strategy to increase the resilience, agility, and visibility of the public health supply chain in support of future emergency response operations. To support White House priorities, HHS seeks a 3-year extension to its Paperwork Reduction Act clearance and will engage with SLTT, trade groups, mixed cross-sector audiences, non-governmental organizations, manufacturers, academia, healthcare providers and facilities, and local communities.

ESTIMATED ANNUALIZED BURDEN TABLE OVER THREE YEARS

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Private sector companies, SLTT, Trade groups and associations, NGOs, Manufacturers, distributors, Academia, Healthcare delivery providers/facilities, Public, USG Supply chain inventory holders, Biopharmaceutical industry, Biotechnology development companies, Communities, GPOs, standards development organizations, logistics, third party contractors, purchasing organizations, professional associations/societies, Mixed cross-sector audience, labor unions, workforce training providers, organizations, state and local workforce boards, and individuals who rely on wearable medical countermeasures.	Informed consent	32,800	1	0.08	2,624
	Demographics standardized questionnaire with decision logic allowing some questions to be omitted.	32,800	1	0.25	8,200
	Cognitive questionnaire	5,990	1	8	47,920
	Formative interviews and focus groups	6,600	2	4	52,800
	Town halls and public meetings	10,200	2	8	163,200
	Supply chain questionnaires	1,000	156	0.5	78,000
	Knowledge-based questionnaires	6,000	1	0.5	3,000
	Interviews and focus groups	3,000	1	1	3,000
	Instrumented information collection	160	1	0.5	80
	Total Burden Hours Over Three Years				358,824

Catherine Howard,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2025-23759 Filed 12-22-25; 8:45 am]

BILLING CODE 4150-37-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

RIN 0955-AA13

Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care

AGENCY: Office of the Deputy Secretary and Assistant Secretary for Technology Policy (ASTP) and Office of the National

Coordinator for Health Information Technology (ONC) (collectively, ASTP/ONC), Department of Health and Human Services.

ACTION: Request for information.

SUMMARY: The HHS Office of the Deputy Secretary in collaboration with ASTP/ONC has published this Request for Information (RFI) to seek broad public comment on what HHS can do to accelerate the adoption and use of AI as part of clinical care.

DATES: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, by February 23, 2026.

ADDRESSES: You may submit comments, identified by "HHS Health Sector AI RFI," by any of the following methods

(please do not submit duplicate comments). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

- *Federal eRulemaking Portal:* Follow the instructions for submitting comments. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word. <http://www.regulations.gov>.

- *Regular, Express, or Overnight Mail:* Department of Health and Human Services, Assistant Secretary for Technology Policy and the Office of the National Coordinator for Health Information Technology, Attention: Request for Information: HHS Health Sector AI RFI, Mary E. Switzer Building,

Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies.

- *Hand Delivery or Courier:* Assistant Secretary for Technology Policy and the Office of the National Coordinator for Health Information Technology, Attention: HHS Health Sector AI RFI, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies. (Because access to the interior of the Mary E. Switzer Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes but is not limited to: a person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered proprietary. We will post all comments that are received before the close of the comment period at <http://www.regulations.gov>.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> or the Department of Health and Human Services, Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201 (call ahead to the contact listed below to arrange for inspection).

FOR FURTHER INFORMATION CONTACT: Steven Posnack, Principal Deputy Assistant Secretary for Technology Policy, ASTP/ONC, 202–690–7151.

SUPPLEMENTARY INFORMATION:

I. Introduction

On December 4, 2025, the Department of Health and Human Services (HHS) issued the HHS Artificial Intelligence (AI) Strategy¹ in response to Office of

Management and Budget (OMB) Memorandum 25–21.² The HHS AI Strategy represents a “OneHHS” approach to AI and is primarily focused on the Department’s internal interests and ambitions to harness the transformative potential of AI and embed it into HHS’s operations, while upholding patient privacy, civil rights, and civil liberties. Consistent with the President’s artificial intelligence (AI) Action Plan,³ recent Executive Orders⁴ on AI, and Office of Management and Budget AI memoranda,⁵ the Department seeks public feedback on the actions it can take to establish a forward-leaning, industry-supportive, and secure approach to accelerate the adoption and use of AI⁶ as part of clinical care. In the past 12 months, HHS Divisions, including the Food and Drug Administration (FDA),⁷ National Institutes of Health (NIH),⁸ Centers for Medicare & Medicaid Services (CMS),⁹ and ASTP/ONC¹⁰ have sought public feedback on various aspects of AI and how it intersects with the Department’s policy interests. In this RFI we seek concrete, experience-based feedback from those building, buying, evaluating, using, and receiving care from AI tools that are part of clinical care as well as

² <https://www.whitehouse.gov/wp-content/uploads/2025/02/M-25-21-Accelerating-Federal-Use-of-AI-through-Innovation-Governance-and-Public-Trust.pdf>.

³ <https://www.whitehouse.gov/wp-content/uploads/2025/07/Americas-AI-Action-Plan.pdf>.

⁴ <https://www.ai.gov/#resources-anchor>.

⁵ See: <https://www.whitehouse.gov/wp-content/uploads/2025/02/M-25-21-Accelerating-Federal-Use-of-AI-through-Innovation-Governance-and-Public-Trust.pdf> and <https://www.whitehouse.gov/wp-content/uploads/2025/02/M-25-22-Driving-Efficient-Acquisition-of-Artificial-Intelligence-in-Government.pdf> and <https://www.whitehouse.gov/wp-content/uploads/2025/12/M-26-04-Increasing-Public-Trust-in-Artificial-Intelligence-Through-Unbiased-AI-Principles-1.pdf>.

⁶ For purposes of this RFI, “artificial intelligence” is defined to be consistent with OMB Memorandum M25–21, which follows the meaning provided in Section 238(g) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019. See section 5 of M25–21 for additional detail.

⁷ FDA Request for Public Comment: Measuring and Evaluating AI-enabled Medical Device Performance in the Real-World <https://www.fda.gov/medical-devices/digital-health-center-excellence/request-public-comment-measuring-and-evaluating-artificial-intelligence-enabled-medical-device>.

⁸ NIH Request for Information: Inviting Comments on the NIH Artificial Intelligence Strategy <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-117.html>.

⁹ CMS Request for Information on Artificial Intelligence Technologies for Improving Health Care Outcomes and Service Delivery <https://www.cms.gov/digital-service/artificial-intelligence-demo-days>.

¹⁰ CMS and ASTP/ONC Request for Information: Health Technology Ecosystem <https://www.federalregister.gov/documents/2025/05/16/2025-08701/request-for-information-health-technology-ecosystem>.

from those who wish to do so but face barriers. Public feedback will inform HHS-wide use of three different approaches: regulation, reimbursement, and research & development. In general, HHS seeks feedback on ways in which these approaches can be most effectively applied to support the rapid adoption and use of AI in clinical care, to foster public trust and confidence in modern technology solutions, to reduce uncertainty that impedes AI innovation, and to align federal incentives so that AI is deployed in ways that enhance productivity, reduce burden, lower health care costs, and improve health outcomes for patients, caregivers, and communities.

II. Solicitation of Public Comments

Regulation

As the nation’s principal health regulator, HHS helps shape the environment in which AI for clinical care is developed, evaluated, and deployed. HHS seeks to establish a regulatory posture on AI that is well understood, predictable, and proportionate to any risks presented to enable rapid innovation while protecting patients and the confidentiality of their identifiable health information, and maintaining public trust. We seek feedback on how current HHS regulations impact AI adoption and use for clinical care.

Reimbursement

HHS’s payment policies and programs have massive effects on how health care is delivered in the United States, often times with unintended consequences. Hypothetically, if a payer is taking financial risk for the long-term health and health costs of an individual, that payer will have an inherent incentive to promote access to the highest-value interventions for patients. Under government designed and dictated fee-for-service regimes, however, coverage and reimbursement decisions are slow. Rarely does covering new innovations reduce net spending; and waste, fraud, and abuse is difficult to prevent, often times leading to massive spending bubbles on concentrated items or services that are not commensurate with the value of such products. Given the inherent flaws in legacy payment systems, we seek to ensure that the potential promises of AI innovations are not diminished through inertia and instead such payment systems are modernized to meet the needs of a changing healthcare system. We seek feedback on payment policy changes that ensure payers have the incentive and ability to promote access to high-

¹ <https://www.hhs.gov/press-room/hhs-unveils-ai-strategy-to-transform-agency-operations.html>.

value AI clinical interventions, foster competition among clinical care AI tool builders, and accelerate access to and affordability of AI tools for clinical care.

Research & Development

HHS supports one of the world's largest health research ecosystems, catalyzing innovation to supplement the market. By enabling applied AI research & development, care delivery research and implementation science, as well as AI entrepreneurship in health care, we can better translate AI technologies from concept to clinical use. We seek input on ways in which HHS may invest in research & development (including public-private partnerships and cooperative research and development agreements (CRADAs)) to integrate AI in care delivery and create new, long-term market opportunities that improve the health and wellbeing of all Americans.

Specific Questions

In addition to the general requests for information above regarding AI regulation, reimbursement, and research & development, HHS seeks input on the following specific questions:

1. What are the biggest barriers to private sector innovation in AI for health care and its adoption and use in clinical care?
2. What regulatory, payment policy, or programmatic design changes should HHS prioritize to incentivize the effective use of AI in clinical care and why? What HHS regulations, policies, or programs could be revisited to augment your ability to develop or use AI in clinical care? Please provide specific changes and applicable Code of Federal Regulations citations.
3. For non-medical devices, we understand that use of AI in clinical care may raise novel legal and implementation issues that challenge existing governance and accountability structures (e.g., relating to liability, indemnification, privacy, and security). What novel legal and implementation issues exist and what role, if any, should HHS play to help address them?
4. For non-medical devices, what are the most promising AI evaluation methods (pre- and post-deployment), metrics, robustness testing, and other workflow and human-centered evaluation methods for clinical care? Should HHS further support these processes? If so, which mechanisms would be most impactful (e.g., contracts, grants, cooperative agreements, and/or prize competitions)?
5. How can HHS best support private sector activities (e.g., accreditation, certification, industry-driven testing, and credentialing) to promote

innovative and effective AI use in clinical care?

6. Where have AI tools deployed in clinical care met or exceeded performance and cost expectations and where have they fallen short? What kinds of novel AI tools would have the greatest potential to improve health care outcomes, give new insights on quality, and help reduce costs?

7. Which role(s), decision maker(s), or governing bodies within health care organizations have the most influence on the adoption of AI for clinical care? What are the primary administrative hurdles to the adoption of AI in clinical care?

8. Where would enhanced interoperability widen market opportunities, fuel research, and accelerate the development of AI for clinical care? Please consider specific data types, data standards, and benchmarking tools.

9. What challenges within health care do patients and caregivers wish to see addressed by the adoption and use of AI in clinical care? Equally, what concerns do patients and caregivers have related to the adoption and use of AI in clinical care?

10. Are there specific areas of AI research that HHS should prioritize to accelerate the adoption of AI as part of clinical care?

- a. Are there published findings about the impact of adopted AI tools and their use clinical care?
- b. How does the literature approach the costs, benefits, and transfers of using AI as part of clinical care?

III. Paperwork Reduction Act

In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), and OMB guidance, this general solicitation is 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.

IV. Response to Comments

Due to the large number of public comments that 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 request for information.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–23641 Filed 12–19–25; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Loan Repayment Programs (LRP), (Office of the Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the NIH will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Matthew Lockhart, Director, Division of Loan Repayment (DLR), National Institutes of Health, 6705 Rockledge Dr, (MSC 7963), Bethesda, Maryland 20892–7963 or email your request, including your address to: matthew.lockhart@nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, 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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Loan Repayment Programs (LRPs), 0925–0361, expiration date 01/31/26, EXTENSION, Office of the Director

(OD), National Institutes of Health (NIH).

Need and Use of Information

Collection: The NIH makes available financial assistance, in the form of educational loan repayment, to M.D., Ph.D., Pharm.D., Psy.D., D.O., D.D.S., D.M.D., D.P.M., D.C., N.D., O.D., D.V.M., or equivalent doctoral degree holders who perform biomedical or behavioral research in NIH intramural laboratories or as extramural grantees or scientists funded by domestic non-profit

organizations for a minimum of two years (three years for the General Research subcategory) in research areas supporting the mission and priorities of the NIH. The information proposed for collection will be used by the DLR to determine an applicant's eligibility for the program.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 20,802.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Initial Extramural Applicants	1,000	1	8	8,000
Renewal Extramural Applicants	1,000	1	8	8,000
Initial Intramural Applicants	20	1	8	160
Renewal Intramural Applicants	50	1	8	400
Recommenders	8,080	1	30/60	4,040
Institutional Contacts	2,000	1	5/60	167
NIH LRP Coordinators	70	1	30/60	35
Total	12,220	12,220		20,802

Dated: December 17, 2025.

Jon Lorsch,

*Deputy Director for Extramural Research,
National Institutes of Health.*

[FR Doc. 2025–23774 Filed 12–22–25; 8:45 am]

BILLING CODE 4140–01–P

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

National Institutes of Health

**Center for Scientific Review; Amended
Notice of Meeting**

Notice is hereby given of a change in the meeting of the Macromolecular Structure and Function A Study Section, January 27, 2026, 09:00 a.m. to January 28, 2026, 07:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on November 25, 2025, 90 FR 53364 Doc 2025–21044.

This meeting is being amended to change the meeting start time to 10:00 a.m. The meeting is closed to the public.

Dated: December 18, 2025.

Sterlyn H. Gibson,

*Program Specialist, Office of Federal Advisory
Committee Policy.*

[FR Doc. 2025–23690 Filed 12–22–25; 8:45 am]

BILLING CODE 4140–01–P

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

National Institutes of Health

**Prospective Grant of an Exclusive
Patent License: Enhanced Tumor
Reactivity of T Cells Lacking SIT1,
LAX1, or TRAT1**

AGENCY: National Institutes of Health,
HHS.

ACTION: Notice.

SUMMARY: The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, an institute of the National Institutes of Health, United States Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the patent applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice to EnZeta Immunotherapies, Inc., a company located in Coral Gables, FL.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center, representing the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, on or before January 7, 2026 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated

an Exclusive Patent License should be directed to: Geoffrey E. Ravilious, Ph.D., NCI Technology Transfer Center, Telephone: 240–276–6391; Email: geoffrey.ravilious@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. United States Provisional Patent Application No. 63/625,354 filed January 26, 2024, and entitled “ENHANCED TUMOR REACTIVITY OF T CELLS LACKING SIT1, LAX1, OR TRAT1” [HHS Reference No. E–004–2024–0–US–01];

2. International Patent Application No. PCT/US2025/013054 filed January 24, 2025, and entitled “ENHANCED TUMOR REACTIVITY OF T CELLS LACKING SIT1, LAX1, OR TRAT1” [HHS Reference No. E–004–2024–0–PC–01]; and

3. any and all other U.S. and ex-U.S. patents and patent applications claiming priority to any one of the foregoing, now or in the future.

The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the following:

“The use of the Licensed Patent Rights to develop, manufacture, distribute, sell and use T-cell-based therapeutics for the treatment of solid tumors, high-grade dysplasia and pre-neoplastic conditions.”

This technology describes modified T cell therapeutics that have reduced expression of one or a combination of transmembrane adaptor proteins SIT1, LAX1 and TRAT1. T cell-based therapeutics such as ex vivo expanded tumor infiltrating lymphocytes (TIL) and chimeric antigen receptor T-cells (CAR-T) have clinical utility against a limited number of solid tumor types, most notably, melanoma. However, to date, efficacy in patients has been limited due to several factors. The subject invention potentially addresses the limited efficacy of T cell therapeutics by reducing expression of SIT1, LAX1 and/or TRAT1 which leads to enhanced T cell cytotoxic activity against tumor cells.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute, representing the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, 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.

Complete applications for a license that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. 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.

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: December 18, 2025.
Richard U. Rodriguez,
Associate Director, Technology Transfer Center, National Cancer Institute.
[FR Doc. 2025–23691 Filed 12–22–25; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; the Clinical Trials Reporting Program (CTRP) Database (NCI)

AGENCY: National Institutes of Health, HHS.
ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide an opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact Melissa Park, PRA Liaison, Office of Management Policy and Compliance, National Cancer Institute, 9609 Medical Center Drive, Room 2E196, Bethesda, MD 20892 or call non-toll-free number (240) 276–5717 or email your request, including your address to: *melissa.park@nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork

Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency’s estimate of the burden of the proposed collection of information, 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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: The Clinical Trials Reporting Program (CTRP) Database, 0925–0600, Expiration Date 02/28/2026–REVISION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Clinical Trials Reporting Program (CTRP) Database is an electronic resource that serves as a single, definitive source of information about all NCI-supported clinical research. This resource allows the NCI to consolidate reporting, aggregate information and reduce redundant submissions. Information is submitted by clinical research administrators as designees of clinical investigators who conduct NCI-supported clinical research. The designees can electronically access the CTRP website to complete the initial trial registration. Subsequent to registration, four amendments and four study subject accrual updates occur per trial annually.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The estimated annualized burden hours are 18,000.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Initial Registration	Individuals	3,000	1	1	3,000
Amendment		1,500	4	1	6,000
Update		1,500	4	1	6,000
Accrual Updates		3,000	4	15/60	3,000
Totals		9,000	27,000		18,000

Dated: December 19, 2025.

Melissa Park,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2025–23713 Filed 12–22–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer at (240) 276–0361.

Project: Mandatory Guidelines for Federal Workplace Drug Testing Programs Federal Drug Testing Custody and Control Form (CCF) (OMB No. 0930–0158) and National Laboratory Certification Program (NLCP) Information Collection Tools—Revision

SAMHSA will request OMB approval for revision of the Federal Drug Testing Custody and Control Form (CCF) for federal agency and federally regulated drug testing programs which must comply with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) dated October 12, 2023 (88 FR 70768) and using Oral Fluid (OFMG) dated October 12, 2023 (88 FR 70814), and OMB approval for information provided by test facilities (laboratories and Instrumented Initial Test Facilities,

IITFs) for the National Laboratory Certification Program (NLCP).

The CCF is used by all federal agencies and by employers regulated by the Department of Transportation (DOT) and the Nuclear Regulatory Commission (NRC) to document the collection and chain of custody of a urine or oral fluid specimen at the collection site, for HHS-certified test facilities to document chain of custody and report results, and for Medical Review Officers (MROs) to document and report a verified result. SAMHSA allows the use of the CCF as a paper or electronic form.

The current OMB-approved CCF has an August 31, 2026 expiration date. SAMHSA has resubmitted the CCF with revisions to the form for OMB approval. During 60-day public comment, 7 commenters submitted comments on the proposed changes to the CCF.

Commenters were comprised of individuals, organizations, and private sector companies. All comments were reviewed and taken into consideration in preparation of the revised CCF. The issues and concerns raised in the public comments are set out at

www.reginfo.gov/public/do/PRAMain.

The revisions are listed below:

Copies 1–5

Revised Step 1

1. Removed drug analytes and checkboxes from Item F and changed “Drug Tests to be Performed” to “Other tests to be performed (specify):”.

Copy 1

Revised Step 4

1. Moved the “Split Specimen Device Expiration Date” field to the right.

Copies 2–5

Revised Step 5

1. Lengthened the email address line and moved it to the right.

2. Replaced the 2 date fields for “Daytime Phone No.” and “Evening Phone No.” with a single field “Phone No.” and moved it to the left.

3. Moved the “Date of Birth” field to the left, reworded as “Birthdate” and moved the text under the line.

Laboratories and IITFs seeking HHS certification under the NLCP must complete and submit the NLCP application form. The NLCP application form has been updated in accordance with the current UrMG and OFMG. The revisions enable provision of information for analytes in the Authorized Testing Panels now published separately from the Mandatory Guidelines, and enable applicant test facilities to submit information on new technologies/instruments.

Prior to an inspection, an HHS-certified laboratory or IITF is required to submit specific information regarding its procedures. Collecting this information prior to an inspection allows the inspectors to thoroughly review and understand the testing procedures before arriving for the onsite inspection. The NLCP information checklist has been updated in accordance with the current UrMG and OFMG. The revisions enable provision of information for analytes in the Authorized Testing Panels now published separately from the Mandatory Guidelines, and enable certified test facilities to submit information on new technologies/instruments.

The annual total burden estimates for the CCF, the NLCP application, the NLCP information checklist, and the NLCP recordkeeping requirements are shown in the following table.

Form/respondent	Number of respondents	Responses per respondent	Total number of responses	Burden per response (hours)	Annual burden (hours)	Hourly wage rate (\$)	Total cost (\$) ³
Custody and Control Form: ¹							
Donor	6,726,610	1	6,726,610	0.08	538,129	25	13,453,225
Collector	6,726,610	1	6,726,610	0.07	470,683	15	7,060,245
Laboratory	6,726,610	1	6,726,610	0.05	336,331	35	11,771,585
IITF	1	0	0	0.05	0	35	0
Medical Review Officer	6,726,610	1	6,726,610	0.05	336,331	150	50,449,650
NLCP Application Form: ²							
Laboratory	20	1	20	3	60	35	2,100
IITF	0	0	0	3	0	35	0
Sections B and C—NLCP Information Checklist:							
Laboratory	19	1	19	1	19	35	665
IITF	1	1	1	1	1	35	35
Record Keeping:							
Laboratory	19	1	19	250	4,750	35	166,250
IITF	0	0	0	250	0	35	0

Form/respondent	Number of respondents	Responses per respondent	Total number of responses	Burden per response (hours)	Annual burden (hours)	Hourly wage rate (\$)	Total cost (\$) ³
Total	6,726,669		26,906,499		1,687,529		82,946,625

¹ **Note:** The time it takes each respondent (*i.e.*, donor, collector, laboratory, IITF, and MRO) to complete the Federal CCF is based on an average estimated number of minutes it would take each respondent to complete their designated section of the form or regulated entities (*e.g.* HHS, DOT, and NRC).

¹ **Note:** The above number of responses is based on an estimate of the total number of specimens collected annually (approximately 150,000 federal agency specimens; 6,500,000 DOT regulated specimens, and 145,000 NRC regulated specimens).

² **Note:** The estimate of 20 applications per year is based on requests for a laboratory application (urine or oral fluid) or IITF application in the past year (*i.e.*, at the time of these calculations).

² **Note:** The estimate of three burden hours to complete the application has not changed.

³ **Note:** At the time of these calculations, there were 18 certified laboratories and one certified IITF undergoing 2 maintenance inspections each year, and 1 applicant laboratory.

³ **Note:** The wage rates listed for each respondent are based on estimated average hourly wages for the individuals performing these tasks.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

Alicia Broadus,
Public Health Advisor.

[FR Doc. 2025–23760 Filed 12–22–25; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Agreement Between the U.S. Department of Homeland Security and the U.S. Department of State and the Paraguayan National Commission for Stateless Persons and Refugees

AGENCY: Department of Homeland Security.

ACTION: Notice of agreement.

SUMMARY: The Department of Homeland Security is publishing the Memorandum

of Understanding Between the U.S. Department of Homeland Security and the U.S. Department of State, on the one side, and the Paraguayan National Commission for Stateless Persons and Refugees, on the other side, for Cooperation in the Examination of Protection Requests, signed at Washington on August 14, 2025. The text is set out below.

Joseph N. Mazzara,
Acting General Counsel, U.S. Department of Homeland Security.

BILLING CODE 9110–9M–P

MEMORANDUM OF UNDERSTANDING

BETWEEN

THE U.S. DEPARTMENT OF HOMELAND SECURITY AND THE U.S. DEPARTMENT OF STATE,

ON THE ONE SIDE,

AND

THE PARAGUAYAN NATIONAL COMMISSION FOR STATELESS PERSONS AND REFUGEES,

ON THE OTHER SIDE,

FOR COOPERATION IN THE EXAMINATION OF PROTECTION REQUESTS

The U.S. Department of Homeland Security and the U.S. Department of State (together, the "U.S. Party"), on the one side, and the Paraguayan National Commission for Stateless Persons and Refugees ("CONARE"), on the other side, (collectively, "the Parties"),

DESIRING TO ensure the dignified, safe, and timely transfer from the United States of America to Paraguay of third country nationals present in the United States of America who may seek protection against return to their home country or country of former habitual residence,

AGREE as follows:

ARTICLE 1

1. The U.S. Party shall propose to CONARE the transfer of third-country nationals present in the United States of America who may seek protection against return to their home country or country of former habitual residence.
2. CONARE shall consider accepting in whole or in part a proposal made by the U.S. Party in accordance with paragraph 1.

ARTICLE 2

The Parties' actions under this Memorandum of Understanding (MOU) shall be in accordance with the obligations of their respective states under the Convention Relating to the Status of Refugees, done at Geneva on July 28, 1951; the Protocol Relating to the Status

of Refugees, done at New York on January 31, 1967; the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, adopted in New York on December 10, 1984; and any other respective international obligations, national constitutions, laws, regulations, and immigration and visa policies of the Parties, including consideration by CONARE of requests by these third country nationals for asylum, refugee protection, or equivalent temporary protection.

ARTICLE 3

1. CONARE agrees not to return any person transferred to Paraguay by the U.S. Department of Homeland Security to their home country or country of former habitual residence until a final decision has been made regarding any pending protection claims.
2. CONARE shall determine a procedure, consistent with its relevant obligations, to resolve the status of those who may abandon pending claims or fail to seek protection.
3. The U.S. Department of Homeland Security shall not transfer unaccompanied minors pursuant to this MOU.

ARTICLE 4

1. The U.S. Party and CONARE shall develop operating procedures to assist with the implementation of this MOU.
2. In the event of a divergence of interpretation or implementation, the Parties commit to resolve such matters through dialogue or diplomatic channels.

ARTICLE 5

1. This MOU shall enter into force upon signature.
2. Either the U.S. Party or CONARE may terminate or suspend this MOU at any time by notifying the other side in writing.

3. The Parties may agree in writing to any amendments to this MOU, and such amendments shall constitute an integral part of this MOU, consistent with any applicable legal requirements.
4. Nothing set forth in this MOU shall be interpreted in such a way that commits the disbursement or allocation of funds by the Parties. The implementation of this MOU shall be subject to the availability of funds and technical capacity of each Party.

DONE, in duplicate, in the English and Spanish languages, both texts being equally authentic.

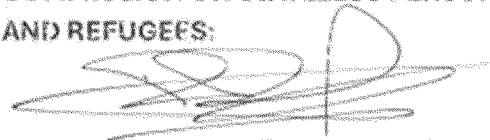
FOR THE U.S. DEPARTMENT OF
HOMELAND SECURITY:



Place: Washington

Date: 8/14/2025

FOR THE PARAGUAYAN NATIONAL
COMMISSION ON STATELESS PERSONS
AND REFUGEES:



Place: Washington

Date: 8/14/2025

FOR THE U.S. DEPARTMENT OF
STATE:



Place: Washington

Date: 8/14/2025

[FR Doc. 2025-23797 Filed 12-19-25; 4:15 pm]

BILLING CODE 9110-9M-C

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS-R4-ES-2025-1067;
FXES11140400000-256-FF04EF4000]

Receipt of Incidental Take Permit Application and Proposed Habitat Conservation Plan for the Sand Skink and Blue-Tailed Mole Skink; Osceola County, FL; Categorical Exclusion

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the Fish and Wildlife Service (Service), announce receipt of an application from Osceola County (Westside Technology Park) (applicant) for an incidental take permit (ITP) under the Endangered Species Act. The applicant requests the ITP to take the federally listed sand skink and blue-tailed mole skink incidental to the construction of a County park in Osceola County, Florida. We request public comment on the application, which includes the applicant's proposed habitat conservation plan (HCP), and on the Service's preliminary determination that the proposed permitting action may be eligible for a categorical exclusion pursuant to the National Environmental Policy Act (NEPA), the Department of the Interior's (DOI) NEPA regulations, and the DOI Departmental Manual (DM). To make this preliminary determination, we prepared a draft screening form and NEPA statement for HCPs, which is available for public review. We invite comment from the public and local, State, Tribal, and Federal agencies.

DATES: We must receive your written comments on or before January 22, 2026.

ADDRESSES:

Obtaining Documents: The documents related to this notice, as well as any comments and other materials that we receive, will be available for public inspection online in Docket No. FWS-R4-ES-2025-1067 at <https://www.regulations.gov>.

Submitting Comments: If you wish to submit comments on any of the documents, you may do so in writing by one of the following methods:

- **Online:** <https://www.regulations.gov>. Follow the instructions for submitting comments on Docket No. FWS-R4-ES-2025-1067;

- **U.S. Mail:** Public Comments Processing, Attn: Docket No. FWS-R4-ES-2025-1067; U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041-3803.

FOR FURTHER INFORMATION CONTACT:

Samantha Hermann, by U.S. mail (see **ADDRESSES**), by telephone at 850-347-2671 or via email at Samantha.Hermann@fws.gov. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the Service, announce receipt of an application from Osceola County (Westside Technology Park) (applicant) for an ITP, also known as a section 10(a)(1)(B) permit, under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The applicant requests the ITP to take federally listed sand skinks (*Neopseps (=Plestiodon) reynoldsi*) and blue-tailed mole skinks (*Eumeces egregius lividus*) (skinks) incidental to the construction and operation of a County park in Osceola County, Florida.

We request public comment on the application, which includes the applicant's HCP, and on the Service's preliminary determination that this proposed ITP may qualify for a categorical exclusion pursuant to NEPA (42 U.S.C. 4321 *et seq.*), DOI's NEPA regulations (43 CFR 46), and DOI's DM (516 DM 8.5(C)(2)). To make this preliminary determination, we prepared a draft screening form and NEPA statement for HCPs, which is available for public review.

Proposed Project

The applicant requests a 5-year ITP to take skinks via the conversion of approximately 0.47 acres (ac) of occupied nesting, foraging, and sheltering skink habitat incidental to the construction and operation of Westside Technology Park on 40 acs, Parcel #07-25-27-000000-200000 in Section 07, Township 25 South, Range 27 East, Osceola County, Florida.

The applicant proposes to mitigate for take of the skinks by purchasing credits equivalent to 0.94 ac of skink-occupied habitat within a Service-approved conservation bank. The Service would require the applicant to purchase the credits no later than 30 days after the issuance of the permit and prior to any

clearing activities. The applicant will provide educational opportunities through signage and QR codes that will focus on native plants and wildlife including the sand and blue-tailed mole skinks and their habitat.

Our Preliminary Determination

The Service has made a preliminary determination that reasonably foreseeable effects of the applicant's proposed project, including the construction of the county park and associated clearing, would have a minor effect on the skinks and the human environment and that no extraordinary circumstances in 43 CFR 46.215 apply. Reasonably foreseeable effects encompass effects of implementation of the action including effects of the action in addition to other past, present, and reasonably foreseeable future effects.

Therefore, we have preliminarily determined that the proposed ESA section 10(a)(1)(B) permit would be a low-effect ITP that may qualify for application of a categorical exclusion (516 DM 8.5(C)(2)), pursuant to NEPA and DOI's NEPA regulations and DM. A low-effect ITP is one that would result in (1) negligible or minor individual or cumulative effects on species covered in the HCP; (2) no significant effect on the human environment; and (3) reasonably foreseeable effects that would not result in significant effects to the human environment.

Next Steps

The Service will evaluate the application and the comments to determine whether to issue the requested ITP. We will also conduct an intra-Service consultation pursuant to section 7 of the ESA to evaluate the effects of the proposed take. After considering the preceding and other matters, we will determine whether the permit issuance criteria of section 10(a)(1)(B) of the ESA have been met. If met, the Service will issue ITP number PER 21116185 to Osceola County.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, be aware that your entire comment, including your personal identifying information, may be made available to the public. If you submit a comment at <https://www.regulations.gov>, your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, such as your address, phone number, or

email address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so.

Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Authority

The Service provides this notice under ESA section 10(c) (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.32) and under NEPA (42 U.S.C. 4321 *et seq.*) and DOI's implementing regulations (43 CFR part 46).

Jose Rivera,

Field Supervisor, Division of Environmental Review, Florida Ecological Services Field Office.

[FR Doc. 2025–23647 Filed 12–22–25; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2025–0935; FXIA1671090000/267/FF09A30000; OMB Control Number 1018–0093]

Agency Information Collection Activities; Federal Fish and Wildlife Permit Applications and Reports—Management Authority

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing to renew a currently approved information collection without change.

DATES: Interested persons are invited to submit comments on or before February 23, 2026.

ADDRESSES: Send your comments on the information collection request (ICR) by one of the following methods (please reference the Office of Management and Budget (OMB) Control No. 1018–0093 in the subject line of your comment):

- *Internet (preferred):* <https://www.regulations.gov>. Follow the instructions for submitting comments on Docket No. FWS–HQ–MB–2025–0803.
- *U.S. mail:* Service Information Collection Clearance Officer, U.S. Fish

and Wildlife Service, 5275 Leesburg Pike, MS: PRB (JAO/3W); Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT:

Madonna L. Baucum, Service Information Collection Clearance Officer, by email at Info_Coll@fws.gov, or by telephone at (703) 358–2503. 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: In accordance with the Paperwork Reduction Act (PRA; 44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR part 1320, all information collections require approval under the PRA. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again inviting the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

- (1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;
- (2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;
- (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and
- (4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your

address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The general permit requirements at 50 CFR part 13 provide the uniform rules, conditions, and procedures for the application for, and the issuance, denial, suspension, revocation, and general administration of, all permits for all of the laws, treaties, and regulations administered by the Service that authorize activities requiring permits. The requirements in 50 CFR part 13 are in addition to any other permit regulations that may apply to a specific circumstance and are outlined in other sections of our regulations.

The Wild Bird Conservation Act (WBCA; 16 U.S.C. 4901–4916) and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES; 27 U.S.T. 1087, March 3, 1973) mandate a system of permits and certificates to help ensure that international trade is legal and does not threaten the survival of wildlife or plant species in the wild. Permits under the U.S. Endangered Species Act (ESA; 16 U.S.C. 1531 *et seq.*) and the Marine Mammal Protection Act (MMPA; 16 U.S.C. 1361 *et seq.*) ensure that activities are consistent with the intent and purposes of the ESA and MMPA. Permitted activities under the Bald and Golden Eagle Act (BGEPA; 16 U.S.C. 668–668d) must be compatible with the preservation of eagles. Permitted activities regarding injurious wildlife under the Lacey Act (18 U.S.C. 42; 16 U.S.C. 3371–3378) regulate the importation into the United States and any shipment between the continental United States, the District of Columbia, Alaska, Hawaii, the Commonwealth of Puerto Rico, or any possession of the United States, of animal species determined to be injurious by the Secretary of the Interior. Such importation and shipments are prohibited, except by permit. Although the Service's Division of Management Authority does not administer the Migratory Bird Treaty Act (MBTA; 16 U.S.C. 704), we receive authorization from the Migratory Bird Program to issue import/export permits under the MBTA.

Prior to the import or export of species listed under the MBTA, MMPA,

BGEPA, Lacey Act, WBCA, ESA, and/or CITES, the Management Authority and Scientific Authority must make appropriate determinations and issue the appropriate documents. Section 8A of the ESA designates the Secretary of the Interior as the U.S. Management Authority and U.S. Scientific Authority for CITES. The Secretary in turn delegated these authorities to the Service.

Before a country can issue an export permit for CITES appendix I or II specimens, the CITES Scientific Authority of the exporting country must determine that the export will not be detrimental to the survival of the species, and the Management Authority must be satisfied that the specimens were acquired legally. For the export of appendix III specimens, the Management Authority must be satisfied that the specimens were acquired legally (CITES does not require findings from the Scientific Authority). Prior to the importation of appendix I specimens, both the Scientific Authority and the Management Authority of the importing country must make required findings. The Scientific Authority must also monitor trade of all species to ensure that the level of trade is sustainable.

Article VIII(3) of the CITES treaty states that participating parties should make efforts to ensure that CITES specimens are traded with a minimum of delay. Section XIII of Resolution Conf. 12.3 (Rev. CoP19) recommends use of simplified procedures for issuing CITES documents to expedite trade that will have no impact, or a negligible impact, on conservation of the species involved.

Applications and Reports

All Service permit applications and reports are in the 3–200 series of forms, each tailored to a specific activity based on the requirements for specific types of permits. In accordance with Federal regulations at 50 CFR 13.12, we collect standard identifier information for all permit applications, such as:

- Applicant's full name, whether an individual or business, and address (street address, city, county, State, and zip code; and mailing address, if different from street address); main and alternate telephone numbers; and an email address (required if filing electronically, optional for a mail-in application); and

—If the applicant resides or is located outside the United States, an address in the United States, and, if the applicant is conducting commercial activities, the name and

address of the applicant's agent inside the United States; and
—If the applicant is a business, corporation, public agency, or institution, the tax identification number; description of the business type, corporation, agency, or institution; and the name and title of the person responsible for the permit (such as president, principal officer, or director);

- Location where the requested permitted activity is to occur or be conducted;
- Reference to the part(s) and section(s) of subchapter B as listed in paragraph (b) of 50 CFR part 13 under which the application is made for a permit or permits, together with any additional justification, including supporting documentation as required by the referenced part(s) and section(s);
- If the requested permitted activity involves the import or re-export of wildlife or plants from or to any foreign country, and the country of origin, or the country of export or re-export restricts the taking, possession, transportation, exportation, or sale of wildlife or plants, documentation as indicated in § 14.52(c) of subchapter B;
- Certification containing the following language:
—I hereby certify that I have read and am familiar with the regulations contained in title 50, part 13, of the Code of Federal Regulations and the other applicable parts in subchapter B of chapter I of title 50, Code of Federal Regulations, and I further certify that the information submitted in this application for a permit is complete and accurate to the best of my knowledge and belief. I understand that any false statement herein may subject me to suspension or revocation of this permit and to the criminal penalties of 18 U.S.C. 1001.

- Desired effective date of permit (except where issuance date is fixed by the part under which the permit is issued);
- Signature date;
- Signature of the applicant;
- Such other information as the Director determines relevant to the processing of the application; and
- Additional information required on applications for other types of permits may be found by referring to table 1 in paragraph (b) in 50 CFR 13.12.

Standardization of general information common to the forms makes the filing of applications easier for the public, as well as expediting our review of applications. The information that we

collect on applications and reports is the minimum necessary for us to determine if the applicant meets/continues to meet issuance requirements for the particular activity.

Miscellaneous Information Collections

- *Request for Approval of a CITES Export Program (American Ginseng, CITES furbearers, American Alligator), 50 CFR 23.68, 50 CFR 23.69, and 50 CFR 23.70*—For States and Tribes that set up and maintain management programs for these species to protect from over-harvest, requesting approval of their management plans allows the Division of Scientific Authority to make programmatic findings under specific requirements that allow the export of these species under CITES. These programmatic findings streamline the permit process for applicants.
- *Report for Furbearer CITES Export Programs, 50 CFR 23.69(b)(3)*—A State or Tribe with an approved CITES export program must submit a CITES furbearer activity report that provides information as to whether or not the population status or management of the species has changed within the State or Tribal lands. If information has not changed, the report may reference information provided in previous years. Range-wide non-detriment findings are re-evaluated at least every 5 years, or sooner if information indicates that there has been a change in the status of management of the species that might lead to different treatment of the species.
- *Report for American Alligator CITES Export Program, 50 CFR 23.70(c)(2)*—A State or Tribe with an approved CITES export program must submit a CITES American alligator activity report that provides information as to whether or not the population status or management of the species has changed within the State or Tribal lands. If information has not changed, the report may reference information provided in previous years. Range-wide non-detriment findings are re-evaluated at least every 5 years, or sooner if information indicates that there has been a change in the status of management of the species that might lead to different treatment of the species.
- *Report—Plant Rescue Program Receipt and Condition of Specimens, 50 CFR 23.79*—Seized plants that are placed with a registered Plant Rescue Center may be required to account periodically for the donation or loan regarding the receipt of those

specimens and the condition in which they arrived.

- *Report Take (Grizzly Bears)*, 50 CFR 17.40(b)—Grizzly bears taken in self-defense or in the defense of others by individuals or their designee in Montana or Wyoming must report the take to the U.S. Fish and Wildlife Service's Office of Law Enforcement within 5 days of the said take. If taken in Idaho or Washington said take must also be reported to the appropriate State and Tribal authorities.
- *Report Take (Mountain Lion)*, 50 CFR 17.40(h)—Mountain lions taken in the State of Florida must be reported to the U.S. Fish and Wildlife Service's Office of Law Enforcement within 5 days of the said take.
- *Application—Participation in the Plant Rescue Center Program*, 50 CFR 23.79—The Plant Rescue Center Program is established to place confiscated live plants quickly to prevent physical damage to plants. Entities that wish to participate may submit a letter requesting participation. A request to become part of the Plant Rescue Center Program comes via a letter. The requestor must address the requirements in the regulation.
- *Marking/Labeling Requirements*—The following contain marking/labeling requirements outlined in the regulations. We do not collect information on this; rather, if items show up with these species without the necessary labelling/markings and permits, they will be seized.
 - Vicuna Products, Beluga Sturgeon Caviar, and African Elephant Sport Hunted Trophies, 50 CFR 23.75, 50 CFR 23.71, 50 CFR 17.44(y), and 50 CFR 17.40(e)
 - Beluga Sturgeon Exemption, 50 CFR 17.44(y)(3)
 - Wildlife Hybrid Exemption, 50 CFR 23.43
 - Exception to Use of CITES Specimens after Import, 50 CFR 23.55
- *International Reporting Requirements*—The Service imposes international reporting requirements specified in 50 CFR parts 13, 17, 18, and 23. These reporting requirements are associated with the findings we must make under the various laws, treaties, and regulations administered by the Service. This may include consultation on sustainable use, population data, management practices, and verification of information received from other sources. The Service does not provide

a form for this collection; rather, we request specific information based on the most current data we hold, in order to enable us to update or clarify that data. We estimate the annual burden associated with the international reporting requirements to be 24 responses and 192 burden hours. There are no nonhour burden costs associated with the international reporting requirements.

- *Recordkeeping Requirements*, 50 CFR 13.46—Permittees must keep records of all activities conducted under certain permits, including those of subpermittees carried out under the authority of the permit, as well as documentation of any take that occurs from the permitted activity and the data gathered through surveys and monitoring. We use these data to assess the conservation benefits or detriments to plant and wildlife populations. Additionally, under 50 CFR 13.47, the Service may enter a permittee's premises at any reasonable hour to inspect any wildlife or plant held or to inspect, audit, or copy any permits, books, or records required to be kept by these regulations for compliance under the permit conditions
- *Amendments to Permit Applications*—Amendments to a permit may be requested by the permittee, or the Service may amend a permit for just cause upon a written finding of necessity. Amendments comprise changes to the permit authorization or conditions. The permittee must apply for amendments to the permit by submitting a description of the modified activity and the changed impacts. These are considered substantive amendments and incur a fee. For CITES permits, if there is a change in the legal individual or business name, this is considered a substantive amendment and incurs a fee. For federal permits, a permittee is not required to obtain a new permit if there is a change in the legal individual or business name, or in the mailing address of the permittee. A permittee is required to notify the issuing office within 10 calendar days of such change. This provision does not authorize any change in location of the conduct of the permitted activity when approval of the location is a qualifying condition of the permit.

The public may access the currently approved versions of all forms contained in this information collection at https://www.reginfo.gov/public/do/PRAICList?ref_nbr=202302-1018-009.

Title of Collection: Federal Fish and Wildlife Permit Applications and Reports—Management Authority (50 CFR 13, 15, 16, 17, 18, 22, 23).

OMB Control Number: 1018–0093.

Form Numbers: 3–200–19 through 3–200–37, 3–200–39 through 3–200–42, 3–200–43a through 3–200–43d, 3–200–46 through 3–200–53, 3–200–58, 3–200–61, 3–200–64 through 3–200–66, 3–200–69, 3–200–70, 3–200–73 through 3–200–76, 3–200–80, and 3–200–85 through 3–200–88.

Type of Review: Extension without change of a currently approved collection.

Description of Respondents/Affected Public: Individuals (including hunters); private sector (including biomedical companies, circuses, zoological parks, botanical gardens, nurseries, museums, universities, antique dealers, exotic pet industry, taxidermists, commercial importers/exporters of wildlife and plants, freight forwarders/brokers); and State, local, Tribal, and Federal government agencies.

Estimated Number of Annual Respondents: 6,139.

Estimated Number of Annual Responses: 8,946.

Estimated Completion Time per Response: Varies from 15 minutes to 40 hours, depending on activity.

Estimated Annual Burden Hours: 9,035.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion or annually, depending on activity.

Total Estimated Annual Nonhour Burden Cost: \$576,387 for costs associated with application processing fees, which range from \$0 to \$250. There is no fee for reports. State, local, Tribal, and Federal government agencies and those acting on their behalf are exempt from processing fees.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2025–23694 Filed 12–22–25; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR**Bureau of Indian Affairs**

[OMB Control Number 1076-0157;
267A2100DD/AAKP300000/
A0A501010.000000]

**Agency Information Collection
Activities; Submission to the Office of
Management and Budget for Review
and Approval; Grazing Permits**

AGENCY: Bureau of Indian Affairs,
Interior.

ACTION: Notice of information collection;
request for comment.

SUMMARY: In accordance with the
Paperwork Reduction Act of 1995, the
Bureau of Indian Affairs (BIA) is
proposing to renew an information
collection.

DATES: Interested persons are invited to
submit comments. To be considered,
your comments must be received on or
before January 22, 2026.

ADDRESSES: Send your written
comments and recommendations for the
proposed information collection request
(ICR) to the Office of Information and
Regulatory Affairs (OIRA) through
[https://www.reginfo.gov/public/do/PRA/
icrPublicCommentRequest?ref_
nbr=202505-1076-004](https://www.reginfo.gov/public/do/PRA/icrPublicCommentRequest?ref_nbr=202505-1076-004) or by visiting
[https://www.reginfo.gov/public/do/
PRAMain](https://www.reginfo.gov/public/do/PRAMain) and selecting “Currently
under Review—Open for Public
Comments” and then scrolling down to
the “Department of the Interior.”

FOR FURTHER INFORMATION CONTACT:

Steven Mullen, Information Collection
Clearance Officer, Office of Regulatory
Affairs and Collaborative Action—
Indian Affairs, U.S. Department of the
Interior, 1001 Indian School Road NW,
Suite 229, Albuquerque, New Mexico
87104; comments@bia.gov; (202) 924-
2650. Individuals in the United States
who are deaf, deafblind, hard of hearing,
or have a speech disability may dial 711
(TTY, TDD, or TeleBraille) to access
telecommunications relay services. You
may also view the ICR at [https://
www.reginfo.gov/public/Forward?
SearchTarget=PRA&textfield=1076-
0157](https://www.reginfo.gov/public/Forward?SearchTarget=PRA&textfield=1076-0157).

SUPPLEMENTARY INFORMATION: In
accordance with the Paperwork
Reduction Act of 1995 (PRA, 44 U.S.C.
3501 *et seq.*) and 5 CFR 1320.8(d)(1), we
provide the general public and other
Federal agencies with an opportunity to
comment on new, proposed, revised,
and continuing collections of
information. This helps us assess the
impact of our information collection
requirements and minimize the public’s
reporting burden. It also helps the

public understand our information
collection requirements and provide the
requested data in the desired format.

A **Federal Register** notice with a 60-
day public comment period soliciting
comments on this collection of
information was published on July 11,
2025 (90 FR 30949). No comments were
received.

As part of our continuing effort to
reduce paperwork and respondent
burdens, we are again soliciting
comments from the public and other
Federal agencies on the proposed ICR
that is described below. We are
especially interested in public comment
addressing the following:

(1) Whether or not the collection of
information is necessary for the proper
performance of the functions of the
agency, including whether or not the
information will have practical utility;

(2) The accuracy of our estimate of the
burden for this collection of
information, including the validity of
the methodology and assumptions used;

(3) Ways to enhance the quality,
utility, and clarity of the information to
be collected; and

(4) How might the agency minimize
the burden of the collection of
information on those who are to
respond, including through the use of
appropriate automated, electronic,
mechanical, or other technological
collection techniques or other forms of
information technology, *e.g.*, permitting
electronic submission of response.

Comments that you submit in
response to this notice are a matter of
public record. Before including your
address, phone number, email address,
or other personal identifying
information in your comment, you
should be aware that your entire
comment—including your personal
identifying information—may be made
publicly available at any time. While
you can ask us in your comment to
withhold your personal identifying
information from public review, we
cannot guarantee that we will be able to
do so.

Abstract: The American Indian
Agricultural Resource Management Act
(AIARMA), 25 U.S.C. 3701 *et seq.*,
authorizes the Secretary of the Interior,
in participation with the beneficial
owner of the land, to manage Indian
agricultural lands in a manner
consistent with identified Tribal goals
and priorities for conservation, multiple
use, sustained yield, and consistent
with trust responsibilities. The
regulations at 25 CFR part 166, “Grazing
Permits,” implement the AIARMA and
include the specific information
collection requirements. Submission of
this information allows individuals or

organizations to acquire or modify a
grazing permit on Tribal land,
individually-owned Indian land, or
government land and to meet bonding
requirements.

Title of Collection: 25 CFR part 166,
“Grazing Permits.”

OMB Control Number: 1076-0157.

Form Number: Form 5-5423—
Performance Bond, Form 5-5514—Bid
for Grazing Privileges, 5-5515 Grazing
Permit, Form 5-5516—Grazing Permit
for Organized Tribes, Form 5-5517—
Free Grazing Permit, Form 5-5519—
Cash Penal Bond, Form 5-5520—Power
of Attorney, Form 5-5521—Certificate
and Application for On-and-Off Grazing
Permit, Form 5522—Modification of
Grazing Permit, Form 5-5523—
Assignment of Grazing Permit, Form 5-
5524—Application for Allocation of
Grazing Privileges, 5-5525 Authority to
Grant Grazing Privileges on Allotted
Lands, Form 5-5528—Livestock
Crossing Permit, and Form 5-5529—
Removable Range Improvement
Records.

Type of Review: Extension of a
currently approved collection.

Respondents/Affected Public: Tribes,
Tribal organizations, individual Indians,
and non-Indian individuals and
associations.

*Total Estimated Number of Annual
Respondents:* 7,810.

*Total Estimated Number of Annual
Responses:* 7,810.

*Estimated Completion Time per
Response:* Varies from 20 minutes to
one hour, with an average of less than
one hour per response.

*Total Estimated Number of Annual
Burden Hours:* 2,701.

Respondent’s Obligation: Required to
obtain or retain a benefit.

Frequency of Collection: Annually.

*Total Estimated Annual Nonhour
Burden Cost:* \$0.

Authority

An agency may not conduct or
sponsor and a person is not required to
respond to a collection of information
unless it displays a currently valid OMB
control number. The authority for this
action is the Paperwork Reduction Act
of 1995 (44 U.S.C. 3501 *et seq.*).

Steven Mullen,

*Information Collection Clearance Officer,
Office of Regulatory Affairs and Collaborative
Action—Indian Affairs.*

[FR Doc. 2025-23744 Filed 12-22-25; 8:45 am]

BILLING CODE 4337-15-P

DEPARTMENT OF THE INTERIOR**Bureau of Reclamation**

[RR85672000, 21XR0680A2,
RX.31480001.0040000; OMB Control
Number 1006–0028]

**Agency Information Collection
Activities; Recreation Survey
Questions**

AGENCY: Bureau of Reclamation,
Interior.

ACTION: Notice of information collection;
request for comments.

SUMMARY: In accordance with the
Paperwork Reduction Act of 1995, we,
the Bureau of Reclamation
(Reclamation), are proposing to renew
an information collection with
revisions.

DATES: Interested persons are invited to
submit comments on or before February
23, 2026.

ADDRESSES: Send written comments on
this information collection request (ICR)
by mail to Ronnie Baca, Bureau of
Reclamation, Asset Management
Division, 86–67200, P.O. Box 25007,
Denver, CO 80225–0007; or by email to
rbaca@usbr.gov. Please reference the
Office of Management and Budget
(OMB) Control Number 1006–0028 in
the subject line of your comments.

FOR FURTHER INFORMATION CONTACT:

Ronnie Baca by email at rbaca@usbr.gov, or by telephone at (303) 445–3257. 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: In
accordance with the Paperwork
Reduction Act of 1995 (PRA, 44 U.S.C.
3501 *et seq.*) and 5 CFR 1320.8(d)(1), all
information collections require approval
under the PRA. We may not conduct or
sponsor and you are not required to
respond to a collection of information
unless it displays a currently valid OMB
control number.

As part of our continuing effort to
reduce paperwork and respondent
burdens, we invite the public and other
Federal agencies to comment on new,
proposed, revised, and continuing
collections of information. This helps us
assess the impact of our information
collection requirements and minimize
the public's reporting burden. It also

helps the public understand our
information collection requirements and
provide the requested data in the
desired format.

We are especially interested in public
comment addressing the following:

(1) Whether or not the collection of
information is necessary for the proper
performance of the functions of the
agency, including whether or not the
information will have practical utility;

(2) The accuracy of our estimate of the
burden for this collection of
information, including the validity of
the methodology and assumptions used;

(3) Ways to enhance the quality,
utility, and clarity of the information to
be collected; and

(4) How might the agency minimize
the burden of the collection of
information on those who are to
respond, including through the use of
appropriate automated, electronic,
mechanical, or other technological
collection techniques or other forms of
information technology, *e.g.*, permitting
electronic submission of response.

Comments that you submit in
response to this notice are a matter of
public record. We will include or
summarize each comment in our request
to OMB to approve this ICR. Before
including your address, phone number,
email address, or other personal
identifying information in your
comment, you should be aware that
your entire comment—including your
personal identifying information—may
be made publicly available at any time.
While you can ask us in your comment
to withhold your personal identifying
information from public review, we
cannot guarantee that we will be able to
do so.

Abstract: Reclamation is responsible
for recreation development at all of its
reservoirs. Presently, more than 240
designated recreation areas exist on our
lands within the 17 Western States,
hosting approximately 40 million
visitors annually. As a result, we must
be able to respond to emerging trends;
changes in the demographic profile of
users; changing values, needs, wants,
and desires; and conflicts between user
groups.

Statistically valid and up-to-date data
derived from the user is essential to
developing and providing recreation
programs relevant to today's visitor.
Reclamation is requesting re-approval
for the collection of data from
recreational users on Reclamation lands
and waterbodies.

To meet our needs for the collection
of visitor data, we will request OMB
authorize a two-part request: survey

questions from which our regional
offices may choose and a survey form
template. This will allow for a custom
designed survey instrument to fit a
specific activity or recreation site. The
custom designed survey would be
created by extracting questions from the
approved list of survey questions that
are applicable to the recreation area and
issue being evaluated. Only questions
included in the pre-approved list of
survey questions will be used.

Revisions to this collection will be
made to adjust respondent demographic
questions to conform with Executive
Order 14168, “Defending Women From
Gender Ideology Extremism and
Restoring Biological Truth to the
Federal Government” (January 20, 2025)
and OMB’s “2024 Statistical Policy
Directive No. 15: Federal Race and
Ethnicity Data Standards.”

Title of Collection: Recreation Survey
Questions.

OMB Control Number: 1006–0028.

Form Number: 7–2675, Recreation
Survey Questions.

Type of Review: Revision of a
currently approved collection.

Respondents/Affected Public:
Respondents to the surveys will be
members of the public engaged in
recreational activities on Reclamation
lands and waterbodies. Visitors will
primarily consist of local residents,
people from large metropolitan areas in
the vicinity of the lake/reservoir, and
people from out of state.

*Total Estimated Number of Annual
Respondents:* 696.

*Total Estimated Number of Annual
Responses:* 696.

*Estimated Completion Time per
Response:* 15 minutes per survey (an
average of 20 questions will be used on
each survey; each question will take
approximately 45 seconds to complete
on average).

*Total Estimated Number of Annual
Burden Hours:* 140.

Respondent's Obligation: Voluntary.

Frequency of Collection: Twice
annually.

*Total Estimated Annual Nonhour
Burden cost:* None.

Reclamation estimates that there will
be a total of 140 out of 696 contacts that
choose not to respond to the survey.
These non-respondents account for 1
burden hour per year.

An agency may not conduct or
sponsor and a person is not required to
respond to a collection of information
unless it displays a currently valid OMB
control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Stephanie McPhee,

Acting Information Collection Clearance Officer, Bureau of Reclamation.

[FR Doc. 2025–23650 Filed 12–22–25; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1470]

Certain Open-Ear Earpiece Devices; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on September 23, 2025, under section 337 of the Tariff Act of 1930, as amended, on behalf of Bose Corporation of Framingham, Massachusetts. Supplements to the complaint were filed on November 20 and 24, 2025, and December 4 and 9, 2025. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain open-ear earpiece devices by reason of the infringement of certain claims of U.S. Patent No. 11,140,469 (“the ‘469 patent”); U.S. Patent No. 11,659,313 (“the ‘313 patent”); U.S. Patent No. 11,997,442 (“the ‘442 patent”); U.S. Patent No. 12,356,132 (“the ‘132 patent”); U.S. Patent No. 12,155,984 (“the ‘984 patent”); and U.S. Patent No. D1,051,103 (“the D103 patent”). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a general exclusion order, or in the alternative a limited exclusion order, and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205–1810. Persons with mobility impairments who will

need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>.

FOR FURTHER INFORMATION CONTACT:

Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission’s Rules of Practice and Procedure, 19 CFR 210.10 (2025).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on December 18, 2025, *ordered that—*

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1–5 and 8–17 of the ‘469 patent; claims 1–4 and 6–20 of the ‘313 patent; claims 1–7, 9–10, 13, 15–17, and 20–25 of the ‘442 patent; claims 1–7, 10–12, and 16–21 of the ‘132 patent; claims 1, 3–9, 11–14, and 16–19 of the ‘984 patent; and the claim of the D103 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission’s Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is “earpiece devices, or more specifically, open-ear earbuds which, unlike traditional in-ear or over-ear headphones, do not block the ear canal, allowing users to hear both their audio and ambient sounds simultaneously”;

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is: Bose Corporation, 100 Mountain Road, Framingham, MA 01701.

(b) The respondents are the following entities alleged to be in violation of

section 337, and are the parties upon which the complaint is to be served:

Dongguan Yuanyu Electronic Co., Ltd. d/b/a Ituoray, No. 36, 3rd Road, Beian, Huangjiang Town, Dongguan City, Guangdong Province, China 523759

Liu, Yiming d/b/a Yomdud, No. 7, Xinzhongdong Land, Xincheng District, Xi’an, China 710000

King Lucky Co., Ltd., 162–170 Pai Road, Dalian Room I–1, 4/F, Phase II, Golden Dragon Industrial Center, Kwai Chung, New Territories 999077, Hong Kong Special Administrative Region, New Territories, China
Shenzhen Zhichuang All Technology Co., Ltd. and/or, Abbott Sanag (UK) Group Co., Ltd. d/b/a Sanag, 31st Floor, West Tower of Xinghe Twin Towers, No. 8 Yaxing Rd., Bantian St., Longgang District, Shenzhen, China and/or

Z015 13 Quad Road, East Lane, Wembley, England, HA9 7NE
Lingzhong Zhao d/b/a Jzones, No. 26, Group 6, Kebei Village, Shibao, Gulin, Sichuan, China 646599

Shenzhen Mengmengwei Electronic Commerce Co., Ltd. d/b/a Lytmi, Room 522, Building A1, 5th Floor, Xuexiangyuan, Yuanchuang Space, Xiangjiaotang Community Bantian Subdistrict, Shenzhen, Longgang District, Guangdong Province, 51811 China

Shenzhen Maosong Tech. Co., Ltd. d/b/a Ansten, 4 dozens, 4th floor, No.1, factory building, Lingya Industrial Park, No.1 Road, Tangtou Community, Shiyan Street, Bao’an District, Shenzhen, China
U2O Global Co., Ltd. d/b/a IWalk, U2O Building, Huanzhu Road 385, Jimei, Xiamen, Fujian, China

Shenzhen Meichi Electronics Co., Ltd. d/b/a HOMSCAM, Room B312 B313, 3/F, Huafeng Business Mansion Qianjin 1st Road, Xin’an 25 Area, Baoan District, Shenzhen, China

Shenzhen Shixinhe Dianzi Shangwu Co., Ltd., d/b/a XINHESHUMA, Huaqiang North Street, Futian District, Shenzhen 4159 Futian District 518048, Guangdong Province, Shenzhen City, China

Shenzhen Landscape Art Co., Ltd. d/b/a Piluyaa, No. 2, Laoweidong 1st Lane, Dafen Oil Painting Village, Buji Subdistrict, Longgang District, Shenzhen City, Guangdong Province, China 518000

Shenzhen Zhiquhui Technology Co., Ltd. d/b/a Yeabomy, 602, 6/F, China Zhenhua Industrial Park Bldg., No 64 Heping Road, Qinghua Community, Longhua Shenzhen, China

Shenzhen Carnival Digital Technology Co., Ltd. and/or, Shenzhen Lida Tech. Communication Co., Ltd. d/b/a Shijiaet, Shenzhen City, Room 403, No. 33, Second Floor, Chiwei Village, Chiwei Community, Futian District, Guangdong Province, 518000 China and/or

13C, Building 4, Yingjun Nianhua, No. 3, Lingbei Road Nanling Village Community, Nanwan St., Longgang District, Shenzhen China

Shenzhen Shibaishi Dianzi Shangwu Co., Ltd., d/b/a Jiayuu and/or YouDaxing, Floor 4, Block C, Electronic Technology Building, No. 2070, Shennan Middle Road, Fuqiang Community Huaqiang North Street, Futian district 518048, Guangdong Province, Shenzhen, China

Buy Worry-Free Trade Co., Ltd. d/b/a BST Supply I, RM 01, 26TH FLOOR, Working View Comm Building, 21 Yiu Wah Street, Causeway Bay, Hong Kong Sha Tin District 999077, Hong Kong Special Administrative Region, New Territories, China

Hong Kong Shihui Technology Co., Ltd. d/b/a Wdingxing, Unit 616 6/F Kam Teem Industrial Building, 135 Connaught Rd., West Sai Ying Pun HK, Central and Western District 999077, Hong Kong Special Administrative Region, Hong Kong Island, China

Hong Kong Chuanboyao Technology Ltd., d/b/a Mmanage and/or Ffaithful, Unit 616 6/F Kam Teem Industrial Building, 135 Connaught Rd., West Sai Ying Pun HK, Central and Western District 999077, Hong Kong Special Administrative Region, Hong Kong Island, China

Hong Kong Dora Cross-Border Trading Co., Ltd. d/b/a Doraomi, Room A17, 29th Floor, Ning Chun Centre, 7 Shing Yip Street, Kwun Tong, Hong Kong, Kwun Tong District 999077, Hong Kong Special Administrative Region, Kowloon, China

Hong Kong Santaizi Technology Co., Ltd. d/b/a STZ Sport, Room A17, 29/F, No.7 Shing Yip Street, Kwun Tong, Hong Kong, Kwun Tong District 999077, Hong Kong Special Administrative Region, Kowloon, China

Shenzhen Shiyi Gian Maoyi Co., Ltd. d/b/a Classic Innovation, 303-1, No. 3, Zone 1, Guangyuan Industrial Zone, Wuhe Community, Bantian Street, Longgang District, Shenzhen Longgang District 518172, Guangdong Province, Shenzhen, China

Shenzhen Yanyin Technology Co., Ltd., No. 138, Fuhua 1st Road, Fu'an Community, Futian Street, Futian District, Shenzhen, China

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW, Suite 401, Washington, DC 20436; and

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: December 19, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025-23721 Filed 12-22-25; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Video-Capable Electronic Devices, DN 3869*; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing

pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205-2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov.

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at <https://www.usitc.gov>. The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at <https://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of InterDigital, Inc. and InterDigital VC Holdings, Inc., on December 18, 2025. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain video-capable electronic devices. The complaint names as respondents: Amazon.com, Inc. and Amazon.com Services, LLC. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, members of the public, and interested government agencies are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due, notwithstanding § 201.14(a) of the Commission's Rules of Practice and Procedure. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number ("Docket No. 3869") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, Electronic Filing Procedures).¹ Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, <https://edis.usitc.gov>.) No in-person paper-based filings or paper copies of

any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at EDIS3Help@usitc.gov.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,² solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.³

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: December 18, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025-23688 Filed 12-22-25; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1325]

Certain Soft Projectile Launching Devices, Components Thereof, Ammunition, and Products Containing Same; Notice of the Commission's Final Determination Finding No Violation of Section 337; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to find no violation of section 337 of the Tariff Act of 1930, as amended in the above-captioned investigation. The investigation is hereby terminated.

FOR FURTHER INFORMATION CONTACT:

Robert Needham, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone 202-205-5468. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone 202-205-1810.

SUPPLEMENTARY INFORMATION:

The Commission instituted this investigation on August 26, 2022, based on a complaint filed by complainants Hasbro, Inc. of Pawtucket, Rhode Island ("Hasbro"), and Spin Master, Inc. of Los Angeles, California ("Spin Master") (together, "Complainants"). 87 FR 52595-96 (Aug. 26, 2022). The complaint, as supplemented, alleges a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 ("section 337"), based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain soft projectile launching devices, components thereof, ammunition, and products containing same by reason of the infringement of one or more of claims 1-15 and 17-21 of U.S. Patent No. 8,371,282 ("the '282 patent") and claims 1-6 and 10-15 of U.S. Patent No. 8,640,683 ("the '683 patent"). *Id.* at 52595. The complaint further alleges

¹ Handbook for Electronic Filing Procedures: https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.

² All contract personnel will sign appropriate nondisclosure agreements.

³ Electronic Document Information System (EDIS): <https://edis.usitc.gov>.

that an industry in the United States exists or is in the process of being established. *Id.* The notice of investigation names as respondents Shenzhen Yi Jin Electronics Science of Shenzhen City, China, Guangdong Yu Lee Technology Corp. of Dongguan City, China, Yu Lee Company Ltd. of Tsuen Wan, Hong Kong, and Gel Blaster Inc. f/k/a Gel Blaster, LLC of Austin, Texas (together, “the Gel Blaster Respondents”); S-Beam Precision Products Ltd. of Zhongshan City, China, Splat-R-Ball, LLC of Rogers, Arkansas, and Daisy Manufacturing Company of Rogers, Arkansas (together, “the Splat-R-Ball Respondents”); and Prime Time Toys Ltd. of Kwun Tong, Hong Kong, Prime Time Toys LLC of Pompton Lakes, New Jersey, and Easebon Services Ltd. of Kwun Tong, Hong Kong (together, “PTT”) (collectively, “Respondents”). *Id.* The Office of Unfair Import Investigations (“OUII”) is a party to the investigation. *Id.* at 52595–96.

The Commission previously terminated the investigation with respect to claims 1–7, 9–15, 17, 18, and 21 of the ‘282 patent and claims 1–4, 6, 10–12, 13 and 15 of the ‘683 patent based on Complainants’ partial withdrawal of the complaint. Order No. 10 (Oct. 25, 2022), *unreviewed by* Comm’n Notice (Nov. 16, 2022); Order No. 21 (Jan. 18, 2023), *unreviewed by* Comm’n Notice (Feb. 14, 2023); Order No. 44 (May 17, 2023), *unreviewed by* Comm’n Notice (May 30, 2023). Accordingly, at the time of the evidentiary hearing, claims 8, 19, and 20 of the ‘282 patent and claims 5 and 14 of the ‘683 patent remained at issue.

On November 10, 2022, Complainants and Respondents stipulated that the ‘282 and ‘683 patents share a common specification and describe projectile launchers, soft projectiles made with “super absorbent polymers,” and systems comprised of projectile launchers and soft projectiles. Technology Stipulation (Nov. 10, 2022).

On November 21, 2022, Respondents stipulated that the importation requirement is satisfied. Gel Blaster Respondents’ Stipulation and Waiver Regarding Importation (Nov. 21, 2022) (EDIS Doc. ID 784955); Prime Time Toys Respondents’ Stipulation and Waiver Regarding Importation (Nov. 21, 2022) (EDIS Doc. ID 784927); Splat-R-Ball Respondents’ Stipulation and Waiver Regarding the Issue of Importation (Nov. 21, 2022) (EDIS Doc. ID 784914). On May 16, 2023, Complainants and Respondents stipulated that the technical prong of the domestic industry requirement is satisfied under the presiding administrative law judge’s (“ALJ”) construction of “super

absorbent polymer.” Stipulation Regarding Domestic Industry Products (May 16, 2023) (EDIS Doc. ID 796608). On May 18, 2023, the parties stipulated regarding the disclosure of prior art. Stipulation Regarding Prior Art (May 18, 2023) (EDIS Doc. ID 796787).

On March 27, 2023, the ALJ issued a claim construction order. Order No. 28 (Mar. 27, 2023). The ALJ held an evidentiary hearing on May 19, and 22–23, 2023.

On April 27, 2023, the ALJ granted a motion for a summary determination that Respondents infringed claims 6, 8, 19, and 20 of the ‘282 patent and claims 1, 5, and 11 of the ‘683 patent. Order No. 37 (Apr. 27, 2023). Shortly thereafter, the Commission terminated the Gel Blaster Respondents and Splat-R-Ball Respondents based on settlement. Order No. 42 (May 17, 2023), *unreviewed by* Comm’n Notice (May 30, 2023); Order No. 45 (May 19, 2023), *unreviewed by* Comm’n Notice (May 30, 2023). Also, as noted above, the Commission subsequently terminated the investigation with respect to claim 6 of the ‘282 patent and claims 1, and 11 of the ‘683 patent. Accordingly, the Commission affirmed the grant of summary determination of infringement against PTT regarding claims 8, 19, and 20 of the ‘282 patent and claims 5 of the ‘683 patent but determined to review and vacate as moot the findings with respect to the Gel Blaster Respondents, Splat-R-Ball Respondents, and the withdrawn claims. Comm’n Notice (May 30, 2023).

On October 25, 2023, the ALJ issued a final initial determination (“Final ID”) finding a violation of section 337 with respect to claims 8, 19, and 20 of the ‘282 patent and claims 5 and 14 of the ‘683 patent. Final ID at ii–iii. Specifically, the Final ID notes that the Commission already found that “the Accused Blasters (*i.e.*, blaster kits with blasters and ammunition)” directly infringe claims 8, 19, and 20 of the ‘282 patent and claim 5 of the ‘683 patent, and that PTT stipulated that the accused products directly infringe claim 14. *Id.* at 21–22, 38–39. The Final ID finds that PTT also induces and contributes to infringement with respect to those claims. *Id.* at 25–30, 39–41. The Final ID further finds that Complainants have satisfied the technical prong of the domestic industry requirement with respect to claims 8, 19, and 20 of the ‘282 patent and claims 5 and 14 of the ‘683 patent. *Id.* at 31–36, 41–44. Additionally, the Final ID finds that the asserted claims are not invalid as obvious under 35 U.S.C. 103 due to PTT’s failure to provide a motivation to combine the references at issue and

Complainants’ showing on secondary considerations. *Id.* at 44–91. Finally, the Final ID finds that Complainants failed to show that a domestic industry exists, but that Complainants did show that a domestic industry is in the process of being established. *Id.* at 91–117.

The Commission received no comments from the public or interested government agencies regarding any public interest issues raised by the ALJ’s recommended determination on remedy. 88 FR 74510–11 (Oct. 31, 2023). The Commission also received no comments concerning the public interest from the parties pursuant to Commission Rule 210.50(a)(4). 19 CFR 210.50(a)(4).

On November 6, 2023, PTT filed a petition for review challenging the Final ID’s findings that: (1) PTT failed to provide motivations to combine prior art to support a finding of obviousness; (2) secondary considerations support a finding of non-obviousness; and (3) Complainants showed an industry in the process of being established. Also on November 6, 2023, Complainants filed a contingent petition for review of the Final ID’s finding that Complainants failed to show that a domestic industry exists. On November 14, 2023, the Complainants and PTT filed responses opposing each other’s petitions, and OUII filed a response opposing both petitions.

On January 30, 2024, the Commission determined to review the Final ID with respect to the Final ID’s findings on obviousness and the economic prong of the domestic industry requirement. Comm’n Notice (Jan. 30, 2024). The Commission sought briefing from the parties on the issue of whether any argument or evidence was presented to the ALJ that a significant and unusual development(s) existed after the complaint was filed in this matter that may justify consideration of post-complaint evidence to support Complainants’ domestic industry claim. The Commission also sought briefing from the parties, interested government agencies, and other interested parties to file written submissions on the issues of remedy, the public interest, and bonding. *Id.* The Commission received initial submissions from Complainants, PTT, OUII, and Brian Hoffer, and reply submissions from Complainants, PTT, and OUII.

Having examined the record of this investigation, including the Final ID, the petitions, responses, and other submissions from the parties, the Commission has determined that Complainants have failed to show a violation of section 337. Specifically, the Commission has determined to: (1)

affirm, under modified reasoning, the Final ID's finding of non-obviousness because PTT failed to show by clear and convincing evidence a motivation to combine the asserted prior art; (2) affirm the Final ID's finding that Complainants' showing of secondary considerations of commercial success and industry praise support a finding of non-obviousness; (3) affirm, under modified reasoning, the Final ID's finding that Complainants' failed to show that a domestic industry exists; and (4) reverse the Final ID's finding that a domestic industry is in the process of being established. Accordingly, the Commission finds that Complainants failed to show a violation of section 337 based on Complainants' failure to establish the economic prong of the domestic industry requirement.

The Commission's reasoning in support of its determinations is set forth more fully in its opinion. Chair Karpel dissents from the Commission's finding of no violation of section 337 for the reasons detailed in her dissenting views. All other findings in the ID under review that are consistent with the Commission's determinations are affirmed. The investigation is hereby terminated.

The Commission vote for this determination took place on December 18, 2025.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: December 18, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025-23689 Filed 12-22-25; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1469]

Certain Vaporizer Devices, Cartridges Used Therewith, and Components Thereof II; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on September 22, 2025, under section 337 of the Tariff Act of 1930, as amended, on behalf of NJOY, LLC of Richmond,

Virginia; Altria Group Distribution Company of Richmond, Virginia; and Altria Client Services LLC of Richmond, Virginia. The complaint was supplemented on December 3, 2025. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain vaporizer devices, cartridges used therewith, and components thereof by reason of the infringement of certain claims of U.S. Patent No. 12,115,303 ("the '303 patent") and U.S. Patent No. 12,194,227 ("the '227 patent"). The complaint, as supplemented, further alleges that an industry in the United States exists and/or is in the process of being established as required by the applicable Federal Statute. The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, as supplemented, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205-2000. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>.

FOR FURTHER INFORMATION CONTACT: Susan Orndoff, The Office of Docket Services, U.S. International Trade Commission, telephone (202) 205-1802.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2025).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on December 18, 2025, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the

United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1-7 of the '303 patent and 1-6 of the '227 patent, and whether an industry in the United States exists or is in the process of being established as required by subsections (a)(2) and (a)(3) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is "vaporizer devices, such as electronic nicotine delivery systems ('ENDS' devices), cartridges used therewith (sometimes referred to as 'pods'), and components thereof (pod mouthpieces, cartridge housings, cartridge bases, liquid nicotine solutions, atomizers, wicks, atomizer subassemblies, device subassemblies, and chargers)";

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are: NJOY, LLC, 6601 W. Broad Street, Richmond, Virginia 23230; Altria Group Distribution Company, 6601 W. Broad Street, Richmond, Virginia 23230, Altria Client Services LLC, 6601 W. Broad Street, Richmond, Virginia 23230.

(b) The respondent is the following entity alleged to be in violation of section 337, and is the party upon which the complaint is to be served: JUUL Labs, Inc., 1000 F Street NW, Suite 800, Washington, DC 20004.

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not participate as a party in this investigation.

Responses to the complaint, as supplemented, and the notice of investigation must be submitted by the named respondent in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not

be granted unless good cause therefor is shown.

Failure of the respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: December 19, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025–23720 Filed 12–22–25; 8:45 am]

BILLING CODE 7020–02–P

LIBRARY OF CONGRESS

Copyright Royalty Board

[Docket Nos. 25–CRB–0016–AU (Cox Media Group); 25–CRB–0017–AU (Hope Media Group); 25–CRB–0018–AU (Pandora Media, LLC); 25–CRB–0019–AU (Saga Communications, Inc.); 25–CRB–0020–AU (SomaFM.com, LLC); 25–CRB–0021–AU (Townsquare Media); 25–CRB–0022–AU (Z Ministries, Inc.); 25–CRB–0023–AU (Mood Media); 25–CRB–0024–AU (Music Choice); and 25–CRB–0025–AU (SiriusXM)]

Notice of Intent to Audit

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Public notice.

SUMMARY: The Copyright Royalty Judges announce receipt from SoundExchange, Inc., of notices of intent to audit the 2022, 2023, and 2024 statements of account submitted by licensees under section 112 and/or 114 of title 17 Cox Media Group (eCRB No. 77868), Hope Media Group (eCRB No. 77869), Pandora Media LLC (eCRB No. 77870), Saga Communications Inc. (eCRB No. 77871), SomaFM.com, LLC (eCRB No. 77872), Townsquare Media (eCRB No. 77873), Z Ministries, Inc. (eCRB No. 77874), Mood Media (eCRB No. 77875), Music Choice (eCRB No. 77876), and SiriusXM (eCRB No. 77877).

ADDRESSES: *Dockets:* For access to the dockets to read background documents, go to eCRB at <https://app.crb.gov> and perform a case search for each corresponding docket number.

FOR FURTHER INFORMATION CONTACT: Anita Brown, (202) 707–7658, crb@loc.gov.

SUPPLEMENTARY INFORMATION: The Copyright Act grants to sound recordings copyright owners the exclusive right to publicly perform sound recordings by means of certain digital audio transmissions, subject to limitations. Specifically, the right is limited by certain exemptions as well the statutory license in section 114, which allows nonexempt noninteractive digital subscription services, eligible nonsubscription services, and preexisting satellite digital audio radio services to perform publicly sound recordings by means of digital audio transmissions. 17 U.S.C. 114(f). In addition, a statutory license in section 112 allows certain services to make necessary ephemeral reproductions to facilitate digital transmission of the sound recording. 17 U.S.C. 112(e).

Licensees may operate under these licenses provided they pay the royalty fees and comply with the terms set by the Copyright Royalty Judges. The rates and terms for the section 112 and 114 licenses are codified in 37 CFR parts 380 and 382–84.

As one of the terms for these licenses, the Judges designated SoundExchange, Inc., (SoundExchange) as the Collective, *i.e.*, the organization charged with collecting the royalty payments and statements of account submitted by licensees, including those that operate commercial and noncommercial webcaster services, preexisting satellite digital audio radio services, new subscription services, and those that make ephemeral copies for transmission to business establishments. The Collective is also charged with distributing the royalties to the copyright owners and performers entitled to receive them under the section 112 and 114 licenses. *See* 37 CFR 380.4(d)(1), 382.5(d)(1), 383.4(a), 384.4(b)(1).

As the Collective, SoundExchange may, only once a year, conduct an audit of a licensee for any or all of the prior three calendar years to verify royalty payments. SoundExchange must first file with the Judges a notice of intent to audit a licensee and deliver the notice to the licensee. *See* 37 CFR 380.6(b), 382.7(b), 383.4(a) and 384.6(b).

On December 12, 2025, SoundExchange filed with the Judges notices of intent to audit the statements of account submitted by licensees Cox Media Group, Hope Media Group, Pandora Media LLC, Saga Communications Inc., SomaFM.com, LLC, Townsquare Media,

Z Ministries, Inc., Mood Media, Music Choice, and SiriusXM for the years 2022, 2023, and 2024. The Judges must publish notice in the **Federal Register** within 30 days of receipt of a notice announcing the Collective's intent to conduct an audit. *See* 37 CFR 380.6(c) 382.7(c), 383.4(a) and 384.6(c). This notice fulfills the Judges' publication obligation.

Dated: December 19, 2025.

Steve Ruwe,

Copyright Royalty Judge.

[FR Doc. 2025–23756 Filed 12–22–25; 8:45 am]

BILLING CODE 1410–72–P

NEIGHBORHOOD REINVESTMENT CORPORATION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m., Thursday, December 18, 2025.

PLACE: via ZOOM.

STATUS: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Regular Board of Directors meeting.

The General Counsel of the Corporation has certified that in her opinion, one or more of the exemptions set forth in the Government in the Sunshine Act, 5 U.S.C. 552b(c)(2) permit closure of the following portion(s) of this meeting:

- Executive (Closed) Session

Agenda

- I. Call to Order
- II. Action Item: Election of Chief of Staff and Senior Deputy Comptroller
Kate Tyrrell as Temporary Board Chair
- III. Action Item: Approval of Government in Sunshine Act Notice Waiver
- IV. Discussion Item: FY25 External Audit with CliftonLarsonAllen
- V. Sunshine Act Approval of Executive (Closed) Session
- VI. Executive Session: FY25 External Audit with CliftonLarsonAllen
- VII. Executive Session: Questions on Reports from Officers & Board Appointees
- VIII. Action Item: Approval of Meeting Minutes for June 26 Annual Board Meeting and September 11 Regular Board Meeting
- IX. Action Item: Internal Audit Report Acceptance
 - a. Active Directory Management
 - b. Cyber Attack Incident Response II
 - c. Network Affiliations
- X. Discussion Item: Change to FY25/26 Internal Audit Plan

- XI. Discussion Item: Lapse in Funding Policy—OMB Requested Edit
- XII. Discussion Item: Management Program Background and Updates
- a. 2026 Board Calendar
 - b. 2026 Board Agenda Planner
 - c. CFO Report
 - i. Financials (through 9/30/25)
 - ii. Single Invoice Approvals \$100K and over
 - iii. Vendor Payments \$350K and over
 - iv. Exceptions
 - d. FY25–FY27 SP Scorecard—Q4
 - e. Network Watchlist Report

PORTIONS OPEN TO THE PUBLIC:
Everything except the Executive (Closed) Session.

PORTIONS CLOSED TO THE PUBLIC:
Executive (Closed) Session.

CONTACT PERSON FOR MORE INFORMATION:
Jenna Sylvester, Paralegal, (202) 568–2560; jsylvester@nw.org.

Jenna Sylvester,
Paralegal.

[FR Doc. 2025–23674 Filed 12–19–25; 11:15 am]

BILLING CODE 7570–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2025–0011]

Information Collection: NRC Form 396, Certification of Medical Examination by Facility Licensee

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, NRC Form 396, “Certification of Medical Examination by Facility Licensee.”

DATES: Submit comments by January 22, 2026. 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: 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” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Heather Dempsey, Acting NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–0856; email: Infocollects.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2025–0011 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–2025–0011.
- *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 ADAMS Public 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. A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession Nos. ML25342A385 and ML25342A431. The supporting statement is available in ADAMS under Accession No. ML25248A313.

- *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, Heather Dempsey, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–0856; email: Infocollects.Resource@nrc.gov.

B. Submitting Comments

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](https://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function.

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 OMB, 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

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, NRC Form 396, “Certification of Medical Examination by Facility Licensee.” The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on September 3, 2025, 90 FR 42626.

1. *The title of the information collection:* NRC Form 396, Certification of Medical Examination by Facility Licensee.

2. *OMB approval number:* 3150–0024.

3. *Type of submission:* Extension.

4. *The form number, if applicable:* NRC Form 396.

5. *How often the collection is required or requested:* Upon application for an initial or upgrade license; every 6 years for the renewal of an operator or senior operator license, and notices of disability that occur during licensed tenure.

6. *Who will be required or asked to respond:* Facility licensees who are tasked with certifying the medical fitness or operator licensee.

7. *The estimated number of annual responses:* 1,862.

8. *The estimated number of annual respondents:* 133.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 2,161 hours (1,729 reporting hours + 432 recordkeeping hours).

10. *Abstract:* NRC Form 396 is used to transmit information to the NRC regarding the medical condition of applicants for initial operator licenses or renewal of operator licenses and for the maintenance of medical records for all licensed operators. The information is used to determine whether the physical condition and general health of applicants for operator licensees is such that the applicant would not be expected to cause operational errors and endanger public health and safety.

Dated: December 18, 2025.

For the Nuclear Regulatory Commission.

Heather Dempsey,

Acting NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2025–23681 Filed 12–22–25; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2025–0041]

Information Collection: NRC Form 754, Armed Security Personnel Firearms Background Check

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, NRC Form 754, “Armed Security Personnel Firearms Background Check.”

DATES: Submit comments by February 23, 2026. 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–2025–0041. 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(s) listed in the “For Further Information Contact” section of this document.

- *Mail comments to:* Heather Dempsey, 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:

Heather Dempsey, Acting NRC Clearance Officer, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–0856; email: Infocollects.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2025–0041 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–2025–0041. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2025–0041 on this website.

- *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 ADAMS Public 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. A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No. ML25164A064. The supporting statement is available in ADAMS under Accession No. ML25164A072.

- *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, Heather Dempsey, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–0856; 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–2025–0041, 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:* NRC Form 754, “Armed Security Personnel Firearms Background Check.”
2. *OMB approval number:* 3150–0204.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* NRC Form 754.
5. *How often the collection is required or requested:* Once every 5 years.
6. *Who will be required or asked to respond:* Licensees who apply for Section 161A authority.
7. *The estimated number of annual responses:* 550.
8. *The estimated number of annual respondents:* 6.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request: 1,220 hours.*

10. *Abstract:* Current NRC security regulations include security requirements pertaining to nuclear power reactors and Category I Strategic Special Nuclear Material (SSNM) facilities for access to enhanced weapons and firearms background checks. NRC Form 754 collects the information required to perform the necessary firearms background checks. The background check uses the person's fingerprints and other identifying information and is performed under the Federal Bureau of Investigation's National Instant Criminal Background Check System to determine if an individual is prohibited under Federal or State law from possessing or receiving firearms. Licensees submit NRC Form 754 for all security personnel protecting Commission designated facilities, radioactive material, or other property whose duties require them to have access to these weapons.

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: December 18, 2025.

For the Nuclear Regulatory Commission.

Heather Dempsey,

Acting NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2025-23680 Filed 12-22-25; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-613; NRC-2024-0078]

US SFR Owner, LLC; Notice of Hearing

AGENCY: Nuclear Regulatory Commission.

ACTION: Construction permit application; Notice of uncontested hearing.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) will commence an uncontested hearing, in which the Commission will receive written evidence in the form of testimony and exhibits regarding the application submitted by TerraPower, LLC (TerraPower), on behalf of US SFR Owner, LLC (USO), for a construction permit to construct a nuclear-powered generating plant termed Kemmerer Power Station Unit 1 in Lincoln County, Wyoming.

DATES: The Commission may issue written questions to the parties (the NRC staff and the applicant) no later than January 12, 2026. For the full schedule for submitting documents in this hearing, see Sections V and VI of the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: Please refer to Docket ID NRC-2024-0078 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-2024-0078. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301-415-0624; email: Stacy.Schumann@nrc.gov. For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to PDR.Resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in 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.

FOR FURTHER INFORMATION CONTACT:

Wesley W. Held, Office of the Secretary, U.S. Nuclear Regulatory Commission,

Washington, DC 20555-0001, telephone: 301-287-3591; email: Wesley.Held@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Commission hereby gives notice that, pursuant to Section 189a of the Atomic Energy Act (AEA) of 1954, as amended, it will commence an uncontested hearing, in which the Commission will receive written evidence in the form of testimony and exhibits regarding the application submitted by TerraPower, on behalf of USO, for a construction permit to construct a nuclear-powered generating plant termed Kemmerer Power Station Unit 1 in Lincoln County, Wyoming.

TerraPower's application was submitted by letter on March 28, 2024 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML24088A060).

The NRC staff's Final Environmental Impact Statement and Safety Evaluation Report may be viewed at ADAMS Accession Nos. ML25287A017 and ML25329A252, respectively. This mandatory hearing will concern safety and environmental matters relating to the requested construction permit application, as more fully described below.

II. Evidentiary Uncontested Hearing

The Commission will conduct this hearing using written materials only. The schedule and process for submitting written materials to the Commission is detailed in Sections V and VI below. The parties to this proceeding are TerraPower and the NRC staff.

III. Presiding Officer

The Commission is the presiding officer for this proceeding.

IV. Matters To Be Considered

The matter at issue in this proceeding is whether the review of the TerraPower Kemmerer Power Station Unit 1 construction permit application by the Commission's staff has been adequate to support the findings found in 10 CFR 50.35, 50.40, 50.50, and 10 CFR 51.105. Those findings are as follows:

Issues Pursuant to the Atomic Energy Act of 1954, as Amended

With respect to the construction permit: (1) whether the applicant has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the

public; (2) whether such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report; (3) whether safety features or components, if any, which require research and development have been described by the applicant and the applicant has identified, and there will be conducted, a research and development program reasonably designed to resolve any safety questions associated with such features or components; (4) whether on the basis of the foregoing, there is reasonable assurance that (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR part 100, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public; (5) whether there is reasonable assurance (i) that the construction of the facility will not endanger the health and safety of the public, and (ii) that construction activities can be conducted in compliance with the Commission's regulations; (6) whether the applicant is technically and financially qualified to engage in the proposed activities in accordance with the Commission's regulations in chapter I of title 10 of the CFR; (7) whether the issuance of a permit for the construction of the facility to the applicant will not, in the opinion of the Commission, be inimical to the common defense and security or to the health and safety of the public; and (8) whether the application meets the standards and requirements of the AEA and the Commission's regulations, and that notifications, if any, to other agencies or bodies have been duly made.

Issues Pursuant to the National Environmental Policy Act (NEPA) of 1969

With respect to the construction permit: (1) determine whether the requirements of Sections 102(2)(A), (C), and (E) of NEPA and the applicable regulations in 10 CFR part 51 have been met; (2) independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken; (3) determine, after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and

considering reasonable alternatives, whether the construction permit should be issued, denied, or appropriately conditioned to protect environmental values; and (4) determine whether the NEPA review conducted by the NRC staff has been adequate.

V. Schedule for Submittal of Written Evidence

All documents to be filed by the parties as described below should be filed in accordance with the requirements of our E-filing rules at 10 CFR 2.304(g) and will be considered exhibits in this proceeding once filed.

No later than December 16, 2025, the NRC staff should E-file the following documents to add them to the docket for this hearing: (1) SECY-25-0102, which will serve as the NRC staff's primary written testimony in this hearing, (2) the construction permit application,¹ (3) the draft construction permit, (4) the safety evaluation, (5) the environmental impact statement, (6) the draft record of decision, and (7) any report submitted by the Advisory Committee on Reactor Safeguards in compliance with § 182(b) of the AEA and 10 CFR 50.58(a) regarding the Kemmerer Power Station Unit 1 construction permit and any NRC staff response thereto. If any of these documents are non-public, then the NRC staff should also file a public version, if practicable.

No later than January 12, 2026, the Commission may issue written questions to one or both of the parties (the NRC staff and the applicant). If such questions are issued, party testimony responding to such questions, and associated exhibits (if any), are due January 26, 2026, unless the Commission directs otherwise. The applicant may also file additional written testimony by January 26, 2026.

VI. Interested Government Participants

No later than January 2, 2026, any interested State, local government body, or Federally recognized Indian Tribe may file with the Commission a statement of any issues or questions that the State, local government body, or Indian Tribe wishes the Commission to give particular attention to as part of the uncontested hearing process. Such statement may be accompanied by any supporting documentation that the State, local government body, or Indian Tribe sees fit to provide. Any statements and supporting documentation (if any)

¹ If, due to its size, the application is too large to file through the E-filing system, the NRC staff may file a document that lists the ADAMS accession number for the package of each part of the application.

received by the Commission using the agency's

E-filing system² by the deadline indicated above will be made part of the record of the proceeding. The Commission will use such statements and documents as appropriate to inform its questions to the NRC staff and applicant and its hearing decision.

Many of the procedures and rights applicable to the inherently adversarial nature of NRC's contested hearing process are not available in this uncontested hearing. Participation in the NRC's contested hearing process is governed by 10 CFR 2.309 (for persons or entities, including a State, local government, or Indian Tribe seeking to file contentions of their own) and 10 CFR 2.315(c) (for an interested State, local government, or Federally recognized Indian Tribe seeking to participate with respect to contentions filed by others). Participation in this uncontested hearing does not affect the right of a State, a local government, or an Indian Tribe to participate in a separate contested hearing process.

Dated at Rockville, Maryland, this 18th day of December, 2025.

For the Nuclear Regulatory Commission.

Carrie Safford,

Secretary of the Commission.

[FR Doc. 2025-23678 Filed 12-22-25; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2024-0222]

Information Collection: NRC Form 244, Registration Certificate—Use of Depleted Uranium

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, NRC Form 244, "Registration Certificate—Use of Depleted Uranium."

² The process for accessing and using the agency's E-filing system is described in the June 4, 2024, notice of hearing (89 FR 47997) that was issued by the Commission for this proceeding. Participants who are unable to use the electronic information exchange (EIE), or who will have difficulty complying with EIE requirements in the time frame provided for submission of written statements, may provide their statements by electronic mail to hearingdocket@nrc.gov.

DATES: Submit comments by January 22, 2026. 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: 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” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Heather Dempsey, Acting NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-0856; email: Infocollects.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2024-0222 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-2024-0222.
- **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 ADAMS Public 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. A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No. ML25323A423. The supporting statement is available in ADAMS under Accession Nos. ML25323A422.

- **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, Heather Dempsey, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-0856; email: Infocollects.Resource@nrc.gov.

B. Submitting Comments

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” or by using the search function.

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 OMB, 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

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, NRC Form 244, “Registration Certificate—Use of Depleted Uranium.” The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on August 15, 2025, 90 FR 39430.

1. *The title of the information collection:* NRC Form 244, Registration Certificate—Use of Depleted Uranium.
2. *OMB approval number:* 3150-0031.
3. *Type of submission:* Extension.

4. *The form number, if applicable:* NRC Form 244.

5. *How often the collection is required or requested:* On occasion.

6. *Who will be required or asked to respond:* Persons who receive, acquire, possess, or use depleted uranium.

7. *The estimated number of annual responses:* 21.

8. *The estimated number of annual respondents:* 8.5.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 12.2 (8.5 reporting + 1.7 recordkeeping + 2.0 third-party disclosure).

10. *Abstract:* The NRC regulations in part 40 of title 10 of the *Code of Federal Regulations*, establishes requirements for the receipt, possession, use and transfer of radioactive source and byproduct materials. Section 40.25 established a general license authorizing the use of depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device. The NRC Form 244 is used to report the receipt and transfer of depleted uranium, as required by 10 CFR 40.25. The registration information required by the NRC Form 244 enables the NRC to make a determination on whether the possession, use, or transfer of depleted uranium source and byproduct material is in conformance with the NRC’s regulations for the protection of public health and safety. General licensees can also use NRC Form 244 to update any of the information contained in the form, once the form is authorized by the NRC.

Dated: December 19, 2025.

For the Nuclear Regulatory Commission.

David Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2025-23722 Filed 12-22-25; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2025-1999]

Monthly Notice; Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Monthly notice.

SUMMARY: Pursuant to section 189a.(2) of the Atomic Energy Act of 1954, as

amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular monthly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration (NSHC), notwithstanding the pendency before the Commission of a request for a hearing from any person.

DATES: Comments must be filed by January 22, 2026. A request for a hearing or petitions for leave to intervene must be filed by February 23, 2026. This monthly notice includes all amendments issued, or proposed to be issued, from October 10, 2025, to December 4, 2025. The last monthly notice was published on November 25, 2025.

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-2025-1999. 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-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Paula Blechman, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2242; email: Paula.Blechman@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2025-1999, facility name, unit number(s), docket number(s), application date, and

subject 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-2025-1999.

- *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 ADAMS Public 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 ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in 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 (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-2025-1999, facility name, unit number(s), docket number(s), application date, and subject, 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. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination

For the facility-specific amendment requests shown in this notice, the Commission finds that the licensees' analyses provided, consistent with section 50.91 of title 10 of the *Code of Federal Regulations* (10 CFR) "Notice for public comment; State consultation," are sufficient to support the proposed determinations that these amendment requests involve NSHC. Under the Commission's regulations in 10 CFR 50.92, operation of the facilities in accordance with the proposed amendments would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The Commission is seeking public comments on these proposed determinations. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determinations.

Normally, the Commission will not issue the amendments until the expiration of 60 days after the date of publication of this notice. The Commission may issue any of these license amendments before expiration of the 60-day period provided that its final determination is that the amendment involves NSHC. In addition, the Commission may issue any of these amendments prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. If the Commission takes action on any of these amendments prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. If the Commission makes a final NSHC determination for any of these amendments, any hearing will take place after issuance. The Commission expects that the need to take action on any amendment before 60 days have elapsed will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person (petitioner) whose interest may be

affected by any of these actions may file a request for a hearing and petition for leave to intervene (petition) with respect to that action. Petitions shall be filed in accordance with the Commission's "Agency Rules of Practice and Procedure" in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

Petitions must be filed no later than 60 days from the date of publication of this notice in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii).

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration, which will serve to establish when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h) no later than 60 days from the date of publication of this notice. Alternatively, a State, local governmental body, Federally recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

For information about filing a petition and about participation by a person not a party under 10 CFR 2.315, see ADAMS Accession No. ML20340A053 (<https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?Accession>

Number=ML20340A053) and on the NRC's public website at <https://www.nrc.gov/about-nrc/regulatory/adjudicatory/hearing.html#participate>.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including documents filed by an interested State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as further discussed, is granted. Detailed guidance on electronic submissions is located in the "Guidance for Electronic Submissions to the NRC" (ADAMS Accession No. ML13031A056), and on the NRC's public website (<https://www.nrc.gov/site-help/e-submittals.html>).

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at Hearing.Docket@nrc.gov, or by telephone at 301-415-1677, to: (1) request a digital identification (ID) certificate which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals/getting-started.html>. After a digital ID certificate is obtained and a docket is created, the participant must submit adjudicatory documents in the Portable Document Format. Guidance on submissions is available on the NRC's public website at <https://www.nrc.gov/site-help/electronic-sub-ref-mat.html>. A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59

p.m. ET on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed in order to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the "Contact Us" link located on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals.html>, by email to MSHD.Resource@nrc.gov, or by a toll-free call at 1-866-672-7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., ET, Monday through Friday, except Federal holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)-(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available at <https://adams.nrc.gov/ehd>, unless otherwise excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as previously described, click "cancel" when the link requests certificates and you will be automatically directed to the NRC's electronic hearing docket where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal

privacy information such as social security numbers, home addresses, or personal phone numbers in their filings unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application,

participants should not include copyrighted materials in their submission.

The following table provides the nuclear power plant names, docket numbers, dates of application, ADAMS accession numbers, and locations in the application of the licensees' proposed NSHC determination. For further details with respect to these license

amendment applications, see the applications for amendment, publicly available portions of which are available for public inspection in ADAMS. For additional direction on accessing information related to this document, see the "Obtaining Information and Submitting Comments" section of this document.

LICENSE AMENDMENT REQUEST(S)

Constellation Energy Generation, LLC; Braidwood Station, Unit 1; Will County, IL

Docket No(s)	50–456.
Application date	October 3, 2025.
ADAMS Accession No	ML25276A085.
Location in Application of NSHC	Pages 4–5 of Attachment 1.
Brief Description of Amendment(s)	The proposed amendment would revise License Conditions 2.C(13)(b)(1) and 2.C(13)(b)(2) to extend the completion date of License Renewal Commitment 30 Enhancements 2 and 3 to October 16, 2026.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Jason Zorn, Associate General Counsel, Constellation Energy Generation, LLC 4300 Winfield Road Warrenville, IL 60555.
NRC Project Manager, Telephone Number	Scott Wall, 301–415–2855.

Constellation Energy Generation, LLC; Quad Cities Nuclear Power Station, Units 1 and 2; Rock Island County, IL

Docket No(s)	50–254, 50–265.
Application date	August 6, 2025.
ADAMS Accession No	ML25218A263.
Location in Application of NSHC	Pages 3–5 of Attachment 1.
Brief Description of Amendment(s)	The proposed amendments request relocation of Technical Specification 3.3.7.2, "Mechanical Vacuum Pump Trip Instrumentation," to an appropriate licensee-controlled document.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Jason Zorn, Associate General Counsel, Constellation Energy Generation, LLC 4300 Winfield Road Warrenville, IL 60555.
NRC Project Manager, Telephone Number	Robert Kuntz, 301–415–3733.

Constellation FitzPatrick, LLC and Constellation Energy Generation, LLC; James A. FitzPatrick Nuclear Power Plant; Oswego County, NY

Docket No(s)	50–333.
Application date	September 5, 2025.
ADAMS Accession No	ML25248A291.
Location in Application of NSHC	Pages 6–8 of Attachment 1.
Brief Description of Amendment(s)	The proposed amendment would revise the Technical Specification (TS) Allowable Value for Reactor Water Cleanup System isolation on low Reactor Pressure Vessel (RPV) water level from Level 3 (≥ 177 inches) to Level 2 (≥ 107 inches) in Table 3.3.6.1–1, "Primary Containment Isolation Instrumentation." TS Table 3.3.5.2–1, "Reactor Pressure Vessel (RPV) Water Inventory Control Instrumentation," would also be revised consistent with the modified Table 3.3.6.1–1.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Jason Zorn, Associate General Counsel, Constellation Energy Generation, LLC, 101 Constitution Ave, NW, Suite 400 East, Washington, DC 20001.
NRC Project Manager, Telephone Number	Richard Guzman, 301–415–1030.

Energy Northwest; Columbia Generating Station; Benton County, WA

Docket No(s)	50–397.
Application date	October 23, 2025.
ADAMS Accession No	ML25300A113.
Location in Application of NSHC	Pages 5–6 of the Enclosure.
Brief Description of Amendment(s)	The proposed amendment would revise Technical Specification 3.1.3, "Control Rod OPERABILITY," to remove an addition of the word "partially" introduced in the licensee's conversion from WordPerfect to Microsoft Word in Surveillance Requirement 3.1.3.2.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Ryan Lukson, Assistant General Counsel, Energy Northwest, MD 1020, P.O. Box 968, Richland, WA 99352.
NRC Project Manager, Telephone Number	Mahesh Chawla, 301–415–8371.

Entergy Operations, Inc.; Arkansas Nuclear One, Unit 2; Pope County, AR

Docket No(s)	50–368.

LICENSE AMENDMENT REQUEST(S)—Continued

Application date	September 4, 2025.
ADAMS Accession No	ML25247A291.
Location in Application of NSHC	Pages 6–7 of the Enclosure.
Brief Description of Amendment(s)	The proposed amendment would correct several related, obvious typographical errors. These errors were inadvertently introduced into the technical specifications by License Amendment No. 323, dated February 8, 2021 (ML20351A153). Part of Amendment 323 revised Surveillance Requirement (SR) 4.4.6.2.1 by deleting subsection 4.4.6.2.1.b and relabeling SR 4.4.6.2.1.a as SR 4.4.6.2.1.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Anna Vinson, Associate General Counsel—Legal—Nuclear, Entergy Services, LLC, 101 Constitution Avenue NW, Suite 200 East, Washington, DC 20001.
NRC Project Manager, Telephone Number	Mahesh Chawla, 301–415–8371.

Nebraska Public Power District; Cooper Nuclear Station; Nemaha County, NE

Docket No(s)	50–298.
Application date	August 23, 2025.
ADAMS Accession No	ML25237A251.
Location in Application of NSHC	Pages 3–5 of Attachment 1.
Brief Description of Amendment(s)	The proposed amendment would adopt Technical Specifications Task Force (TSTF) Traveler 576, “Revise Safety/Relief Valve Requirements.” The proposed change would revise the safety/relief valve and safety valve technical specification to align the overpressure protection requirements with the safety limits and the regulations.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	John C. McClure, Executive Vice President External Affairs and General Counsel Nebraska Public Power District, P.O. Box 499, Columbus, NE 68601.
NRC Project Manager, Telephone Number	Thomas Byrd, 301 415–3719.

Southern Nuclear Operating Company, Inc.; Joseph M. Farley Nuclear Plant, Units 1 and 2; Houston County, AL

Docket No(s)	50–348, 50–364.
Application date	September 25, 2025.
ADAMS Accession No	ML25268A279.
Location in Application of NSHC	Pages E–13 to E–14 of the Enclosure.
Brief Description of Amendment(s)	The proposed amendments would revise diesel generator frequency and voltage ranges for Technical Specification 3.8.1, “AC [Alternating Current] Sources—Operating,” as described in their submittal.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Millicent Ronnlund, Vice President and General Counsel, Southern Nuclear Operating Co., Inc., P. O. Box 1295, Birmingham, AL 35201–1295.
NRC Project Manager, Telephone Number	G. Ed Miller, 301–415–2481.

Virginia Electric and Power Company, Dominion Nuclear Company; North Anna Power Station, Units 1 and 2; Louisa County, VA

Docket No(s)	50–338, 50–339.
Application date	November 7, 2025.
ADAMS Accession No	ML25316A170.
Location in Application of NSHC	Pages 3–5 of Enclosure 1.
Brief Description of Amendment(s)	The proposed amendments would add a new Technical Specification 3.6.9, “Containment Sump,” and add an Action to address the condition of the containment sump made inoperable as described in the application.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	W. S. Blair, Senior Counsel, Dominion Energy Services, Inc., 120 Tredegar St., RS–2, Richmond, VA 23219.
NRC Project Manager, Telephone Number	G. Ed Miller, 301–415–2481.

Vistra Operations Company LLC; Davis-Besse Nuclear Power Station, Unit 1; Ottawa County, OH

Docket No(s)	50–346.
Application date	November 19, 2025.
ADAMS Accession No	ML25323A016.
Location in Application of NSHC	Pages 5–7 of Attachment 1.
Brief Description of Amendment(s)	The proposed amendment would revise Technical Specification (TS) 3.3.9, “Source Range Neutron Flux,” to allow the use of alternate source range neutron monitoring instrumentation per TS Table 3.3.17–1, “Post Accident Monitoring Instrumentation,” Function 17.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Roland Backhaus, Senior Lead Counsel-Nuclear, Vistra Corp., 325 7th Street NW, Suite 520, Washington, DC 20004.
NRC Project Manager, Telephone Number	Robert Kuntz, 301–415–3733.

III. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last monthly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating

license or combined license, as applicable, proposed NSHC determination, and opportunity for a hearing in connection with these actions, were published in the **Federal Register** as indicated in the safety evaluation for each amendment.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has

made a determination based on that assessment, it is so indicated in the safety evaluation for the amendment.

For further details with respect to each action, see the amendment and associated documents such as the Commission's letter and safety evaluation, which may be obtained using the ADAMS accession numbers indicated in the following table. The safety evaluation will provide the ADAMS accession numbers for the application for amendment and the **Federal Register** citation for any environmental assessment. All of these items can be accessed as described in the "Obtaining Information and Submitting Comments" section of this document.

LICENSE AMENDMENT ISSUANCE(S)

Pacific Gas and Electric Company; Diablo Canyon Nuclear Power Plant, Units 1 and 2; San Luis Obispo County, CA

Docket No(s)	50-275, 50-323.
Amendment Date	December 2, 2025.
ADAMS Accession No	ML25324A367.
Amendment No(s)	254 (Unit 1) and 256 (Unit 2).
Brief Description of Amendment(s)	The amendments revised Technical Specification 3.8.1, "AC [Alternating Current] Sources—Operating," using the Risk-Informed Process for Evaluations (RIPE). The RIPE process is an NRC staff approved risk-informed method that is used to disposition applications of very low safety significance.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Southern Nuclear Operating Company, Inc.; Vogtle Electric Generating Plant, Units 1 and 2; Burke County, GA

Docket No(s)	50-424, 50-425.
Amendment Date	November 26, 2025.
ADAMS Accession No	ML25272A237.
Amendment No(s)	229 (Unit 1) and 211 (Unit 2).
Brief Description of Amendment(s)	The amendments revised Vogtle Electric Generating Plant, Units 1 and 2, Technical Specification 3.6.6, "Containment Spray and Cooling Systems," Surveillance Requirement 3.6.6.8 to change the frequency to verify each containment spray system spray nozzle is unobstructed.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Southern Nuclear Operating Company, Inc.; Vogtle Electric Generating Plant, Units 3 and 4; Burke County, GA

Docket No(s)	52-025, 52-026.
Amendment Date	November 25, 2025.
ADAMS Accession No	ML25269A107.
Amendment No(s)	209 (Unit 3) and 207 (Unit 4).
Brief Description of Amendment(s)	The amendments revised Technical Specification (TS) 3.8.2, "DC [Direct Current] Sources—Shutdown," Condition B. The amendments revised the entry requirements to Condition B of TS 3.8.2.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Susquehanna Nuclear, LLC and Allegheny Electric Cooperative, Inc.; Susquehanna Steam Electric Station, Units 1 and 2; Luzerne County, PA

Docket No(s)	50-387, 50-388.
Amendment Date	September 23, 2025.
ADAMS Accession No	ML25253A408.
Amendment No(s)	289 (Unit 1) and 273 (Unit 2).

LICENSE AMENDMENT ISSUANCE(S)—Continued

Brief Description of Amendment(s)	The amendments revised technical specifications (TS) for the Susquehanna Steam Electric Station, Units 1 and 2. Specifically, the amendments modified the primary containment leak rate testing program TS by: increasing the integrated leak rate test program interval; extending test intervals for Type A, B, and C leakage rate tests; extending the drywell-to-suppression chamber bypass leak rate test frequency; extending the frequency of containment isolation valve leakage rate testing; and using American National Standards Institute/American Nuclear Society Standard 56.8–2020, “Containment System Leakage Testing Requirements.” The amendments also replaced certain guidance document references and deleted information regarding the performance of tests that have been successfully performed.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

IV. Notice of Issuance of Amendment to Facility Operating Licenses and Combined Licenses and Final Determination of No Significant Hazards Consideration and Opportunity for a Hearing (Exigent Circumstances or Emergency Situation)

Since publication of the last monthly notice, the Commission has issued the following amendment. The Commission has determined for this amendment that the application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission’s rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission’s rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

Because of exigent circumstances or emergency situation associated with the date the amendment was needed, there was not time for the Commission to publish, for public comment before issuance, its usual notice of consideration of issuance of amendment, proposed NSHC determination, and opportunity for a hearing.

For exigent circumstances, the Commission has either issued a **Federal Register** notice providing opportunity for public comment or has used local media to provide notice to the public in the area surrounding a licensee’s facility of the licensee’s application and of the Commission’s proposed determination of NSHC. The Commission has provided a reasonable opportunity for the public to comment, using its best efforts to

make available to the public means of communication for the public to respond quickly, and in the case of telephone comments, the comments have been recorded or transcribed as appropriate and the licensee has been informed of the public comments.

In circumstances where failure to act in a timely way would have resulted, for example, in derating or shutdown of a nuclear power plant or in prevention of either resumption of operation or of increase in power output up to the plant’s licensed power level (an emergency situation), the Commission may not have had an opportunity to provide for public comment on its NSHC determination. In such case, the license amendment has been issued without opportunity for comment prior to issuance. Nonetheless, the State has been consulted by telephone whenever possible.

Under its regulations, the Commission may issue and make an amendment immediately effective, notwithstanding the pendency before it of a request for a hearing from any person, in advance of the holding and completion of any required hearing, where it has determined that NSHC is involved. The Commission has applied the standards of 10 CFR 50.92 and has made a final determination that the amendments involve NSHC. The basis for this determination is contained in the NRC staff safety evaluation related to each action. Accordingly, the amendment has been issued and made effective as indicated.

For those amendments that have not been previously noticed in the **Federal Register**, within 60 days after the date

of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the guidance concerning the Commission’s “Agency Rules of Practice and Procedure” in 10 CFR part 2 as discussed in section II.A of this document.

Unless otherwise indicated, the Commission has determined that the amendment satisfies the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for this amendment. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated in the safety evaluation for the amendment.

For further details with respect to these actions, see the amendment and associated documents such as the Commission’s letter and safety evaluation, which may be obtained using the ADAMS accession numbers indicated in the following table. The safety evaluation will provide the ADAMS accession number(s) for the application for amendment and the **Federal Register** citation for any environmental assessment. All of these items can be accessed as described in the “Obtaining Information and Submitting Comments” section of this document.

LICENSE AMENDMENT ISSUANCE—EXIGENT CIRCUMSTANCES

Constellation Energy Generation, LLC; Calvert Cliffs Nuclear Power Plant, Unit 2; Calvert County, MD

Docket No(s)	50–318.
Amendment Date	November 03, 2025.
ADAMS Accession No	ML25304A004.
Amendment No(s)	330.
Brief Description of Amendment(s)	The amendment added a license condition that allowed the swap of control element assembly group assignments in support of a down-power.
Local Media Notice (Yes/No)	Yes.

LICENSE AMENDMENT ISSUANCE—EXIGENT CIRCUMSTANCES—Continued

Public Comments Requested as to Proposed NSHC (Yes/No).

Yes.

Dated: December 17, 2025.

For the Nuclear Regulatory Commission.

Hipólito González,*Acting Deputy Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.*

[FR Doc. 2025–23679 Filed 12–22–25; 8:45 am]

BILLING CODE 7590–01–P

POSTAL SERVICE**International Product Change—Priority Mail Express International, Priority Mail International & First-Class Package International Service Agreements****AGENCY:** Postal Service.**ACTION:** Notice.**SUMMARY:** The Postal Service gives notice of filing requests with the Postal Regulatory Commission to add certain Priority Mail Express International, Priority Mail International & First-Class Package International Service contracts

to the list of Negotiated Service Agreements in the Competitive Product List in the Mail Classification Schedule.

DATES: Date of notice: December 23, 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), it filed with the Postal Regulatory Commission the following requests:

Date filed with Postal Regulatory Commission	Negotiated service agreement product category and No.	MC docket No.	K docket No.
12/16/2025	PMEI, PMI & FCPIS 102	MC2026–135	K2026–135
12/16/2025	PMEI, PMI & FCPIS 103	MC2026–139	K2026–139
12/16/2025	PMEI, PMI & FCPIS 104	MC2026–138	K2026–138
12/16/2025	PMEI, PMI & FCPIS 105	MC2026–137	K2026–137

Documents are available at www.prc.gov.**Jeffrey Boblick,***Attorney, Ethics and Legal Compliance.*

[FR Doc. 2025–23708 Filed 12–22–25; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION**[Release No. 34–104460; File No. SR–SAPPHIRE–2025–44]****Self-Regulatory Organizations; MIAX Sapphire, LLC; Notice of Filing of a Proposed Rule Change To Amend Exchange Rule 402, Criteria for Underlying Securities, To List and Trade Options on Commodity-Based Trust Shares**

December 18, 2025.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b–4 thereunder,² notice is hereby given that on December 5, 2025, MIAX Sapphire, LLC (“MIAX Sapphire” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) a 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 Exchange Rule 402, Criteria for Underlying Securities, to permit options on Commodity-Based Trust Shares. Specifically, the Exchange proposes to amend the rule to (1) redefine Commodity-Based Trust; (2) require additional qualifying criteria, based on the criteria outlined by the primary listing market to list options on a Commodity-Based Trust; and (3) require that the crypto asset held by the Commodity-Based Trust have a comprehensive surveillance sharing agreement. This filing also defines a crypto asset. Additionally, this filing proposes to amend Exchange Rule 403(g) to update the relevant citations to Exchange Rule 402, which are revised pursuant to this filing.

The text of the proposed rule change is available on the Exchange’s website at <https://www.miaxglobal.com/markets/us-options/miax-sapphire/rule-filings> and at the Exchange’s principal office.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements

concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**1. Purpose**

The Exchange proposes to amend its listing rules at Exchange Rule 402, Criteria for Underlying Securities.³ Specifically, the Exchange proposes to amend the criteria for listing options on Exchange-Traded Fund Shares (“ETFs”) at Exchange Rule 402(i). This is a competitive filing substantively identical to the proposal submitted by Nasdaq ISE, LLC (“ISE”) to the Securities and Exchange Commission

³ The Exchange notes that its affiliate options exchanges, Miami International Securities Exchange, LLC (“MIAX”) and MIAX Pearl, LLC (“MIAX Pearl”), submitted (or will submit) substantively similar proposals. The Exchange notes that the rules of Chapter IV of MIAX, including Exchange Rule 402, are incorporated by reference into the MIAX Emerald, LLC (“MIAX Emerald”) rulebook.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

(the “Commission”), which was recently deemed approved.⁴

The Exchange initially filed SR–SAPPHIRE–2025–12, as Modified by Partial Amendment Nos. 1, 2 and 3 [sic], a proposed rule change to amend its listing rules at Exchange Rule 402, Criteria for Underlying Securities, to allow the listing and trading of options on interests in a Commodity-Based Trust on March 5, 2025, which was published in the Federal Registrar [sic] on March 19, 2025.⁵ On April 25, 2025, the Commission issued a notice designating a longer period for Commission action, which designated June 17, 2025, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove the filing.⁶ On June 17, 2025, the Commission issued an order instituting proceedings to determine whether to approve or disapprove the filing.⁷ The Commission did not receive any comments on the proposed rule change. On September 8, 2025, the Commission extended the time period for approving or disapproving the proposed rule changes, as modified by the applicable Partial Amendments, for an additional 60 days, designating November 14, 2025 as the date by which the Commission will either approve or disapprove the proposed rule change, as modified by

the applicable Partial Amendments.⁸ The Commission did not act to either approve or disapprove the proposal on or before November 14, 2025, therefore the proposal, as published in the **Federal Register** on March 5, 2025, was deemed approved as of November 14, 2025.⁹ On November 6, 2025, during the government shutdown, the Exchange submitted Amendment 3 to SR–SAPPHIRE–2025–12. The Exchange is now proposing the current change to reiterate the changes proposed in Amendment 3 to SR–SAPPHIRE–2025–12 to codify the proposed rule text in the Exchange’s Rulebook.

The Exchange proposes to amend Rule 402 to adopt new listing criteria in subparagraph (i)(6) to permit the listing and trading of options on a Commodity-Based Trust that meets the generic listing standards for Commodity-Based Trust Shares of the applicable primary listing market, except that the Commodity-Based Trust holds a single crypto asset.¹⁰

On September 17, 2025, the Commission approved proposals by The Nasdaq Stock Market LLC, Cboe BZX Exchange, Inc. and NYSE Arca, Inc., to Adopt Generic Listing Standards for Commodity-Based Trusts.¹¹ In the

approval order, the Commission noted that each of the exchanges proposed to adopt substantially identical “generic” listing standards for Commodity-Based Trusts. Those generic listing standards define the term shares of a “Commodity-Based Trust” as a security¹² that:

(1) is issued by a trust, limited liability company, partnership, or other similar entity (“Trust”) that, if applicable, is operated by a registered commodity pool operator pursuant to the Commodity Exchange Act (“CEA”), and is not registered as an investment company pursuant to the Investment Company Act of 1940, or series or class thereof;

(2) is designed to reflect the performance of one or more reference assets or an index of reference assets;

(3) in order to reflect the performance, is issued by a Trust that holds (a) one or more commodities or commodity-based assets, and (b) in addition to such commodities or commodity-based assets, may hold securities, cash, and cash equivalents;

(4) is issued by such Trust in a specified aggregate minimum number in return for a deposit of (a) a specified quantity of the underlying commodities, commodity-based assets, securities, cash, and/or cash equivalents or (b) a cash amount with a value based on the next determined net asset value per Trust share; and

(5) when aggregated in the same specified minimum number, may be redeemed at a holder’s request by such Trust which will deliver to the redeeming holder (a) the specified quantity of the underlying commodities, commodity-based assets, securities, cash, and/or cash equivalents or (b) a cash amount with a value based on the next determined net asset value per Trust share.

The Exchange proposes to amend Exchange Rule 402(i) to create a new subparagraph (6)(iii) that states,¹³

Additionally, with respect to a Commodity-Based Trust that meets the

for Commodity-Based Trust Shares Approval”). The Exchange believes that it is appropriate to rely on the generic listing standards outlined by the primary listing market due to the potential proliferation of new primary listing markets and the Commission’s acknowledgment that the definition of shares of a Commodity-Based Trust across those primary listing markets is substantially identical.

¹² Shares of the applicable Commodity-Based Trust trade as equity securities. *See* Securities Exchange Act Release No. 50603 (Oct. 28, 2004), 69 FR 64614, 64619 (Nov. 5, 2004) (SR–NYSE–2004–22) (approving the listing and trading of streetTRACKS Gold Shares) (“Spot Gold Approval Order”) and ETP Request for Comments, *infra* note 20, at 34731. *See also* Nasdaq Rule 5711(d)(ii); proposed BZX Rule 14.11(e)(4)(B); proposed NYSE Arca Rule 8.201–E(b) (Generic) (stating that Commodity-Based Trust Shares are included within the definition of a “security” as such term is used in the Exchanges’ rules and are subject to the Exchanges’ existing rules governing the trading of equity securities).

¹³ The Exchange proposes to renumber current Exchange Rules 402(i)(5)(i) and 402(i)(5)(ii) to Exchange Rules 402(i)(6)(i) and 402(i)(6)(ii) for ease of reference, clarity, and consistency of the Rulebook.

⁴ *See* Securities Exchange Act Release No. 102465 (February 7, 2025), 90 FR 10740 (February 26, 2025) (SR–ISE–2025–08) (Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, to Adopt Listing Criteria for Options on a Commodity-Based Trust) [sic].

⁵ *See* Securities Exchange Act Release No. 102660 (March 5, 2025), 90 FR 12859 (March 19, 2025) (SR–SAPPHIRE–2025–12) (Self-Regulatory Organizations; Notice of Filing of a Proposed Rule Change, as Modified by Partial Amendment Nos. 1 and 2, by MIAX Sapphire, LLC To Amend Exchange Rule 402, Criteria for Underlying Securities, To List and Trade Options on Commodity-Based Trust Shares).

⁶ *See* Securities Exchange Act Release No. 102928 (April 25, 2025), 90 FR 18717 (May 1, 2025) (SR–SAPPHIRE–2025–12) (Self-Regulatory Organizations; MIAX Sapphire, LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change, as Modified by Partial Amendment Nos. 1 and 2, To Amend Exchange Rule 402, Criteria for Underlying Securities, To List and Trade Options on Commodity-Based Trust Shares).

⁷ *See* Securities Exchange Act Release No. 103283 (June 17, 2025), 90 FR 26634 (June 23, 2025) (SR–SAPPHIRE–2025–12) (Self-Regulatory Organizations; Miami International Securities Exchange, LLC; MIAX PEARL, LLC; MIAX Sapphire, LLC; Order Instituting Proceedings To Determine Whether To Approve or Disapprove Proposed Rule Changes, as Modified by Partial Amendments Thereto, To Amend Rule 402, Criteria for Underlying Securities, To List and Trade Options on Commodity-Based Trust Shares).

⁸ *See* Securities Exchange Act Release No. 103903 (September 8, 2025), 90 FR 44123 (September 11, 2025) (SR–SAPPHIRE–2025–12) (Self-Regulatory Organizations; Miami International Securities Exchange, LLC; MIAX PEARL, LLC; MIAX Sapphire, 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 Partial Amendments Thereto, To Amend Rule 402, Criteria for Underlying Securities, To List and Trade Options on Commodity-Based Trust Shares).

⁹ *See* Securities Exchange Act Release No. 104210 (November 18, 2025), 90 FR 52727 (November 21, 2025) (SR–SAPPHIRE–2025–12) (Self-Regulatory Organizations; BOX Exchange LLC, Cboe Exchange, Inc., Cboe BYX Exchange, Inc., Cboe BZX Exchange, Inc., Cboe EDGX Exchange, Inc., Miami International Securities Exchange, LLC, MIAX PEARL, LLC, MIAX Sapphire, LLC, Nasdaq ISE, LLC, New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE National, Inc., and NYSE Texas, Inc.; Notice of Deemed Approval of Various Proposed Rule Changes).

¹⁰ For example, a multi-coin ETF would not be subject to Exchange Rule 402(i)(6). For purposes of this rule the term “crypto asset” means an asset that is generated, issued and/or transferred using a blockchain or similar distributive ledger technology network, including but not limited to, assets known as “tokens,” “digital assets,” “virtual currencies,” and “coins” and that relies on cryptographic protocols. *See* definition at proposed Exchange Rule 402(i)(6)(iii).

¹¹ *See* Securities Exchange Act Release No. 103995 (Sept. 17, 2025), 90 FR 45414 (Sept. 22, 2025) (Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Cboe BZX Exchange, Inc.; NYSE Arca, Inc.; Order Granting Accelerated Approval of Proposed Rule Changes, as Modified by Amendments Thereto, To Adopt Generic Listing Standards for Commodity-Based Trust Shares) (SR–NASDAQ–2025–056; SR–CboeBZX–2025–104; SR–NYSEARCA–2025–54) (“Generic Listing Standards

requirements of Exchange Rule 402(i)(6), the following requirements are satisfied: (A) the total global supply of the underlying crypto asset held by the Commodity-Based Trust has an average daily market value of at least \$700 million over the last 12 months; and (B) the crypto asset held by the Commodity-Based Trust underlies a derivatives contract that trades on a market with which the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in the Intermarket Surveillance Group. For purposes of this rule the term “crypto asset” means an asset that is generated, issued and/or transferred using a blockchain or similar distributive ledger technology network, including but not limited to, assets known as “tokens,” “digital assets,” “virtual currencies,” and “coins” and that relies on cryptographic protocols.

The proposed additional criteria would require a Commodity-Based Trust to: (1) meet the generic criteria for Commodity-Based Trust Shares of the applicable primary listing market and hold only a single crypto asset; (2) meet the criteria and guidelines set forth in Exchange Rule 402(a)¹⁴ and (b),¹⁵ or Exchange Rule 402(i)(6)(i)(B);¹⁶ and meet the requirements in 402(i)(6)(iii) prior to listing options on the Commodity-Based Trust.

As proposed, Exchange Rule 402(i)(6)(iii) requires Commodity-Based Trust that meets the requirements of 402(i)(6) to also satisfy the following requirements: (A) the total global supply of the underlying crypto asset held by the Commodity-Based Trust has an average daily market value of at least \$700 million over the last 12 months; and (B) the crypto asset held by the Commodity-Based Trust underlies a derivatives contract that trades on a market with which the Exchange has a

comprehensive surveillance sharing agreement, whether directly or through common membership in the Intermarket Surveillance Group (“ISG”).

The Exchange defines a “crypto asset” at Exchange Rule 402(i)(6)(iii) to mean, for purposes of this rule, an asset that is generated, issued and/or transferred using a blockchain or similar distributive ledger technology network, including but not limited to, assets known as “tokens,” “digital assets,” “virtual currencies,” and “coins” and that relies on cryptographic protocols.

The market value of the underlying crypto asset will be calculated by taking the total global supply of the particular crypto asset multiplied by the token price.¹⁷ Total supply of crypto assets includes all crypto assets currently issued and does not include unissued crypto assets.¹⁸

Further, the Exchange has specified in proposed Exchange Rule 402(i)(6)(iii) that the crypto asset held by the Commodity-Based Trust must underlie a derivatives contract that trades on a market with which the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in ISG.¹⁹ The Exchange will be required to ensure that this requirement is met prior to listing options on a Commodity-Based Trust pursuant to proposed Exchange Rule 402(i)(6).

As a result of this filing, the proposed listing criteria would permit a Commodity Based Trust that is generically listed on the applicable primary listing market and holds a single crypto asset to qualify for the listing of options on that ETF, provided Exchange Rule 402(i)(6)(iii) has also been met, as well as the listing criteria in Exchange Rule 402(a) and (b), or Exchange Rule 402(i)(6)(i)(B).

Similar to options on any ETF, an option on a Commodity-Based Trust that meets the requirements of Exchange Rule 402(i)(6) would also be subject to the Exchange’s continued listing standards for options on ETFs set forth in Exchange Rule 403(g). Pursuant to

Exchange Rule 403(g), ETFs approved for options trading pursuant to Exchange Rule 402(i) will not be deemed 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 ETFs, if the ETFs are delisted from trading pursuant to Exchange Rule 403(b)(4),²⁰ are halted or suspended from trading in their primary market.²¹ Additionally, options on ETFs may be subject to the suspension of opening transactions in any of the following circumstances:²²

(1) in the case of options covering ETFs approved for trading under Exchange Rule 402(i)(6)(i)(A), in accordance with the terms of paragraphs (b)(1), (2), and (3) of Exchange Rule 403;²³

(2) in the case of options covering ETFs approved for trading under Exchange Rule 402(i)(6)(i)(B), following the initial twelve-month period beginning upon the commencement of trading in the ETFs on a national securities exchange and are defined as an NMS stock, there are fewer than 50 record and/or beneficial holders of such ETFs 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 ETFs 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.

Consistent with current Exchange Rule 404, which governs the opening of options series on a specific underlying security (including ETFs), the Exchange will open at least one expiration

¹⁴ Exchange Rule 402(a) provides that a security (which includes an ETF) on which options may be listed and traded on the Exchange must be a security registered (with the Commission) and be an NMS stock (as defined in Rule 600 of Regulation NMS under the Act), and the security shall be characterized by a substantial number of outstanding shares that are widely held and actively traded.

¹⁵ Exchange Rule 402(b) provides criteria and guidelines when evaluating potential underlying securities for the listing of options.

¹⁶ Exchange Rule 402(i)(6)(i)(B) provides that the Exchange-Traded Fund Shares are available for creation or redemption each business day from or through the issuing trust, investment company, commodity pool or other entity in cash or in kind at a price related to net asset value, and the issuer is obligated to issue Exchange-Traded Fund Shares in a specified aggregate number even if some or all of the investment assets and/or cash required to be deposited have not been received by the issuer, subject to the condition that the person obligated to deposit the investment assets has undertaken to deliver them 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 of the Exchange-Traded Fund Shares, all as described in the Exchange-Traded Fund Shares’ prospectus.

¹⁷ The market supply information can be obtained from publicly available sources such as [coingecko.com](https://www.coingecko.com) or coinmarketcap.com.

¹⁸ For example, if Bitcoin were the underlying crypto asset, the Exchange would consider the total supply of all Bitcoin currently issued instead of the maximum supply, which would be currently issued as well as unminted Bitcoin. As of September 12, 2025, Bitcoin’s total supply was 19,919,915 (the maximum supply was 21,000,000). See <https://www.coingecko.com/en/coins/bitcoin>. The Exchange would calculate market value by utilizing the total supply number multiplied by the Bitcoin price on that day.

¹⁹ For a list of the current members and affiliate members [sic] of ISG, see <https://isgportal.org/publicmembers>.

²⁰ Exchange Rule 403(b)(5) provides, if an underlying security is approved for options listing and trading under the provisions of Rule 402(c), the trading volume of the Original Equity Security (as therein defined) prior to but not after the commencement of trading in the Restructure Security (as therein defined), including “when-issued” trading, may be taken into account in determining whether the trading volume requirement of subparagraph (3) is satisfied.

²¹ See Exchange Rule 403(g). With this filing the Exchange is also proposing to amend Exchange Rule 403(g) to reflect the changes in numbering proposed herein for Exchange Rule 402(i).

²² See *id.*

²³ Exchange Rule 403(b)(1) through (3) provides, if: (1) there are fewer than 6,300,000 shares of the underlying security held by persons other than those who are required to report their security holdings under Section 16(a) of the Act, (2) there are fewer than 1,600 holders of the underlying security, (3) the trading volume (in all markets in which the underlying security is traded) has been less than 1,800,000 shares in the preceding twelve (12) months.

month²⁴ for options on a Commodity-Based Trust that are approved subject to Exchange Rule 402(i)(6) and may also list series of options on Commodity-Based Trust Share for trading on a weekly,²⁵ monthly,²⁶ or quarterly²⁷ basis. The Exchange may also list long-term equity option series (“LEAPS”) that expire from 12 to 39 months from the time they are listed.²⁸

Pursuant to Exchange Rule 404, Interpretation and Policy .06, which governs strike prices of series of options on ETFs, the interval between strike prices of series of options on ETFs approved for options trading pursuant to Exchange Rule 402(i) shall be fixed at a price per share which is reasonably close to the price per share at which the underlying security is traded in the primary market at or about the same time such series of options is first open for trading on the Exchange, or at such intervals as may have been established on another options exchange prior to the initiation of trading on the Exchange. With respect to the Short Term Options Series or Weekly Program, during the month prior to expiration of an option class that is selected for the Short Term Option Series Program, the strike price intervals for the related non-Short Term Option (“Related non-Short Term Option”) shall be the same as the strike price intervals for the Short Term Option.²⁹ Specifically, the Exchange may open for trading Short Term Option

Series at strike price intervals of (i) \$0.50 or greater where the strike price is less than \$100, and \$1 or greater where the strike price is between \$100 and \$150 for all option classes that participate in the Short Term Options Series Program; (ii) \$0.50 for option classes that trade in one dollar increments and are in the Short Term Option Series Program; or (iii) \$2.50 or greater where the strike price is above \$150.³⁰ Additionally, the Exchange may list series of options pursuant to the \$1 Strike Price Interval Program,³¹ the \$0.50 Strike Program,³² and the \$2.50 Strike Price Program.³³ Pursuant to Exchange Rule 510, where the price of a series of options on a Commodity-Based Trust 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 \$0.10³⁴ consistent with the minimum increments for options on other ETFs listed on the Exchange. Any and all new series of a [sic] Commodity-Based Trust options that the Exchange lists will be consistent and comply with the expirations, strike prices, and minimum increments set forth in Rules 404 and 510, as applicable.

Further, options on a [sic] Commodity-Based Trusts that are approved subject to Exchange Rule 402(i)(6) would trade in the same manner as options on other ETFs on the Exchange. The Exchange Rules that currently apply to the listing and trading of all options on ETFs on the Exchange, including, for example, Rules that govern listing criteria, expirations, exercise prices, minimum increments, position and exercise limits, margin requirements, customer accounts and trading halt procedures would apply to the listing and trading of options on Commodity-Based Trusts that are approved subject to Exchange Rule 402(i)(6) in the same manner.

Position and exercise limits for options on Commodity-Based Trusts that are approved pursuant to Exchange Rule 402(i)(6) would be determined pursuant to Exchange Rules 307 and 309, respectively, as is the case for other options on other ETFs. Position and exercise limits for options on ETF vary according to the number of outstanding shares and the trading volumes of the underlying ETF over the past six months, where the largest in capitalization and the most frequently

traded ETFs have an option position and exercise limits of 250,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market; and smaller capitalization ETFs have position and exercise limits of 200,000, 75,000, 50,000 or 25,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market. Further, Exchange Rule 1502, which governs margin requirements applicable to trading on the Exchange, including options on ETFs, will also apply to the trading of options on a [sic] Commodity-Based Trusts listed pursuant to Exchange Rule 402(i)(6).

The Exchange represents that the same surveillance procedures applicable to all other options on other ETFs currently listed and traded on the Exchange will apply to the trading of options on Commodity-Based Trusts that are approved subject to Exchange Rule 402(i)(6).³⁵ The Exchange represents that it has the necessary systems capacity to support the new option series. The Exchange believes that its existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior which might potentially arise from listing and trading options on ETFs, including the listing of options on Commodity-Based Trusts that are approved subject to Exchange Rule 402(i)(6). Also, the Exchange may obtain information from designated contract markets that are members of the ISG related to a financial instrument that is based, in whole or in part, upon an interest in or performance of a crypto asset, as applicable. The Exchange has specified in proposed Exchange Rule 402(i)(6) that the crypto asset held by the Commodity-Based Trust must underlie a derivatives contract that trades on a market with which the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in ISG.³⁶ The Exchange will be required to ensure that this requirement is met prior to listing options on a Commodity-Based Trust listed pursuant to proposed Exchange Rule 402(i)(6).

Additionally, the Exchange has also analyzed its capacity and represents that

²⁴ See Exchange Rule 404(b). The monthly expirations are subject to certain listing criteria for underlying securities described within Exchange Rule 404 and its Interpretations and Policies. 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 Exchange Rule 404(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. Pursuant to Exchange Rule 404(e), 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.

²⁵ See Exchange Rule 404, Interpretation and Policy .02.

²⁶ See Exchange Rule 404, Interpretation and Policy .13.

²⁷ See Exchange Rule 404, Interpretation and Policy .03.

²⁸ See Exchange Rule 406.

²⁹ See Exchange Rule 404, Interpretation and Policy .02(e).

³⁰ *Id.*

³¹ See Exchange Rule 404, Interpretation and Policy .01.

³² See Exchange Rule 404, Interpretation and Policy .04.

³³ See Exchange Rule 404(f).

³⁴ See Exchange Rule 510.

³⁵ The surveillance program includes real-time patterns for price and volume movements and post-trade surveillance patterns (e.g., spoofing, marking the close, ping, phishing).

³⁶ There are a number of futures contracts on digital asset commodities that are listed and trading on the CME and Coinbase Derivatives, both of which are ISG members. See <https://www.cmegroup.com/markets/cryptocurrencies.html#products>. See also <https://www.coinbase.com/derivatives>.

it believes the Exchange and the Options Price Reporting Authority or “OPRA” have the necessary systems capacity to handle the additional traffic associated with the listing of new series of ETFs, including options on a [sic] Commodity-Based Trusts, that are approved subject to Exchange Rule 402(i)(6), up to the number of expirations currently permissible under the Exchange Rules.

Finally, today, the Exchange lists and trades options on ETFs that would qualify for listing as an option on a Commodity-Based Trust under proposed Exchange Rule 402(i)(6),³⁷ and it has not identified any issues with the listing and trading of options on those ETFs.

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.³⁸ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)³⁹ 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)⁴⁰ 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 its proposal to establish new listing criteria at Exchange Rule 402(i)(6) with respect to options on Commodity-Based Trusts, without the need for additional approvals, 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 it would allow the Exchange to immediately list and trade qualifying options on Commodity-Based Trusts, provided the initial listing criteria has been met, without any additional approvals from the Commission.

Specifically, the Exchange’s proposal to adopt Exchange Rule 402(i)(6) to allow the listing and trading of options on units that represent interests in Commodity-Based Trusts that meet the generic listing standards for Commodity-Based Trust Shares of the applicable primary listing market,⁴¹ and hold a single crypto asset, is consistent with the Act because it will permit the Exchange to offer options on Commodity-Based Trusts soon after the listing of the ETF on the primary listing market, provided that all the generic listing standards for that Commodity-Based Trust on that primary listing market have been met. Listing these options will avail market participants of the opportunity to hedge their positions in the Commodity-Based Trusts in a timely manner, thereby providing investors with the ability to hedge their exposure to the underlying Commodity-Based Trust. Options on Commodity-Based Trusts benefits investors, similar to the listing of any other option on an ETF, by providing investors with a relatively lower-cost risk management tool to manage their positions and associated risk in their portfolios more easily in connection with exposure to the price of a crypto asset. Additionally, listing options on Commodity-Based Trusts provides investors with the ability to transact in such options on a listed market as opposed to the OTC options market, which increases market transparency and enhances the process of price discovery to the benefit of all investors.

Also, this proposal would permit options on Commodity-Based Trusts to be listed on the Exchange in the same manner as all other securities that are subject to the current listing criteria in Exchange Rule 402. The Exchange notes that the majority of ETFs are able to list and trade options once the initial listing criteria have been met without the need for additional approvals. The proposed rule change would allow options on certain Commodity-Based Trusts to likewise list and trade options once the initial listing criteria on the primary listing market have been met without the need for additional approvals.

As proposed, the Exchange would list options in a Commodity-Based Trust that met the generic criteria of the applicable primary listing market,

provided the Commodity-Based Trust held only a single crypto asset. Further, these options on Commodity-Based Trusts would also be required to satisfy the conditions in proposed Exchange Rule 402(i)(6)(iii). Specifically, a Commodity-Based Trust that met the requirements of proposed Exchange Rule 402(i)(6) would also have to satisfy the following requirements in proposed Exchange Rule 402(i)(6)(iii): (A) the total global supply of the underlying crypto asset held by the Commodity-Based Trust has an average daily market value of at least \$700 million over the last 12 months; and (B) the crypto asset held by the Commodity-Based Trust underlies a derivatives contract that trades on a market with which the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in the ISG.

These requirements are consistent with the Act and the protection of investors as they should ensure that the underlying ETF has sufficient liquidity prior to listing options, which will serve to prevent disruption to the underlying market. The Exchange believes that market supply serves as a good measure of liquidity to prevent the addition of options trading on the Commodity-Based Trust from disrupting the market for the underlying security. Requiring the underlying crypto asset to have a requisite amount of deliverable supply, in addition to all the other criteria the ETF is required to have under the applicable primary listing market rules, should ensure adequate liquidity prior to listing. Further, ensuring the crypto asset held by the Commodity-Based Trust underlies a derivatives contract that trades on a market with which the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in the ISG, will provide the Exchange with information to adequately surveillance options on qualifying Commodity-Based Trusts. Today, the Exchange has a comprehensive surveillance sharing agreement in place with both the CME and Coinbase Derivatives through its common membership in ISG. This facilitates the sharing of information that is available to the CME and Coinbase Derivatives through their surveillance of their respective markets, including their surveillance of their respective digital asset futures markets.

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

³⁷ The following ETFs currently have options listed on them on the Exchange: iShares Bitcoin Trust, the Fidelity Wise Origin Bitcoin Fund, the ARK21Shares Bitcoin ETF, the Grayscale Bitcoin Trust (BTC), the Grayscale Bitcoin Mini Trust BTC, and the Bitwise Bitcoin ETF. See Exchange Rule 402(i)(4). The Exchange filed rule proposals and received the appropriate regulatory notice or approval to list the aforementioned options on the ETFs.

³⁸ 15 U.S.C. 78f(b).

³⁹ 15 U.S.C. 78f(b)(5).

⁴⁰ *Id.*

⁴¹ See *supra* note 11.

Commission. Options on qualifying Commodity-Based Trusts must satisfy the initial listing standards and continued listing standards currently in the Exchange Rules applicable to options on all ETFs, including ETFs that hold other crypto assets already deemed appropriate for options trading on the Exchange in addition to the proposed criteria. Options on qualifying Commodity-Based Trusts would trade in the same manner as any other ETF options—the same Exchange Rules that currently govern the listing and trading of all ETF options, including permissible expirations, strike prices and minimum increments, and applicable position and exercise limits and margin requirements, will govern the listing and trading of options on qualifying Commodity-Based Trusts.

The Exchange represents that it has the necessary systems capacity to support the listing and trading of options on qualifying Commodity-Based Trusts. 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 of these options on Commodity-Based Trust, particularly in light of the additional requirement that the crypto asset held by the Commodity-Based Trust underlies a derivatives contract that trades on a market with which the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in ISG.

Finally, today, the Exchange lists and trades options on ETFs that would qualify for listing as an option on a Commodity-Based Trust under proposed Exchange Rule 402(i)(6),⁴² and it has not identified any issues with the listing and trading of options on those ETFs.

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. In this regard and as indicated above, the Exchange notes that the rule change is being

proposed as a competitive response to the filing submitted by ISE.⁴³

The Exchange does not believe that the proposal to amend the listing criteria at Exchange Rule 402(i)(6), with respect to ETFs, to adopt new criteria to permit the listing and trading of options on certain Commodity-Based Trusts that hold a single crypto asset and that were listed pursuant to the generic listing standards for Commodity-Based Trust Shares of the applicable primary listing market, without the need for additional approvals, will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Options on qualifying Commodity-Based Trusts would need to satisfy the initial listing standards set forth in the Exchange Rules in the same manner as any other ETF before the Exchange could list options on them. Additionally, options on qualifying Commodity-Based Trusts will be equally available to all market participants who wish to trade such options. The Exchange Rules currently applicable to the listing and trading of options on ETFs on the Exchange will apply in the same manner to the listing and trading of all options on qualifying Commodity-Based Trusts.

Additionally, the Exchange notes that listing and trading options on qualifying Commodity-Based Trusts 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 in a timely manner.

The Exchange does not believe that the proposal to adopt new listing criteria at Exchange Rule 402(i)(6) to permit the listing and trading of certain options on a Commodity-Based Trust, without the need for additional approvals, will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Other options exchanges are free to amend their applicable rules to permit them to list and trade options on Commodity-Based Trusts.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act⁴⁴ and subparagraph (f)(6) of Rule 19b-4 thereunder.⁴⁵

A proposed rule change filed under Rule 19b-4(f)(6)⁴⁶ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),⁴⁷ the Commission may designate a shorter time if such action is consistent with protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. The Commission believes that waiving 30-day operative delay is consistent with the protection of investors and the public interest because the proposal seeks to amend the Exchange's rules to be consistent with an amendment filed by the Exchange during a government shutdown, and which would have replaced the proposed rule change that did become effective if the Commission could have received amendments during the pendency of the government shutdown.⁴⁸ The proposal also aligns the rule text relating to Commodity-Based Trust Shares with the rule text of other exchanges and does not introduce any novel regulatory issues.⁴⁹ Accordingly, the Commission

⁴² The following ETFs currently have options listed on them on the Exchange: iShares Bitcoin Trust, the Fidelity Wise Origin Bitcoin Fund, the ARK21Shares Bitcoin ETF, the Grayscale Bitcoin Trust (BTC), the Grayscale Bitcoin Mini Trust BTC, and the Bitwise Bitcoin ETF. See Exchange Rule 402(i)(4). The Exchange filed rule proposals and received the appropriate regulatory notice or approval to list the aforementioned options on the ETFs.

⁴³ See *supra* note 4.

⁴⁴ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴⁵ 17 CFR 240.19b-4(f)(6). 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 Commission is waiving this requirement.

⁴⁶ 17 CFR 240.19b-4(f)(6).

⁴⁷ 17 CFR 240.19b-4(f)(6)(iii).

⁴⁸ See *supra* Section II.A.1.

⁴⁹ See e.g., Nasdaq ISE, LLC, Options Rules, Options 4, Section 3(h); Cboe Exchange, Inc. Rule 4.3(a).

designates the proposed rule change to be operative upon filing.⁵⁰

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule 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-SAPPHIRE-2025-44 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-SAPPHIRE-2025-44. 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 filing 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-SAPPHIRE-2025-44 and should be submitted on or before January 13, 2026.

⁵⁰ For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁵¹

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-23654 Filed 12-22-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104447; File No. SR-CboeBZX-2025-072]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Withdrawal of a Proposed Rule Change To Exempt Closed-End Management Investment Companies Registered Under the Investment Company Act of 1940 That are Listed as of or After May 20, 2025 From the Annual Meeting of Shareholders Requirement Set Forth in Exchange Rule 14.10(f)

December 18, 2025.

On May 20, 2025, Cboe BZX Exchange, Inc. ("BZX" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Exchange Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to exempt closed-end management investment companies registered under the Investment Company Act of 1940 ("1940 Act")³ that are listed as of or after May 20, 2025 from the annual meeting of shareholders requirement set forth in Exchange Rule 14.10(f). The proposed rule change was published for comment in the **Federal Register** on June 6, 2025.⁴

On July 14, 2025, pursuant to Section 19(b)(2) of the Exchange Act,⁵ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.⁶ On September 2, 2025, the Commission instituted proceedings under Section 19(b)(2)(B) of the Exchange Act⁷ to determine

⁵¹ 17 CFR 200.30-3(a)(12), (59).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 80a-1 *et seq.*

⁴ See Securities Exchange Act Release No. 103166 (June 2, 2025), 90 FR 24172 ("Notice"). Comments on the proposed rule change are available at: <https://www.sec.gov/comments/sr-cboebzx-2025-072/srcboebzx2025072.htm>.

⁵ 15 U.S.C. 78s(b)(2).

⁶ See Securities Exchange Act Release No. 103452, 90 FR 33449 (July 17, 2025). The Commission designated September 4, 2025, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

⁷ 15 U.S.C. 78s(b)(2)(B).

whether to approve or disapprove the proposed rule change.⁸ On December 2, 2025, the Commission extended the period for consideration of the proposed rule change to February 1, 2026.⁹

On December 12, 2025, the Exchange withdrew the proposed rule change (CboeBZX-2025-072).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁰

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-23672 Filed 12-22-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235-0510]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension: Rule 302

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 ("SEC" or "Commission") is soliciting comments on the proposed collection of information provided for in Rule 302 (17 CFR 242.302) of Regulation ATS (17 CFR 242.302 *et seq.*) under the Securities and Exchange Act of 1934 ("Exchange Act") (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget ("OMB") for extension and approval.

Regulation ATS sets forth a regulatory regime for "alternative trading systems" ("ATSs").¹ An entity that meets the definition of an exchange must register, pursuant to section 5 of the Exchange Act, as a national securities exchange under section 6 of the Exchange Act² or operate pursuant to an appropriate exemption.³ One of the available

⁸ See Securities Exchange Act Release No. 103824, 90 FR 42991 (Sept. 5, 2025).

⁹ See Securities Exchange Act Release No. 104285, 90 FR 56220 (Dec. 5, 2025).

¹⁰ 17 CFR 200.30-3(a)(12).

¹ Regulation ATS consists of 17 CFR 242.300 through 242.304 (Rules 300 through 304 under the Exchange Act).

² See 15 U.S.C. 78e and 78f. A "national securities exchange" is an exchange registered as such under section 6 of the Exchange Act.

³ 15 U.S.C. 78a *et seq.*

exemptions is for ATSs.⁴ Exchange Act Rule 3a1–1(a)(2) exempts from the definition of “exchange” under section 3(a)(1) an organization, association, or group of persons that complies with Regulation ATS.⁵ Regulation ATS requires an ATS to, among other things, register as a broker-dealer with the Commission, file a Form ATS or Form ATS–N with the Commission to notice its operations, and establish written safeguards and procedures to protect subscribers’ confidential trading information. An ATS that complies with Regulation ATS and operates pursuant to the Rule 3a1–1(a)(2) exemption would not be required by section 5 to register as a national securities exchange.

To comply with the condition set forth in Rule 301(b)(8) of Regulation ATS (17 CFR 242.301(b)(8)), an ATS must make and keep current certain records relating to trading activity set forth in Rule 302 of Regulation ATS (17 CFR 242.302).⁶ Under Rule 302, ATSs are required to, among other things, make a record of subscribers to the ATS, daily summaries of trading in the ATS, and time-sequenced records of order information in the ATS.

The information required to be collected under Rule 302 should increase the abilities of the Commission, state securities regulatory authorities, and the self-regulatory organizations to ensure that ATSs are in compliance with Regulation ATS as well as other applicable rules and regulations. If the information is not collected or collected less frequently, the regulators would be limited in their ability to comply with their statutory obligations, provide for the protection of investors, and promote the maintenance of fair and orderly markets.

Respondents consist of ATSs that choose to operate pursuant to the

exemption provided by Regulation ATS from registration as national securities exchanges. There are currently 111 respondents. These respondents will spend a total of approximately 4,773 hours per year (111 respondents at 43 burden hours/respondent) to comply with the recordkeeping requirements of Rule 302. At an average cost per burden hour of \$89, the resultant total related total internal cost of compliance for these respondents is approximately \$424,797 per year (4,773 burden hours multiplied by \$89/hour).

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.

Please direct your written comment to Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Tanya Ruttenberg, 100 F Street NE, Washington, DC 20549 and send it by email to

PaperworkReductionAct@sec.gov within 60 days of publication of this notice, by February 23, 2026.

Dated: December 19, 2025.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025–23686 Filed 12–22–25; 8:45 am]

BILLING CODE 8011–01–P

⁴ Rule 300(a) of Regulation ATS provides that an ATS is “any organization, association, person, group of persons, or system: (1) [t]hat constitutes, maintains, or provides a market place or facilities for bringing together purchasers and sellers of securities or for otherwise performing with respect to securities the functions commonly performed by a stock exchange within the meaning of [Exchange Act Rule 3b–16]; and (2) [t]hat does not: (i) [s]et rules governing the conduct of subscribers other than the conduct of subscribers’ trading on such [ATS]; or (ii) [d]iscipline subscribers other than by exclusion from trading.”

⁵ See 17 CFR 240.3a1–1(a)(2).

⁶ Rule 301(b)(8)(i) of Regulation ATS provides that an ATS shall “make and keep current the records” specified in Rule 302 of Regulation ATS. Further, Rule 301(b)(8)(ii) provides that an ATS shall preserve the records specified in Rule 303 of Regulation ATS. Rule 303 requires an ATS to preserve, among other things, all records required to be made pursuant to Rule 302 for a period of not less than three years, the first two years in an easily accessible place. 17 CFR 242.303.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–104448; File No. SR–CBOE–2025–068]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Add P.M.-Settled Options on the Cboe Magnificent 10 Index With Third Friday Expirations, Nonstandard Expirations, and Quarterly Index Expirations

December 18, 2025.

I. Introduction

On September 10, 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 add p.m.-settled options on the Cboe Magnificent 10 Index (“MGTN”) with third Friday expirations, nonstandard expirations, and quarterly index expirations. The proposed rule change was published for comment in the **Federal Register** on September 26, 2025.³ On November 3, 2025, the Commission designated a longer period within which to take action on the proposed rule change.⁴ On December 8, 2025, the Exchange filed Amendment No. 1 to the proposed rule change as described in Item II below, which Item has been prepared by the Exchange. Amendment No. 1 superseded the original proposed rule change in its entirety.⁵ The Commission is publishing this notice to solicit comments on Amendment No. 1 from

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Securities Exchange Act Release No. 104019 (Sept. 23, 2025), 90 FR 46424 (Sept. 26, 2025). The Commission did not receive any comments on the proposal.

⁴ See Securities Exchange Act Release No. 104173 (Nov. 3, 2025), 90 FR 51424 (Nov. 17, 2025).

⁵ Amendment No. 1 revises the proposed rule change to reflect changes to the rule text made by a separate filing that had proposed several of the same changes but was approved subsequent to the filing of this proposed rule change. See Securities Exchange Act Release No. 103997 (Sept. 17, 2025), 90 FR 45431 (Sept. 22, 2025) (adopting p.m.-settled options on the Cboe Bitcoin U.S. ETF Index (“CBTX”) and the Mini-Cboe Bitcoin U.S. ETF Index (“MBTX”) with third Friday expirations, nonstandard expirations, and quarterly index expirations) (“P.M.-Settled CBTX and MBTX Options Approval Order”). Amendment No. 1 also adds references to CBTX and MBTX options to the proposed rule change as well as details about the market capitalization and trading volume of the current MGTN index components. Amendment No. 1 is available at: <https://www.sec.gov/comments/sr-cboe-2025-068/srcboe2025068-683087-2110994.pdf>.

interested persons, and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change, as Modified by Amendment No. 1

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 Rules 4.13 and 5.1. First, the Exchange proposes to amend Rule 4.13(e), which governs its Nonstandard Expirations Program ("Program"), to permit P.M.-settled options on the Cboe Magnificent 10 Index ("MGTN options") that expire any Monday, Tuesday, Wednesday, Thursday, or Friday (other than the third Friday-of-the-month ("Expiration Friday")) or days that coincide with an end-of-month expiration ("Weekly Expirations") and that expire on the last trading day of the month ("EOMs"). Currently, under this Program, the Exchange is permitted to list P.M.-settled options on any broad-based index eligible for standard trading and the Cboe Bitcoin U.S. ETF Index ("CBTX") and the Mini-Cboe Bitcoin U.S. ETF Index ("MBTX") (which are narrow-based indexes) that expire on: (1) any Monday, Tuesday, Wednesday, Thursday, or Friday (other than the third Friday-of-the-month or days that coincide with an EOM expiration) and (2) the last trading day of the month.⁶ The proposal expands the availability of Weekly and EOM expirations to MGTN options, which are narrow-based index options eligible for standard options trading.⁷

The Nonstandard Expiration Program will apply to MGTN options in the same manner as it currently applies to other index options. Weekly and EOM Expirations are subject to all provisions of Rule 4.13 and treated the same as options on the same underlying index that expire on the third Friday of the expiration month; provided, however, that Weekly and EOM Expirations are P.M.-settled, and new series in Weekly and EOM Expirations may be added up to and including on the expiration date for an expiring Weekly or EOM Expiration.

The maximum number of expirations that may be listed for each Weekly Expiration (*i.e.*, a Monday expiration, Tuesday expiration, Wednesday expiration, Thursday expiration, or Friday expiration, as applicable) and each EOM expiration in a given class is the same as the maximum number of expirations permitted in Rule 4.13(a)(2) for standard options on the same index (which is currently six for MGTN options). Weekly Expirations need not be for consecutive Monday, Tuesday, Wednesday, Thursday, or Friday expirations as applicable; however, the expiration date of a nonconsecutive expiration may not be beyond what would be considered the last expiration date if the maximum number of expirations were listed consecutively. Weekly Expirations that are first listed in a given class may expire up to four weeks from the actual listing date. Similarly, EOM expirations need not be for consecutive end of month expirations; however, the expiration date of a nonconsecutive expiration may not be beyond what would be considered the last expiration date if the maximum number of expirations were listed consecutively. EOM Expirations that are first listed in a given class may expire up to four weeks from the actual listing date. If the Exchange lists EOMs and Weekly Expirations in a given class, the Exchange will list an EOM instead of a Weekly Expiration that expires on the same day in the given class. Other expirations in the same class are not counted as part of the maximum number of Weekly or EOM Expirations for an applicable index class.

If the Exchange is not open for business on a respective Monday, the normally Monday expiring Weekly Expirations will expire on the following business day. If the Exchange is not open for business on a respective Tuesday, Wednesday, Thursday, or Friday, the normally Tuesday,

Wednesday, Thursday, or Friday expiring Weekly Expirations will expire on the previous business day. If two different Weekly Expirations on an index would expire on the same day because the Exchange is not open for business on a certain weekday, the Exchange will list only one of such Weekly Expirations. In addition, pursuant to Rule 4.13(e)(3), transactions in expiring index options with Weekly and EOM Expirations may be effected on the Exchange between the hours of 9:30 a.m. and 4:00 p.m. on their last trading day (Eastern Time).

Second, the Exchange proposes to amend Rule 4.13(c), which governs quarterly index expirations ("QIXs"), to add MGTN options to the list of options in Rule 4.13(c) that are eligible for quarterly index expirations ("QIXs"), which are currently available for options on the S&P 100 Index ("OEX options"), S&P 500 Index ("SPX options"), Mini-S&P 500 Index ("XSP options"), S&P 500 Equal Weight Index (full-value) ("SPEQ options"), S&P 500 Equal Weight Index (1/10th reduced-value) ("SPEQX options"), Russell 2000 Index ("RUT options"), Mini-Russell 2000 Index ("MRUT options"), CBTX options, and MBTX options.⁸ Pursuant to Rule 4.13(c), there may be up to eight near-term quarterly expirations open for trading in a class, and these options will be P.M.-settled. The QIX program will apply to MGTN options in the same manner as it currently applies to the other options currently eligible for those expirations. QIXs are subject to all provisions of Rule 4.13 and treated the same as options on the same underlying index that expire on the third Friday of the expiration month, except that QIXs, are P.M.-settled.

Third, the Exchange proposes to amend Rule 4.13, Interpretation and Policy .13, to permit the listing of P.M.-settled MGTN options that expire on Expiration Fridays. Currently, pursuant to Rule 4.13, Interpretation and Policy .13, the Exchange is permitted to list P.M.-settled SPX options, XSP options, SPEQ options, SPEQX options, RUT options, MRUT options, CBTX options, and MBTX options that expire on Expiration Fridays. Combined with the proposed rule change above to permit the Exchange to list P.M.-settled MGTN options with Weekly Expirations, the

⁶ See Rule 4.13(e).

⁷ The Exchange notes MGTN options are eligible for the Monthly Options Series program pursuant to Rule 4.13(a)(2)(C), which permits p.m.-settled options that expire on the last trading day of the month (as do options with EOM expirations). The Exchange proposes to make these options eligible for the EOM expirations pursuant to the Nonstandard Expiration for consistency since the

Exchange is proposing to make these options eligible for the Weekly Expirations, which are part of the Nonstandard Expiration Program.

⁸ The Exchange notes MGTN options are currently eligible for the Quarterly Options Series program pursuant to Rule 4.13(a)(2)(B), which permits P.M.-settled options that expire on the last trading day of the quarter (as do QIXs). The Exchange proposes to make these options eligible for QIXs for consistency, since QIXs are currently available for certain index options available for trading on the Exchange (which options are also eligible for the Nonstandard Expirations Program).

Exchange would be permitted to list P.M.-settled MGTN options with expirations on all Fridays (in addition to all other days of the week). MGTN options that are P.M.-settled and expire on Expiration Fridays are subject to all provisions of Rule 4.13 and treated the same as A.M.-settled MGTN options, except that they are P.M.-settled.

Finally, the Exchange proposes to amend Rule 5.1, which governs trading days and hours, in conjunction with the proposed addition of MGTN options that are P.M.-settled and expire on Expiration Friday. Rule 5.1(b)(2)(C) currently provides that on their last trading day, Regular Trading Hours for index options with Nonstandard Expirations, as well as expiring P.M.-settled SPX, XSP, RUT, MRUT, CBTX, and MBTX options, may be effected on the Exchange between 9:30 a.m. and 4:00 p.m. Eastern Time⁹ (as opposed to the 9:30 a.m. to 4:15 p.m. Regular Trading Hours for options with those expirations that are non-expiring). The proposed rule change amends Rule 5.1(b)(2)(C) to include MGTN P.M.-settled options.¹⁰ The primary listing markets for the component securities that comprise the Cboe Magnificent 10 Index close trading in those securities at 4:00 p.m., just as the primary listing markets for the component securities that comprise the S&P 500, Mini-S&P 500, Russell 2000, Mini-Russell 2000, Cboe Bitcoin U.S. ETF, and Cboe Mini-Bitcoin U.S. ETF Indexes close trading at 4:00 p.m. The primary listing exchanges for the component securities disseminate closing prices for the component securities, which are used to calculate the exercise settlement value of these indexes. The Exchange believes that, under normal trading circumstances, the primary listing markets have sufficient bandwidth to prevent any data queuing that may cause any trades that are executed prior to the closing time from being reported after 4:00 p.m. If trading in expiring MGTN P.M.-settled options continued an additional fifteen minutes until 4:15 p.m. on their last trading day, these expiring options would be trading after the settlement index value for those expiring options was calculated. Therefore, in order to mitigate potential investor confusion and the potential for increased costs to investors as a result of potential pricing divergence at the

end of the trading day, the Exchange believes that it is appropriate to cease trading in the expiring MGTN P.M.-settled options at 4:00 p.m., as it already does for expiring P.M.-settled SPX, XSP, RUT, MRUT, CBTX, and MBTX options that expire on Expiration Fridays and for expiring indexes with Nonstandard Expirations (which are P.M.-settled) for the same aforementioned reasons.¹¹ The Exchange does not believe that the proposed rule change will impact volatility on the underlying cash market comprising the Cboe Magnificent 10 Index at the close on Expiration Fridays, as it already closes trading on the last trading day for expiring P.M.-settled index options at 4:00 p.m., which the Exchange does not believe has had an adverse impact on fair and orderly markets on Expiration Fridays for the underlying securities comprising the corresponding indexes.¹²

As noted above, current Rules permit the Exchange to list P.M.-settled MGTN options with expirations on the last calendar of the month and quarter.¹³ As a result, it is already possible under the Rules for options on the Cboe Magnificent 10 Index to be P.M.-settled and to expire on any day of the week (as the end of the month or the end of a quarter may fall on any day of the week). The Rules also already allow options on the Cboe Magnificent 10 Index to expire on Thursdays for normally Friday expiring options when the Exchange is not open for business on a respective Friday. Further, options on the Cboe Magnificent 10 Index will be available for FLEX trading pursuant to Rule 4.20 upon initial listing on the Exchange, which would permit market participants to select expiration dates for these FLEX options for any day of the week and may select p.m.-settlement.

The Exchange believes that the introduction of Weekly Expirations and Expiration Friday expirations for options on the Cboe Magnificent 10 Index that are P.M.-settled will provide market participants with additional

hedging tools and greater trading opportunities, regardless of in which index option market they participate. By offering expanded expirations along with the current standard A.M.-settled expirations (as well as P.M.-settled monthly and quarterly expirations), the proposed rule change will allow market participants to purchase options on the Cboe Magnificent 10 Index available for trading on the Exchange in a manner more aligned with specific timing needs (such as to hedge special events) and more effectively tailor their investment and hedging strategies and manage their portfolios. In particular, the proposed rule change will allow market participants to roll their positions on more trading days, thus with more precision, spread risk across more trading days and incorporate daily changes in the markets, which may reduce the premium cost of buying protection. For example, the Exchange believes that market participants may pay for more protection than they need if they are seeking to hedge weekend or special event risk that occurs. Therefore, the Exchange believes that P.M.-settled daily expirations (including on all Fridays) would allow market participants to purchase an option based on their needed timing and allow them to tailor their investment or hedging needs more effectively. In addition, because P.M.-settlement permits trading throughout the day on the day the contract expires, the Exchange believes this will permit market participants to more effectively manage overnight risk and trade out of their positions up until the time the contract settles.

The Exchange believes there is sufficient investor interest and demand in Weekly Expirations and Expiration Friday P.M.-settled expirations for options on the Cboe Magnificent 10 Index to warrant inclusion in the Program and in the Rules, and that the Program and the Rules, as amended, will continue to provide investors with additional means of managing their risk exposures and carrying out their investment objectives.¹⁴

With regard to the impact of this proposal on system capacity, the Exchange has analyzed its capacity and represents that it believes that the Exchange and OPRA have the necessary systems capacity to handle any potential additional traffic associated with trading of P.M.-settled Weekly and Expiration Friday expirations for MGTN options. The Exchange does not believe that its

⁹ See Rule 1.6, which states that unless otherwise specified, all times in the Rules are Eastern Time.

¹⁰ Current Rule 5.1(b)(2)(C) would apply to MGTN options with Nonstandard Expirations and QIXs, as proposed; therefore, the addition of MGTN P.M.-settled options to the list of options set forth in this Rule covers these options that expire on Expiration Fridays.

¹¹ See Securities Exchange Act Release Nos. 68888 (February 8, 2013), 78 FR 10668 (February 14, 2013) (SR-CBOE-2012-120) ("SPXPM Pilot Approval Order"); 70087 (July 31, 2013), 78 FR 47809 (August 6, 2013) (SR-CBOE-2013-055) ("XSPPM Pilot Approval Order"); and 91067 (February 5, 2021), 86 FR 9108 (February 11, 2021) (SR-CBOE-2020-116) ("MRUTPM Pilot Approval Order").

¹² See Securities Exchange Act Release Nos. 98454 (September 20, 2023), 88 FR 66103 (September 26, 2023) (SR-CBOE-2023-005) ("SPXPM Permanent Approval Order"); and 98455 (September 20, 2023), 88 FR 66073 (September 26, 2023) (SR-CBOE-2023-019) ("XSPPM and MRUTPM Permanent Approval Order").

¹³ See Rule 4.13(a)(2)(C) and (B), respectively.

¹⁴ The Exchange currently may list Weekly, EOM, QIX, and Expiration Friday P.M.-Settled Expirations for SPX, XSP, RUT, MRUT, CBTX, and MBTX options.

Trading Permit Holders (“TPHs”) will experience any capacity issues as a result of this proposal and represents that it will monitor the trading volume associated with any possible additional series of options on the Cboe Magnificent 10 Index listed as a result of this proposal and the effect (if any) of these additional series on market fragmentation and on the capacity of the Exchange’s automated systems.

In addition to this, the Exchange believes that its existing surveillance and reporting safeguards in place are adequate to deter and detect possible manipulative behavior which might arise from listing and trading MGTN options with Weekly Expirations or Expiration Friday expirations (as the Exchange currently applies these surveillances to other options that are P.M.-settled with these expirations and would for MGTN options that are P.M.-settled with monthly and quarterly expirations pursuant to current Rules) and will support the protection of investors and the public interest. Furthermore, the trading of MGTN options with Weekly and Expiration Friday expirations will be subject to the same rules that currently govern the trading of options on the Cboe Magnificent 10 Index with other expirations, including governing customer accounts, position and exercise limits,¹⁵ margin requirements and trading halt procedures, among other Rules, which are designed to prevent fraudulent and manipulative acts and practices.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the “Act”) and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of

Section 6(b) of the Act.¹⁶ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁷ 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 facilitation 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)¹⁸ 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 proposed rule change will 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 introduction of P.M.-settled Weekly and Expiration Friday expirations for MGTN options will provide investors with expanded hedging tools and greater trading opportunities and flexibility for an additional index option.¹⁹ As a result, investors will have additional means to manage their risk exposures and carry out their investment objectives. By offering expanded expirations for options on the Cboe Magnificent 10 Index (along with the currently available P.M.-settled monthly and quarterly options and standard A.M.-settled options), the proposed rule change will allow market participants to purchase options on an additional index in a manner more aligned with specific timing needs and more effectively tailor their investment and hedging strategies and manage their portfolios. For example, the proposed rule change will allow market participants to roll their positions in options on the Cboe Magnificent 10 Index on more trading

days, thus with more precision, spread risk across more trading days and incorporate daily changes in the markets, which may reduce the premium cost of buying protection. The Exchange represents that it believes that it has the necessary systems capacity to support any additional traffic associated with trading of options on the Cboe Magnificent 10 Index with Weekly and Expiration Friday (P.M.-settled) expirations and does not believe that its TPHs will experience any capacity issues as a result of this proposal.

The Exchange does not believe that the addition of MGTN options to the Nonstandard Expirations Program, to the P.M.-settled Expiration Friday program, or the QIX program will raise any prohibitive regulatory concerns, nor adversely impact fair and orderly markets on expiration days. The Exchange has not experienced any meaningful regulatory concerns, nor adverse impact on fair and orderly markets, in connection with these programs and is unaware of any reason why adding P.M.-settled options with expirations each day of the week for MGTN options would be create such concerns or impact. Particularly, the Exchange does not believe increases in the number of P.M.-settled options series and expirations will have any significant adverse economic impact on the futures, index, or underlying index component securities markets.²⁰ The Exchange believes that the proposed rule change will provide investors with greater trading and hedging opportunities and flexibility, allowing them to transact in options on the Cboe Magnificent 10 Index in a manner more aligned with specific timing needs and more effectively tailor their investment and hedging objectives by listing these options that expire each trading day of the week, in addition to options that expire at the end of calendar month and quarter (which, as noted above, current Rules already permit the Exchange to do).

As also discussed above, current Rules permit the Exchange to list P.M.-settled options on the Cboe Magnificent 10 Index that expire on the last calendar day of the month and quarter; the proposed rule change merely permits these listings to occur under different programs within the Rules for consistency within the Exchange’s Rules.²¹ Therefore, it is already possible

¹⁵ Pursuant to Rule 8.32(f), positions in Nonstandard Expiration Program, QIXs, and P.M.-Settled Third Friday Index Options series are aggregated with positions in options contracts in the same index class. Therefore, MGTN options positions that have Nonstandard Expirations, QIXs, and third-Friday P.M.-settlement will be aggregated for purposes of position limits with positions in MGTN options, respectively with other expirations (including short-term, monthly, and quarterly expirations). This is consistent with the treatment of positions for purposes of position limits for other classes that participate in the Nonstandard Expiration Program, as well as QIXs and P.M.-Settled Third Fridays. See Rule 8.31(b). Pursuant to Rule 8.32(a) and 8.42(b) (which provides that the exercise limits for index options are equivalent to the position limits set forth in Rule 8.32), the current position and exercise limits for MGTN options are 24,000 contracts (and may not be more than 31,500 without rule changes). Therefore, investors would not be able to maintain significant open interest in these options, which may further prevent investors from being able to impact the value of the index.

¹⁶ 15 U.S.C. 78f(b).

¹⁷ 15 U.S.C. 78f(b)(5).

¹⁸ *Id.*

¹⁹ Options on the Cboe Magnificent 10 Index may already be listed with P.M.-settlement and expirations on the last calendar day of the month or quarter pursuant to Rule 4.13(a)(2)(C) and (B), respectively; therefore, the additional series that this proposed rule would permit to be listed are P.M.-settled Weeklys and Expiration Friday expirations. The proposed rule change merely adds these options to different programs within the Rules that permit these same expirations for consistency within the Rules.

²⁰ The Exchange’s affiliate, the Cboe Futures Exchange, LLC (“CFE”), currently lists MGTN futures.

²¹ For example, it may be confusing to list Weeklys under the Nonstandard Expirations Program but monthlys under the Monthly program

under the Rules for options on the Cboe Magnificent 10 Index to be P.M.-settled and to expire on any day of the week (as the end of the month or the end of a quarter may fall on any day of the week). The Rules also already allow options on the Cboe Magnificent 10 Index to expire on Thursdays for normally Friday expiring options when the Exchange is not open for business on a respective Friday. Further, options on the Cboe Magnificent 10 Index will be available for FLEX trading pursuant to Rule 4.20 when the Exchange begins listing these options, and thus, market participants will be able to select expiration dates for these FLEX options for any day of the week and may select p.m.-settlement. The Exchange has no reason to believe this proposed rule change will cause any significant adverse economic impact on the futures, index, or underlying index component securities markets as a result of these listings.

The Commission previously recognized that listing P.M.-settled index options with Weekly Expirations and Expiration Friday expirations (in addition to EOM Expirations (which would include expirations on the last day of calendar quarters)) was consistent with the Act.²² The Commission noted that expirations in those index options would “offer additional investment options to investors and may be useful for their investment or hedging objectives”²³ The Exchange also notes it previously listed P.M.-settled broad-based index options with Weekly, EOM, and Expiration Friday expirations

rather than the Nonstandard Expirations Program. As proposed, all index options the Exchange lists with expirations other than Expiration Fridays would be eligible for those expirations under the same programs.

²² See Securities Exchange Act Release Nos. 98454 (September 20, 2023), 88 FR 66103 (September 26, 2023) (SR-CBOE-2023-005) (“SPXPM Permanent Approval Order”); 98455 (September 20, 2023), 88 FR 66073 (September 26, 2023) (SR-CBOE-2023-019) (“XSPPM and MRUTPM Permanent Approval Order”) (the Exchange initially listed P.M.-Settled SPX, XSP, and MRUT options that expire on Expiration Fridays pursuant to pilot programs, so the Commission could monitor the impact of P.M. settlement of cash-settled index derivatives on the underlying cash markets (while recognizing that these risks may have been mitigated given enhanced closing procedures in use in the primary equity markets); 94682 (April 12, 2022), 87 FR 22993, 22994 (April 18, 2022) (SR-CBOE-2022-005) (approval of proposed rule change to list P.M.-settled SPX options that expire on Tuesdays and Thursdays) (“Daily SPX Option Approval”); and 95795 (September 15, 2022), 87 FR 57745, 57746 (September 21, 2022) (SR-CBOE-2022-039) (approval of proposed rule change to list P.M.-settled XSP options that expire on Tuesdays and Thursdays) (“Daily XSP Option Approval”).

²³ See Daily SPX Option Approval at 22995; and Daily XSP Option Approval at 57746.

pursuant to pilot programs, so the Commission could monitor the impact of P.M.-settlement of cash-settled index derivatives on the underlying cash markets (while recognizing that these risks may have been mitigated given enhanced closing procedures in use in the primary equity markets); however, the Commission approved proposed rule changes to make those pilot programs permanent. The Commission noted that the data it reviewed in connection with the pilot demonstrated that these options “benefitted investors and other market participants by providing more flexible trading and hedging opportunities while also having no disruptive impact on the market” and were thus consistent with the Act.²⁴ The proposed rule change is consistent with these findings, as it will benefit investors and other market participants that participate in the markets for additional index options in the same manner by providing them with more flexible trading and hedging opportunities.

Further, the Exchange believes P.M.-settlement is appropriate for options on the Cboe Magnificent 10 Index because they will be trading within a complex of other correlated instruments that track the performance of the underlying components, in addition to the underlying components themselves (e.g., options on the components, ETFs that track the most active stocks (including the components), and futures on the Cboe Magnificent 10 Index). This reduces the risk that listing these options would strain liquidity providers. Further, the size of the markets of the underlying components²⁵ and the equal weighting

²⁴ See SPXPM Permanent Approval Order at 66106; and XSPPM and MRUTPM Permanent Approval Order at 66076 (citing data the Commission reviewed in connection with the pilot programs);

²⁵ The index is designed to measure the price return of a group of large capitalization U.S. technology and growth-oriented companies and are intended to be among the most actively traded stocks. Pursuant to the methodology for the Cboe Magnificent 10 Index, each component will have a market capitalization of at least \$500,000,000, a free float of at least 25%, a minimum of 1,000,000 shares trading volume in the preceding six months, and one of the 100 largest market capitalizations. The Exchange notes the market capitalizations of the current ten constituents range from approximately 257,334,000,000 to 4,321,000,000,000 and are within the top 34 among listed stocks, the minimum free float of the constituents is approximately 84.1%, and the six-month trading volume ranges from approximately 787,775,000,000 to 4,262,320,000,000. Additionally, the narrow-based listing criteria pursuant to which these index options are listed impose various requirements on the component securities related to the market capitalization and liquidity, which further reduce the risk that the markets for the components would be impacted by additional

of the components make it unlikely the proposed rule change would materially impact the component markets, the index value, or the broader market.

As is the case for options on other indexes eligible for P.M.-settlement (including broad-based and narrow-based indexes), the Exchange does not believe the listing of additional P.M.-settled options on the Cboe Magnificent 10 Index (which are narrow-based index options) will have any significant economic impact (such as on market quality or volatility) on the component securities underlying the index surrounding the close as a result of expiring p.m.-settled options or impact market quality. This is based on the data provided to and reviewed by the Commission (and the Commission’s own conclusions with respect to broad-based indexes based on that review, as noted above) and due to the significant changes in closing procedures in the decades since index options moved to a.m.-settlement.²⁶ The Exchange believes the potential for any such impact is not only no greater for narrow-based indexes than broad-based indexes, but may be less likely for narrow-based indexes such as the Cboe Magnificent 10 Index, as the indexes underlying such options are by definition not representative of an entire market (as is the case for options on the S&P 500 Index). Therefore, any potential impact would likely be limited in scope (as noted above, the Commission found no material impact with respect to P.M.-settled broad-based index options). Therefore, because, as noted above, the Commission found no material impact with respect to broad-based index options, the Exchange believes that it is reasonable to infer that no material impact would occur with respect to MGTN options for the reasons described above (including the significant

derivatives. For example, pursuant to Rule 4.10(b): (1) the market capitalization for the lowest-weighted component securities in the index that in the aggregate account for no more than 10% of the weight of the index must be at least \$50 million, and the market capitalization of all other components must be at least \$75 million; (2) the trading volume in each component must be at least 1,000,000 shares for each of the last six months (from October 2024 through March 2025, the lowest monthly trading volume for a component was over 1.5 million shares), except that for each of the lowest-weighted component securities in the index that in the aggregate account for no more than 10% of the weight of the index, the trading volume must be at least 500,000 shares for each of the last six months; and (3) no single component security may represent more than 25% of the weight of the index, and the five highest-weighted component securities in the index may not in the aggregate account for more than 50% (60% for an index consisting of fewer than 25 component securities) of the weight of the index.

²⁶ See *id.*

liquidity of the components and correlation of the component securities and the availability of multiple correlated instruments for hedging). The Exchange believes this to be particularly true given that the components of the Cboe Magnificent 10 Index are also components of the S&P 500 Index, which was the index the Commission considered in those findings. The narrow scope of narrow-based indexes aligns closer to the scope of equity options (which are P.M.-settled, such as the options overlying the constituent securities that comprise the Cboe Magnificent 10 Index).

Further, the Cboe Magnificent 10 Index satisfies the generic listing criteria in Rule 4.10(b). Upon approval of those listing criteria, the Commission noted that these generic standards were reasonably designed to ensure the protection of investors and the public interest and to ensure that the trading markets for the components were adequately capitalized and sufficiently liquid, and that no one component dominated the index, thus minimizing the potential for manipulation.²⁷ This listing criteria includes the following:

- each component security has a market capitalization of at least \$75 million, except that for each of the lowest weighted component securities in the index that in the aggregate account for no more than 10% of the weight of the index, the market capitalization is at least \$50 million;
- trading volume of each component security has been at least one million shares for each of the last six months, except that for each of the lowest weighted component securities in the index that in the aggregate account for no more than 10% of the weight of the index, trading volume has been at least 500,000 shares for each of the last six months;
- in a capitalization-weighted index or a modified capitalization-weighted index, the lesser of the five highest weighted component securities in the index or the highest weighted component securities in the index that in the aggregate represent at least 30% of the total number of component

securities in the index each have had an average monthly trading volume of at least 2,000,000 shares over the past six months;

- no single component security represents more than 25% of the weight of the index, and the five highest weighted component securities in the index do not in the aggregate account for more than 50% (60% for an index consisting of fewer than 25 component securities) of the weight of the index; and
- component securities that account for at least 90% of the weight of the index and at least 80% of the total number of component securities in the index satisfy the requirements of Rule 4.3 applicable to individual underlying securities.

Additionally, as described above, the constituents of the Cboe Magnificent 10 Index are large, highly capitalized, and heavily traded, which further reduce the potential for manipulation of the index. Therefore, by satisfying the generic listing criteria for narrow-based index options, the Cboe Magnificent 10 Index is, like broad-based indexes and the narrow-based Cboe Bitcoin U.S. ETF and Cboe Mini-Bitcoin U.S. ETF Indexes, designed to minimize the potential for manipulation, further reducing any potential concerns associated with P.M.-settlement.

Further, the Exchange believes that because MGTN options listed with Nonstandard Expirations, QIXs, and P.M.-settlement on Third Fridays will be aggregated with other options within those classes for purposes of position (and exercise) limits, will further prevent fraudulent and manipulative acts and practices and to promote just and equitable principles of trade, and thus protect investors. This aggregation is consistent with the treatment of positions for purposes of position (and exercise) limits for other classes that may be listed with Nonstandard Expirations, QIXs, and third Friday p.m.-settlement.²⁸ Therefore, the current position and exercise limits that apply to options on the Cboe Magnificent 10 Index will continue to apply, as the proposed additional expirations for these options would have no impact on the number of positions that may be held (or exercised) within a single account.

In addition, the Exchange believes that the proposal to end trading at 4:00 p.m. on the last trading day for transactions in expiring P.M.-settled MGTN options will prevent continued trading on a product after the exercise settlement value has been fixed, thereby

mitigating potential investor confusion and the potential for increased costs to investors as a result of potential pricing divergence at the end of the trading day.

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 because P.M.-settled options on the Cboe Magnificent 10 Index with Weekly and Expiration Friday expirations will be available to all market participants. By listing options on the Cboe Magnificent 10 Index with these expirations (in addition to the monthly, quarterly, and standard Expiration Friday expirations (A.M.-settled) that are currently permitted under the Rules), the proposed rule change will provide all investors that participate in the markets for these index options available for trading on the Exchange with greater trading and hedging opportunities and flexibility to meet their investment and hedging needs, which are already available for several other index options (both broad-based and narrow-based). Further, the proposed change to make options on the Cboe Magnificent 10 Index that are P.M.-settled and expire on the last business day of the month or quarter eligible for listing under different programs under the Rules will have any burden on competition, as this proposed rule change is intended to maintain consistency within the Rules and will result in the same series being listed. The proposed 4:00 p.m. closing time for expiring P.M.-settled MGTN options on their expiration dates will apply equally to all market participants trading these options.

The Exchange does not believe that the proposal to list P.M.-options on the Cboe Magnificent 10 Index with Weekly and Expiration Friday expirations will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because these options are proprietary Exchange products. The Exchange may currently list the same expirations for other index options, so the proposed rule change merely expands the availability of these expiration programs to additional products. Other exchanges offer similar expirations for index options as well as short-term options programs for certain

²⁷ See Securities Exchange Act Release No. 34157 (June 3, 1994), 59 FR 30062 (June 10, 1994) (SR-Amex-92-35, SR-CBOE-93-59, SR-NYSE-94-17, SR-PSE-94-07, and SR-Phlx-94-10). The Commission made substantially similar findings with respect to generic listing criteria for broad-based index options. See Securities Exchange Act Release No. 53266 (February 9, 2006), 71 FR 8321 (February 16, 2006) (SR-CBOE-2005-59) (the Commission noted that the listing criteria were “designed to ensure that the markets for the index’s component stocks are adequately capitalized and sufficiently liquid, and that no one stock dominates the index” and thus “minimize the potential for manipulating the underlying index”).

²⁸ See Rule 8.31(b).

equity options that expire each day of the week, at the end of the calendar month, at the end of the calendar quarter, and on Expiration Fridays²⁹ and are welcome to similarly propose to list options on those index or equity products with similar expirations. To the extent that the addition of these expirations for options on the Cboe Magnificent 10 Index makes 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, options on the Cboe Magnificent 10 Index with these expirations will trade in the same manner as other options with these expirations currently do.

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 comments on the proposed rule change.

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange.³⁰ In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act,³¹ which requires, among other things, that the Exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

In evaluating whether this proposal is consistent with Section 6(b)(5), and, in particular, whether it is designed to prevent fraudulent and manipulative acts and practices and to protect investors and the public interest, the

Commission considered the potential impacts of p.m.-settled, cash-settled options on the underlying cash equities markets, and in particular, the potential for added market volatility and sharp price movements near the close on expiration days. The Commission has had concerns about the adverse effects and impact of p.m.-settlement upon market volatility and the operation of fair and orderly markets on the underlying cash market at or near the close of trading on expiration days.³² However, the Commission approved proposals from several exchanges, including the Exchange, to permanently establish programs permitting the listing and trading of certain p.m.-settled broad-based index options.³³ In approving these proposals, the Commission reviewed data provided by the exchanges in their filings, the exchanges' pilot data and reports, as well as an analysis conducted at the direction of Staff from the Commission's Division of Economic and Risk Analysis and concluded that analysis of the pilot data did not identify any significant economic impact on the underlying component securities surrounding the close as a result of expiring p.m.-settled options nor did it indicate a deterioration in market quality for an existing product when a new p.m.-settled expiration was introduced.³⁴ Further, the Commission stated that significant changes in closing procedures in the decades since index options moved to a.m.-settlement may also serve to mitigate the potential impact of p.m.-settled index options on the underlying cash markets.³⁵ In addition, in September 2025, the Commission approved the listing of p.m.-settled options on two narrow-based indexes—CBTX and MBTX—with Weekly Expirations, EOM expirations,

Expiration Friday expirations and QIX expirations.³⁶

In support of this proposal, the Exchange states that it does not believe that the proposal would adversely impact fair and orderly markets on expiration days.³⁷ The Exchange explains that it has not experienced any meaningful regulatory concerns, nor adverse impact on fair and orderly markets, in connection with its Nonstandard Expirations Program, Expiration Friday expirations, or QIX program.³⁸

The Exchange states that p.m.-settlement is appropriate for MGTN options for several reasons. According to the Exchange, the size of the markets of the underlying components³⁹ and the equal weighting of the components make it unlikely that the proposal would result in a material impact on the component markets, the index value, or the broader market.⁴⁰ The Exchange states that MGTN is “designed to measure the price return of a group of large capitalization U.S. technology and growth-oriented companies and are intended to be among the most actively traded stocks,”⁴¹ and that “each [index] component will have a market capitalization of at least \$500,000,000, a free float of at least 25%, a minimum of 1,000,000 shares trading volume in the preceding six months, one of the 100 largest market capitalizations, and one of the highest six-month aggregate dollar values of average daily trading volume.”⁴² In Amendment No. 1, the Exchange provides market capitalization and trading volume ranges for the current ten index components.⁴³ The Exchange also states that MGTN options will trade within a complex of other correlated instruments that track the performance of the underlying components, in addition to the underlying components—such as options on the underlying components,

³² See Securities Exchange Act Release No. 65256 (Sept. 2, 2011), 76 FR 55969, at 55972 (Sept. 9, 2011) (SR-C2-2011-008) (Order Approving Proposed Rule Change to Establish a Pilot Program to List and Trade SPXPM Options on the C2 Options Exchange, Inc.).

³³ See e.g., SPXPM Permanent Approval Order and XSPPM and MRUTPM Permanent Approval Order, *supra* note 12. See also Securities Exchange Act Release Nos. 98450 (Sept. 20, 2023), 88 FR 66111 (Sept. 26, 2023) (SR-ISE-2023-08) (Order Granting Approval of a Proposed Rule Change, as Modified by Amendment No. 1, to Make Permanent Certain P.M.-Settled Pilots); 98451 (Sept. 20, 2023), 88 FR 66088 (Sept. 26, 2023) (SR-PHLX-2023-07) (Order Approving a Nonstandard Expirations Pilot Program and P.M.-Settled XND Options); and Securities Exchange Act Release Nos. 98935 (Nov. 14, 2023), 88 FR 80792 (Nov. 20, 2023) (SR-ISE-2023-20) (Order Approving the Listing and Trading of P.M.-Settled Nasdaq-100 Index Options with a Third Friday-of-the-Month Expiration).

³⁴ See e.g., XSPPM and MRUTPM Permanent Approval Order, *supra* note 12, 88 FR at 66075–76.

³⁵ See *id.*

³⁶ See P.M.-Settled CBTX and MBTX Options Approval Order, *supra* note 5.

³⁷ See Amendment No. 1, *supra* note 5, at 14.

³⁸ See *id.*

³⁹ See *id.* at 17. Further, according to the Exchange, MGTN satisfies the generic listing criteria for narrow-based index options in Rule 4.10(b), which are designed to ensure that the trading markets for the components are adequately capitalized and sufficiently liquid, and that no one component dominates the index, thus minimizing the potential for manipulation. See *id.* at 19.

⁴⁰ See *id.* at 17–18.

⁴¹ *Id.* at 17, n.21.

⁴² *Id.*

⁴³ See *id.* The Exchange states that, for the current index components, the market capitalizations range from approximately \$257,334,000,000 to \$4,321,000,000,000, the minimum free float is approximately 84.1%, and six-month trading volumes range from approximately 787,775,000,000 to 4,262,320,000,000 shares. See *id.*

²⁹ See, e.g., Nasdaq PHLX, LLC Options 4A, Section 12 (permitting nonstandard expirations, including daily expirations for Nasdaq-100 index options and Nasdaq 100-Micro index options); and Nasdaq ISE, LLC Options 4, Section 5, Supplementary Material .03 (permitting short-term options series with daily expirations for SPY and QQQ options).

³⁰ In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

³¹ 15 U.S.C. 78f(b)(5).

ETFs that trade the most active stocks (including the components), and MGTN futures—and that this reduces the risk that listing these options would strain liquidity providers or materially impact the component markets, the index value, or the broader market.⁴⁴

As noted above, in evaluating the proposals permitting the listing and trading of other p.m.-settled index options, the Commission evaluated the potential for negative impacts on the underlying component securities of the indexes and on options market quality.⁴⁵ In its approval of p.m.-settled CBTX and MBTX options, the Commission observed that the index components for CBTX and MBTX trade within a complex with multiple highly correlated instruments available for hedging and that the underlying components of the indexes are generally highly liquid and closely correlated with one another.⁴⁶ The Commission stated that, as a result, it would be unlikely for p.m.-settled options on CBTX and MBTX to increase market and price volatility in the underlying index components or in the CBTX and MBTX options market.⁴⁷ The index components for MGTN similarly trade within a complex of other correlated instruments that track the performance of the underlying components, in addition to the underlying components—such as options on the underlying components, ETFs that trade the most active stocks (including the components), and MGTN futures. Further, the index components have large market capitalizations and the trading markets for the components are highly liquid.⁴⁸ As a result, it would be unlikely for p.m.-settled MGTN options to increase market and price volatility in the underlying index components or in the market for MGTN options.

The Exchange's proposal to expand the Nonstandard Expirations Program and the QIX program to MGTN options and make the options eligible for p.m.-settled Expiration Friday expirations, is a reasonably designed expansion of existing p.m.-settled index option programs that may provide the investing public and other market participants with more flexible trading and hedging opportunities. Further, pursuant to Rule 8.32(a) and 8.42(b), MGTN options are subject to position and exercise limits of 24,000 contracts (and may not be more

than 31,500 without rule changes),⁴⁹ and p.m.-settled MGTN options would be subject to Rule 8.32(f), which provides that positions in the Nonstandard Expirations Program series, QIXs, and P.M.-Settled Third Friday Index Options will be aggregated with positions in options contracts in the same index class.⁵⁰ Therefore positions in MGTN options would be aggregated across expirations in the same class, which could reduce the potential incentives to manipulate or disrupt the underlying market to benefit the options position and would not allow the maintenance of significant open interest in the options. The Exchange also represents that it has a surveillance program in place to monitor trading in the proposed p.m.-settled MGTN options and the systems capacity to support the proposed new options series.⁵¹ The Commission expects the Exchange to continue to monitor any potential risks from large P.M.-settled positions and take appropriate action on a timely basis if warranted.

For the foregoing reasons, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act⁵² and the rules and regulations thereunder applicable to a national securities exchange.

IV. Solicitation of Comments on Amendment No. 1 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning whether 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-CBOE-2025-068 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-2025-068 on the subject line. 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 filing 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-2025-068 on the subject line, and should be submitted on or before January 13, 2026.

V. Accelerated Approval of Proposed Rule Change, as Modified and Superseded by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, prior to the thirtieth day after the date of publication of notice of the filing of Amendment No. 1 in the **Federal Register**. Amendment No. 1 updates the proposed rule change to reflect Commission approval of changes to the rule text made by a separate filing,⁵³ and adds market capitalization and trading volume ranges for the current MGTN index component securities.⁵⁴ Amendment No. 1 makes no substantive changes to the proposed rule change. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,⁵⁵ to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis prior to the 30th day after publication of notice of the filing of Amendment No. 1 in the **Federal Register**.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,⁵⁶ that the proposed rule change (SR-CBOE-2025-068), as modified by Amendment No. 1, be and hereby is approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁵⁷

Sherry R. Haywood,

Assistant Secretary.

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⁴⁴ See *id.* at 17–18.

⁴⁵ See e.g., SPXPM Permanent Approval Order, *supra* note 12, 88 FR at 66106.

⁴⁶ See P.M.-Settled CBTX and MBTX Options Approval Order, *supra* note 5, 90 FR at 45434.

⁴⁷ See *id.*

⁴⁸ See *supra* note 43.

⁴⁹ See Amendment No. 1, *supra* note 5, at 12, n.11.

⁵⁰ See *id.*

⁵¹ See *id.* at 11–12.

⁵² 15 U.S.C. 78f(b)(5).

⁵³ See P.M.-Settled CBTX and MBTX Options Approval Order, *supra* note 5.

⁵⁴ See *supra* note 25.

⁵⁵ 15 U.S.C. 78s(b)(2).

⁵⁶ *Id.*

⁵⁷ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–104459; File No. SR–CboeBZX–2025–167]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Permit the Exchange To Extend the Quote-Only Period

December 18, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on December 16, 2025, Cboe BZX Exchange, Inc. (the “Exchange” or “BZX”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I and II below, which Items have been substantially prepared by the Exchange. The Exchange filed the proposal as a “non-controversial” proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³ and Rule 19b–4(f)(6) thereunder.⁴ 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 is filing with the Commission a proposal to permit the Exchange to extend the Quote-Only Period⁵ where there is a security that is the subject of an initial pricing on the Exchange that has not been listed on a national securities exchange immediately prior to the initial pricing. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission’s website (<https://www.sec.gov/rules/sro.shtml>), the Exchange’s website (https://www.cboe.com/us/equities/regulation/rule_filings/bzx/), and at the principal office of the Exchange.

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 add a new subsection (vi) to Rule 11.23(d)(2)(B) to permit the Exchange to extend the Quote-Only Period where there is a security that is the subject of an initial pricing on the Exchange that has not been listed on a national securities exchange immediately prior to the initial pricing. The proposed ability to extend the Quote-Only Period is substantively identical to capabilities on other exchanges.⁶ The Exchange believes this proposal reinforces the Exchange’s broad discretionary authority over the initial and continued listing of securities.⁷

Exchange Rule 11.23(d)(2) sets forth the IPO and Halt Auction Process. Specifically, Rule 11.23(d)(2)(B) provides that the Quote-Only Period for an IPO Auction⁸ may be extended in five specific instances: (i) there are unmatched market orders on the Auction Book⁹ associated with the auction; (ii) the underwriter requests an extension; (iii) where the Indicative Price¹⁰ moves the greater of 10% or fifty (50) cents in the fifteen (15) seconds prior to the auction; (iv) in the event of a technical or systems issue at the Exchange that may impair the ability of Users¹¹ to participate in the IPO Auction or of the Exchange to complete the IPO Auction; or (v) where a Derivative Security¹² fails to meet the Exchange’s listing qualification requirements as set forth in Rule 14.11. Now, the Exchange proposes to adopt

⁶ See e.g., NYSE American Rule 7.18E(e); Securities and Exchange Commission No. 95945 (September 29, 2022) 87 FR 60428 (October 5, 2022) (SR–NYSEAMER–2022–44) (Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Permit the Exchange to Declare a Regulatory Halt).

⁷ See Exchange Rules 14.2 (Regulatory Authority of Exchange) and 14.6 (Obligations for Companies Listed on the Exchange).

⁸ See Exchange Rule 11.22(l)(2)(B) (defining “IPO Auction”).

⁹ See Exchange Rule 11.23(a)(1) (defining “Auction Book”).

¹⁰ See Exchange Rule 11.23(a)(10) (defining “Indicative Price”).

¹¹ See Exchange Rule 1.5(cc) (defining “Users”).

¹² See Exchange Rule 1.5(dd) (defining “Derivative Security”).

Rule 11.23(d)(2)(B)(vi) which would provide that the Quote-Only Period may be extended where there is a security that is the subject of an initial pricing on the Exchange that has not been listed on a national securities exchange immediately prior to the initial pricing.

NYSE American LLC (“NYSE American”) Rule 7.18E(e) states “[t]he Exchange may declare a regulatory halt in a security that is the subject of an initial pricing on the Exchange of a security that has not been listed on a national securities exchange immediately prior to the initial pricing. This regulatory halt will be terminated when the security opens.” This proposal is identical to the NYSE American rule except that the NYSE American rule references a regulatory halt instead of extension of the Quote-Only Period. Additionally, the Exchange is proposing slightly different language than the NYSE American rule to clarify that the rule only references one security. Further, the Exchange is proposing to not include reference to the extension period being terminated when the security opens, as this language is redundant with respect to the Exchange’s rules. While NYSE American’s rule references a regulatory halt and additional language, the Exchange’s approach of extending the Quote-Only Period achieves the same protective purpose through a mechanism that is consistent with the Exchange’s existing auction framework under Rule 11.23(d)(2)(B). Additionally, this proposal is identical to NYSE Arca, Inc. (“Arca”) Rule 7.18–E(b)(1)(B)(i)¹³ and Nasdaq Rule 4120(a)(7).¹⁴ Initial pricings of securities without prior exchange listing history can be subject to heightened volatility and uncertainty, particularly where there may be significant public interest or rapidly

¹³ See Arca Rule 7.18–E(b)(1)(B)(i), which provides that “[t]he Exchange may declare a Regulatory Halt in trading for any security for which it is the Primary Listing Market . . . of a security that is the subject of an initial pricing on the Exchange that has not been listed on a national securities exchange immediately prior to initial pricing (“Initial Listing Regulatory Halt”).” See also Securities and Exchange Commission No. 103476 (July 16, 2025) 90 FR 34314 (July 21, 2025) (SR–NYSEARCA–2025–50) (Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Rule 7.18–E To Effectuate Amendments to Second Restatement of the CTA Plan and the Restated CQ Plan and To Make Confirming Changes to Rules 1.1, 7.11–E, and 7.35–E).

¹⁴ See Nasdaq Rule 4120(a)(7), which provides that “[i]n circumstances in which Nasdaq deems it necessary to protect investors and the public interest, Nasdaq, pursuant to the procedures set forth in paragraph (c) . . . may halt trading in a security that is the subject of an Initial Public Offering on Nasdaq.”

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴ 17 CFR 240.19b–4(f)(6).

⁵ See Exchange Rule 11.23(a)(17).

changing market conditions. This authority complements the existing extension provisions in Rule 11.23(d)(2)(B) and provides an additional safeguard specifically tailored to the unique circumstances of initial pricings.

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.¹⁵ Specifically, the Exchange believes the proposed rule change is consistent with Section 6(b)(5)¹⁶ 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)¹⁷ 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 proposed Rule 11.23(d)(2)(B)(vi) will remove impediments to and perfect the mechanism of a free and open market and a national market system by providing the Exchange with necessary operational flexibility to ensure orderly opening auctions for newly listed securities that have not been listed on a national securities exchange immediately prior to the initial pricing. The proposed rule change clarifies the Exchange's broad authority over initial and continued listings, including ETPs subject to an IPO. This authority allows the Exchange to extend the Quote-Only Period when necessary to prevent disorderly openings and ensure that the initial price is established through a fair and transparent process.

The Exchange believes the proposed rule change is consistent with the protection of investors and the public interest because it clarifies the Exchange's broad authority over initial and continued listings, including ETPs subject to an IPO. This authority allows the Exchange to extend the Quote-Only

Period when necessary to prevent disorderly openings and ensure that the initial price is established through a fair and transparent process. Initial pricings of securities without prior exchange listing history can be subject to significant public interest or rapidly changing market conditions. This authority complements the existing extension provisions in Rule 11.23(d)(2)(B) and provides an additional safeguard specifically tailored to the unique circumstances of initial pricing.

The Exchange believes the proposed rule change is consistent with the requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers because the proposed extension authority will apply uniformly to all securities that are subject to an initial pricing on the Exchange and have not been listed on a national securities exchange immediately prior to the initial pricing. The Exchange's discretion to extend the Quote-Only Period will be exercised to facilitate the orderly establishment of an initial price, and all market participants will benefit equally from any additional time provided during an extended Quote-Only Period. The extension mechanism is transparent and consistent with the Exchange's existing auction procedures and discretionary authority under Rule 11.23(d)(2)(B).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed extension authority will apply uniformly to all securities that are subject to an initial pricing on the Exchange and have not been listed on a national securities exchange immediately prior to the initial pricing. The Exchange's discretion to extend the Quote-Only Period will be exercised to facilitate the orderly establishment of an initial price, and all market participants will benefit equally from any additional time provided during an extended Quote-Only Period. The proposed rule change does not benefit or burden any specific type of market participant, as it applies equally to all Users and their customers participating in IPO Auctions on the Exchange.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in

furtherance of the purposes of the Act. The proposed rule change does not affect the ability of other exchanges to conduct opening auctions for their listed securities or the manner in which they choose to manage their auction processes. Market participants on other exchanges are welcome to seek listings on the Exchange if they determine that this proposed rule change has made the Exchange more attractive or favorable as a listing venue.

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 comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁸ and paragraph (f) of Rule 19b-4¹⁹ thereunder. Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act²⁰ and subparagraph (f)(6) of Rule 19b-4 thereunder.²¹

A proposed rule change filed under Rule 19b-4(f)(6)²² under the Act does not normally become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),²³ the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that the proposed rule change does not significantly affect the protection of investors or the public interest and will benefit investors and

¹⁸ 15 U.S.C. 78s(b)(3)(A).

¹⁹ 17 CFR 240.19b-4(f).

²⁰ 15 U.S.C. 78s(b)(3)(A)(iii).

²¹ 17 CFR 240.19b-4(f)(6). 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 Commission has waived the pre-filing requirement.

²² 17 CFR 240.19b-4(f)(6).

²³ 17 CFR 240.19b-4(f)(6)(iii).

¹⁵ 15 U.S.C. 78f(b).

¹⁶ 15 U.S.C. 78f(b)(5).

¹⁷ *Id.*

the public interest because the proposal will provide the Exchange with operational flexibility to ensure orderly opening auctions for newly listed securities that have not been listed on a national securities exchange immediately prior to the initial pricing. The Exchange further states that by exercising its discretion to extend the Quote-Only Period during initial pricings, the Exchange will be able to allow additional time for market participants to assess pricing information, submit or modify orders, and ensure that the opening price is established through a fair and transparent process. The Exchange believes that this discretionary authority is particularly important for securities without prior exchange trading history, where price discovery may require additional time and there is no reference price from prior trading activity.

The Commission believes that waiver of the operative delay could benefit investors by allowing the Exchange additional flexibility to offer more time in connection with initial pricing for securities with no prior exchange listing history. In addition, the proposal does not present any unique or novel regulatory issues because similar functionality is currently in place on other national securities exchanges. Therefore, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.²⁴

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule 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-CboeBZX-2025-167 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-CboeBZX-2025-167. 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 filing 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-CboeBZX-2025-167 and should be submitted on or before January 13, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁵

Sherry R. Haywood,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104442; File No. SR-NASDAQ-2025-105]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Discontinue the Good-Till-Cancelled Time-in-Force Order Attribute in Its Equities Market

December 18, 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 December 12, 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 discontinue the Good-Till-Cancelled Time-in-Force Order Attribute in its equities market.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/nasdaq/rulefilings>, and at the principal office of the Exchange.

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 discontinue the Time-in-Force of Good-Till-Cancelled from its equities market.

Participants who trade equities in the Exchange can choose among many Order Types.³ Participants can also choose to apply different Order Attributes to their Orders.⁴ One of those

³ The term "Order" means an instruction to trade a specified number of shares in a specified System Security submitted to the Nasdaq Market Center by a Participant. An "Order Type" is a standardized set of instructions associated with an Order that define how it will behave with respect to pricing, execution, and/or posting to the Nasdaq Book when submitted to Nasdaq. See Nasdaq Equity 1, Section 1(a)(7). The Nasdaq Book is a montage for quotes and orders that collects and ranks all quotes and orders submitted by Participants. See Nasdaq Equity 1, Section 1(a)(3)(A).

⁴ An "Order Attribute" is a further set of variable instructions that may be associated with an Order to further define how it will behave with respect to pricing, execution, and/or posting to the Nasdaq Book when submitted to Nasdaq. The available Order Types and Order Attributes, and the Order Attributes that may be associated with particular

²⁴ 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).

²⁵ 17 CFR 200.30-3(a)(12), (59).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

Order Attributes is Time-in-Force (“TIF”).⁵ The TIF assigned to an Order is the period of time that the Nasdaq Market Center will hold the Order for potential execution. Participants specify an Order’s TIF by designating a time at which the Order will become active and a time at which the Order will cease to be active.⁶ Among the times available for Order deactivation is one year after Order entry.⁷

An Order that is designated to deactivate one year after entry may be referred to as a “Good-till-Cancelled” or “GTC” Order. If a GTC Order is designated as eligible for execution during Market Hours⁸ only, it may be referred to as having a Time in Force of “Market Hours Good-till-Cancelled” or “MGTC.”⁹ If a GTC Order is designated as eligible for execution during System Hours,¹⁰ it may be referred to as having a Time in Force of “System Hours Good-till-Cancelled” or “SGTC.”¹¹ Therefore, both in the Exchange’s rules and in this filing, references to the TIF of GTC include both the TIF of MGTC and the TIF of SGTC.

The Exchange proposes to discontinue the availability of the GTC TIF on its equities market. In order to do so, the Exchange proposes to modify Nasdaq Equity 4, Rule 4703(a) to delete “one year after entry” from the list of available times for deactivating an Order. The Exchange also proposes to modify Nasdaq Equity 4, Rule 4703(a)(3), which contains the definition of the GTC TIF, by deleting it in its entirety and reserving that rule number.

In order to remove references elsewhere in its rulebook to the GTC TIF, the Exchange proposes to remove a reference to GTC Orders in the listing standards for Exchange-Traded Managed Fund Shares (“NextShares”). Specifically, Nasdaq Rule 5745(b)(6)(B) currently specifies that the TIF of GTC

(and, by implication, MGTC and SGTC) is not applicable to Orders for NextShares. Given that the Exchange is removing the TIF of GTC from its Equity Rules, the Exchange proposes to eliminate the reference to GTC in this listing rule, as that reference would be obsolete. Consistent with this change, the Exchange also proposes to redesignate Rule 5745(b)(6)(A) as Rule 5745(b)(6), and to rephrase the rule to reflect that there is now only one exception to the Order Attributes applicable to NextShares.

The Exchange also proposes to make the following conforming changes to its Equity Rules, to delete all other references to GTC Orders:

- Nasdaq Equity 4, Rule 4702(b)(7)(B) specifies that a Market Maker Peg Order may not have a TIF of GTC. The Exchange proposes to remove this reference to GTC.

- Nasdaq Equity 4, Rule 4752 concerns the Exchange’s opening process:

- Rule 4752(a)(10) includes in the definition of Market Hours Orders those that have a TIF of MGTC. The Exchange proposes to remove this reference to MGTC.

- Rule 4752(a)(11) includes in the definition of Open Eligible Interest any quotation or any order that may be entered into the system and designated with a TIF of SGTC. The Exchange proposes to remove this reference to SGTC.

- Nasdaq Equity 4, Rule 4754 concerns the Nasdaq Closing Cross. Rule 4754(a)(1) defines Close Eligible Interest to mean any quotation or any order that may be entered into the system and designated with a TIF of SGTC or MGTC, among others. The Exchange proposes to remove this reference to SGTC and MGTC.

- Nasdaq Equity 4, Rule 4761 concerns procedures in response to issuer corporate actions, including any dividend (whether payable in cash or securities or both), payment, distribution, forward or reverse stock split, symbol change, or change in primary listing venue. Rule 4761(b) contains only such procedures that are specific to Orders with a TIF of GTC. Therefore, the Exchange proposes to remove Rule 4761(b) in its entirety.

Consistent with this change, the Exchange proposes to redesignate Rule 4761(a) as Rule 4761, and to remove the introductory “Except as provided below,” introductory phrase to that rule.

- Nasdaq Equity 6, Section 5 sets out the risk settings that the Exchange offers to a Participant’s activities on the Exchange. Section 5(c) concerns Cancel-on-Disconnect Control. This optional

control allows a Participant, when it experiences a disruption in its connection to the Exchange, to immediately cancel all pending Exchange Orders except GTC Orders, among others. The Exchange proposes to remove this reference to GTC Orders.

- Nasdaq Equity 9, Section 1 concerns the adjustment of open orders. Section 1(d) defines “open order” as an order to buy or an open stop order to sell, including but not limited to, “good ‘til cancelled” orders, among others. The Exchange proposes to remove this reference to “good ‘til cancelled.”

Starting on the day that the Exchange discontinues the GTC TIF Order Attribute, any new GTC Orders sent to the Exchange will be rejected. Any GTC Orders remaining on the Nasdaq Book at the close of the trading day immediately preceding the discontinuation of the GTC TIF Order Attribute will be cancelled by the Exchange. The discontinuation of the GTC TIF Order Attribute will become operative in the first quarter of 2026. The Exchange currently intends to discontinue GTC Orders on February 2, 2026. Therefore, any GTC Orders remaining on the Nasdaq Book at the close of trading on January 30, 2026, would be cancelled by the Exchange.¹² If the Exchange were to postpone this February 2, 2026, discontinuation date to a later date in the first quarter of 2026, the new discontinuation date would be communicated by the Exchange through an Equity Trader Alert.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,¹³ in general, and furthers the objectives of Section 6(b)(5) of the Act,¹⁴ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

It is consistent with the Act for the Exchange to modify the Order Attributes available on equities orders on the Exchange. Nasdaq has found that very few Participants avail themselves of the GTC TIF. Retaining this functionality

Order Types, are described in Equity 4, Rules 4702 and 4703. One or more Order Attributes may be assigned to a single Order; provided, however, that if the use of multiple Order Attributes would provide contradictory instructions to an Order, the System will reject the Order or remove non-conforming Order Attributes. *See id.*

⁵ *See* Nasdaq Equity 4, Rule 4703(a).

⁶ *See id.*

⁷ *See id.*

⁸ Market Hours means the period of time beginning at 9:30 a.m. ET and ending at 4:00 p.m. ET (or such earlier time as may be designated by Nasdaq on a day when Nasdaq closes early). *See* Nasdaq Equity 1, Section 1(a)(9).

⁹ *See* Nasdaq Equity 4, Rule 4703(a)(3).

¹⁰ System Hours means the period of time beginning at 4:00 a.m. ET and ending at 8:00 p.m. ET (or such earlier time as may be designated by Nasdaq on a day when Nasdaq closes early). *See* Nasdaq Equity 1, Section 1(a)(9).

¹¹ *See* Nasdaq Equity 4, Rule 4703(a)(3).

¹² *See* Nasdaq Equity Trader Alert #2025–83, “Nasdaq to Decommission Good-Till-Cancelled (GTC) Orders” (Oct. 24, 2025), available at <https://www.nasdaqtrader.com/TraderNews.aspx?id=ETA2025-83>; Nasdaq Equity Trader Alert #2025–97, “UPDATE IN TIMING: Nasdaq to Decommission Good-Till-Cancelled (GTC) Orders” (Dec. 3, 2025), available at <https://www.nasdaqtrader.com/TraderNews.aspx?id=ETA2025-97>.

¹³ 15 U.S.C. 78f(b).

¹⁴ 15 U.S.C. 78f(b)(5).

adds complexity to the Exchange's rulebook that outweighs its utility to Participants. Discontinuing this disused functionality will 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 streamlining the TIFs offered on the Exchange.

It is also consistent with the Act to delete all references GTC Orders found in the Exchange's listing rules and Equity Rules. Removing this now-obsolete rule text will 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 avoiding any possible confusion as to the discontinuation of the GTC TIF functionality.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In this regard, proposed changes that streamline the Order Attributes available on the Exchange are pro-competitive because they bolster the efficiency, functionality, and overall attractiveness of the Exchange in an absolute sense and relative to its peers. Moreover, the proposed changes will not unduly burden intra-market competition among various Exchange participants. Nasdaq has observed that very few Participants currently avail themselves of the GTC TIF, so that it is no longer worthwhile for the Exchange to retain this functionality and its attendant complexity. The Exchange would continue to offer Participants many other TIF options to help them achieve their trading objectives. Furthermore, if there are Participants who are dissatisfied with the proposal, they are free to shift their order flow to competing venues that may offer them order handling functionality that better suits their trading objectives.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public

interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁵ and subparagraph (f)(6) of Rule 19b-4 thereunder.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. 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-2025-105 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-2025-105. 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 filing 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

¹⁵ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁶ 17 CFR 240.19b-4(f)(6). 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.

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-2025-105 and should be submitted on or before January 13, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁷

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-23667 Filed 12-22-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104457; File No. SR-SAPPHIRE-2025-40]

Self-Regulatory Organizations; MIAX Sapphire, LLC; Notice of Filing of a Proposed Rule Change To Amend Exchange Rule 516, Order Types, To Remove the Definition of a Route to Floor Order

December 18, 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 December 5, 2025, MIAX Sapphire, LLC ("MIAX Sapphire" or "Exchange") filed with the Securities and Exchange Commission ("Commission") a 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 Exchange Rule 516 to remove the definition of Route to Floor Order.

The text of the proposed rule change is available on the Exchange's website at <https://www.miaxglobal.com/markets/us-options/miax-sapphire/rule-filings>, and at the Exchange's principal office.

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

¹⁷ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. 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

On July 15, 2024, the U.S. Securities and Exchange Commission (the "Commission") approved the Exchange's Form 1 application to register as a national securities exchange under Section 6 of the Exchange Act.³ At that time, the Exchange adopted its Rulebook which established rules for both the electronic market and the physical Trading Floor,⁴ even though the physical Trading Floor⁵ was slated to launch several months following the launch of the electronic market.⁶ Included in the Rulebook was Rule 516, Order Types, which established a "Route to Floor Order" order type, among other order types. At the time the Exchange adopted Rule 516 (July 15, 2024), the Exchange believed that such an order type might be desired by Members once the Trading Floor actually launched. However, to date, there has been no such Member interest to implement and support such order type. Accordingly, since this order type was never built in the Exchange's

System⁷ or implemented on the Exchange, and since the Exchange does not propose to build and implement this order type in the future, the Exchange proposes to remove this order type from the Exchange's Rulebook. To the extent that the Exchange changes its opinion and desires to implement such an order type in the future, the Exchange will file a separate rule change with the Commission under Rule 19b-4.

Proposal To Remove the Definition of Route to Floor Order

The Exchange proposes to amend Exchange Rule 516 to remove the definition of Route to Floor Order. Currently, Exchange Rule 516(k) provides that, "[a] Route to Floor order is an order that is routed to a designated Floor Broker⁸ on the Exchange's Trading Floor. An order routed to the Trading Floor is handled in accordance with Rule 2040." The Exchange notes that Route to Floor orders have never been implemented and are not currently in use. Additionally, the Exchange has no plans to implement this order type and now proposes to remove paragraph (k) of Rule 516 in its entirety. The purpose of the proposed change is to remove an unused order type from the Exchange's Rulebook to provide greater clarity to Members⁹ and the public regarding the Exchange's offerings and functionality.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,¹⁰ in general, and furthers the objectives of Section 6(b)(5) of the Act,¹¹ in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to

remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Specifically, the Exchange believes that the proposed rule change will provide greater clarity to Members and the public regarding the Exchange's Rulebook by removing the description of an order type that was not implemented for use on the Exchange, thereby providing accuracy and consistency within the Exchange's Rulebook.

The Exchange believes that the proposed rule change also furthers the objectives of Section 6(b)(5) of the Act.¹² In particular, that it is designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. The Exchange believes the proposed change promotes 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 because the proposed rule change will provide greater clarity to Members and the public regarding the Exchange's Rulebook by removing the description of an order type which was not implemented for use on the Exchange, thereby removing any inconsistency between the Exchange's Rulebook and its System. It is in the public interest for the Exchange's Rulebook to be accurate and concise so as to eliminate the potential for confusion.

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.

Intramarket Competition

The Exchange believes that the proposed rule change does not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act as the order type was never implemented for use on the Exchange, therefore removal of the description of the order type from the Rulebook is benign. The proposed rule change is not

³ See Securities Exchange Act Release No. 100539 (July 15, 2024), 89 FR 58848 (July 19, 2024) (File No. 10-240) (order approving application of MIAX Sapphire, LLC for registration as a national securities exchange). (Exhibit B) (establishing rules for the physical Trading Floor).

⁴ The term "Trading Floor" or "Floor" means the physical trading floor of the Exchange located in Miami, Florida. The Trading Floor shall consist of one "Crowd Area" or "Pit" where Floor Participants will be located and option contracts will be traded. The Crowd Area or Pit shall be marked with specific visible boundaries on the Trading Floor, as determined by the Exchange. A Floor Broker must represent all orders in an "open outcry" fashion in the Crowd Area. See Exchange Rule 100.

⁵ Physical trading began on the MIAX Sapphire Trading Floor on September 12, 2025. See MIAX Press Release, Miami International Holdings Launches Next-Generation Options Trading Floor in Miami, available online at https://www.miaxglobal.com/sites/default/files/press_release-files/MIAX_Press_Release_09162025.pdf.

⁶ Electronic trading began on MIAX Sapphire on August 12, 2024. See MIAX Press Release, Miami International Holdings Announces Successful Launch of MIAX Sapphire Options Exchange, available online at https://www.miaxglobal.com/sites/default/files/press_release-files/MIAX_Press_Release_08132024.pdf.

⁷ The term "System" means the automated trading system used by the Exchange for the trading of securities. See Exchange Rule 100.

⁸ A Floor Broker is an individual who is registered with the Exchange for the purpose, while on the Trading Floor, of accepting and handling options orders. A floor Broker must be registered as a Floor Participant prior to registering as a Floor Broker. A Floor Broker may take into his own account, and subsequently liquidate, any position that results from an error made while attempting to execute, as Floor Broker, an order. See Exchange Rule 2015.

⁹ The term "Member" means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed "members" under the Exchange Act. See Exchange Rule 100.

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(5).

¹² 15 U.S.C. 78f(b)(5).

intended to address any competitive issue but rather is concerned solely with ensuring the Exchange's Rulebook accurately reflects functionality currently in place on the Exchange.

Intermarket Competition

The Exchange believes the proposed rule change does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address any competitive issue but rather is concerned solely with updating the Exchange's Rulebook to provide accuracy and consistency regarding functionality offered by the Exchange and eliminate the potential for confusion.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act¹³ and Rule 19b-4(f)(6)¹⁴ thereunder. Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁵ and Rule 19b-4(f)(6)¹⁶ thereunder.

A proposed rule change filed under Rule 19b-4(f)(6)¹⁷ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),¹⁸ the Commission may designate a shorter time if such action is consistent with the protection

of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, because it will allow the Exchange to immediately remove the description of an order type that was never implemented for use on the Exchange from the Exchange's Rulebook, which will provide greater accuracy, clarity and consistency to Members and the public regarding the Exchange's Rulebook. Accordingly, the Commission designates the proposed rule change to be operative upon filing.¹⁹

At any time within 60 days of the filing of this proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-SAPPHIRE-2025-40 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-SAPPHIRE-2025-40. 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 filing also will be available for inspection and copying at the principal office of the

¹⁹ For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

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-SAPPHIRE-2025-40 and should be submitted on or before January 13, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-23656 Filed 12-22-25; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104452; File No. SR-PHLX-2025-70]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend PHLX Equity 6, Section 4 (Exchange Sharing of PSX Participant Risk Settings) To Permit the Allocation of Responsibility to Clearing Members

December 18, 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 December 10, 2025, Nasdaq PHLX LLC ("PHLX" 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 PHLX Equity 6, Section 4 (Exchange Sharing of PSX Participant Risk Settings) to permit the allocation of responsibility to clearing members, and to make some technical changes to that rule.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/PHLX/rulefilings>, and at the principal office of the Exchange.

²⁰ 17 CFR 200.30-3(a)(12) and (59).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

¹³ 15 U.S.C. 78s(b)(3)(A).

¹⁴ 17 CFR 240.19b-4(f)(6).

¹⁵ 15 U.S.C. 78s(b)(3)(A).

¹⁶ 17 CFR 240.19b-4(f)(6). 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, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹⁷ 17 CFR 240.19b-4(f)(6).

¹⁸ 17 CFR 240.19b-4(f)(6)(iii).

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 PHLX Equity 6, Section 4 to permit the allocation of responsibility to clearing members. Specifically, the Exchange proposes to add a new Section 4(b) (Clearing Member Designation) to allow a PSX Participant that does not self-clear to allocate responsibility for establishing and adjusting its risk levels to a clearing member that clears transactions on behalf of the PSX Participant.³ A clearing member guarantees transactions executed on the Exchange for PSX Participants with whom it has entered into a clearing arrangement, and therefore bears the risk associated with those transactions. Because a clearing member bears the risk on behalf of its associated PSX Participant, the Exchange believes that it is appropriate for the clearing member to have knowledge of what risk settings the PSX Participant may utilize within the Exchange's trading system, as well as the option to set and adjust the risk levels. Therefore, the Exchange proposes to make a PSX Participant's risk settings in PHLX Equity 6, Section 5 available to a clearing member, as well as the option to set and adjust the risk levels, if authorized by a PSX Participant.

For clarification, the Exchange does not guarantee that these risk controls will be sufficiently comprehensive to meet all of a PSX Participant's needs, nor are the controls designed to be the sole means of risk management, and using these controls will not necessarily meet a PSX Participant's obligations required by Exchange or federal rules—including, without limitation, Rule

15c3–5 under the Act⁴ (“Rule 15c3–5”). Use of the Exchange's risk settings in PHLX Equity 6, Section 5 will not automatically constitute compliance with Exchange or federal rules, and the responsibility for compliance with all Exchange and federal rules remains with the PSX Participant.⁵

If a PSX Participant chooses to designate responsibility to a clearing member, the PSX Participant may view any risk levels established by the clearing member pursuant to proposed PHLX Equity 6, Section 4(b). Even if a clearing member is designated, a PSX Participant will continue to be notified by the Exchange of any action taken regarding its trading activity. A PSX Participant may revoke the responsibility it has allocated to a clearing member at any time.

The Exchange also proposes labeling current rule PHLX Equity 6, Section 4(a) as PHLX Equity 6, Section 4(a) (Sharing Risk Settings). Additionally, the Exchange proposes to make a technical correction to PHLX Equity 6, Section 4(a). That rule currently refers to “the commentary below,” but the rule has no associated commentary. What happened is that in 2021, as part of a major rulebook reorganization effort, the Exchange redesignated PSX Rule 3215 as PHLX Equity 6, Section 4 and Section 5.⁶ The text of PSX Rule 3215, minus its commentary, was redesignated as PHLX Equity 6, Section 4. Meanwhile, the commentary to PSX Rule 3215 was redesignated as PHLX Equity 6, Section 5. Therefore, the Exchange proposes substituting the reference to “the commentary below” in PHLX Equity 6, Section 4(a) with a reference to PHLX Equity 6, Section 5. The substance of the newly labeled and corrected PHLX Equity 6, Section 4(a) remains unchanged.

The Exchange will announce the implementation date of the change described in this filing in an Equity Trader Alert at least 30 days prior to implementation. At present, the Exchange expects that the functionality described in this filing will be ready for

implementation in the first quarter of 2026, although that time frame is subject to change.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁷ in general, and furthers the objectives of Section 6(b)(5) of the Act,⁸ in particular, 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.

As a preliminary matter, the Exchange notes that this proposal is not novel. Earlier this year The Nasdaq Stock Market LLC made a parallel change to its rulebook.⁹ The language of Nasdaq Equity 6, Section 4(b) is substantively identical to the new rule text proposed by the Exchange in the present filing.¹⁰

The Exchange believes that the proposed amendment to PHLX Equity 6, Section 4 would provide clearing members, who have assumed certain risks of PSX Participants, greater control over risk tolerance and exposure on behalf of their correspondent PSX Participant, while helping to ensure that both the PSX Participant and its clearing member are aware of developing issues.

A clearing member guarantees transactions executed on Nasdaq for members with whom it has entered into a clearing arrangement, and therefore bears the risk associated with those transactions. The Exchange therefore believes that it is appropriate for a clearing member to have knowledge of what risk settings a PSX Participant may utilize within the Exchange's trading system, as well as the option to set and

⁷ 15 U.S.C. 78f(b).

⁸ 15 U.S.C. 78f(b)(5).

⁹ See Securities Exchange Act Release No. 103211 (June 9, 2025), 90 FR 25095 (June 13, 2025) (File No. SR–NASDAQ–2025–043) (Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend Equity 6, Section 4 (Exchange Sharing of Participant Risk Settings) to Permit the Allocation of Responsibility to Clearing Members) (“Nasdaq Filing”).

¹⁰ As adopted in the Nasdaq Filing, this Nasdaq rule reads as follows: “Clearing Member Designation. A Participant that does not self-clear may allocate the responsibility for establishing and adjusting the risk levels identified in Equity 6, Section 5 to a clearing member that clears transactions on behalf of the Participant, if designated in a manner prescribed by the Exchange. A Participant that chooses to allocate responsibility to its clearing member may view any risk levels established by the clearing member pursuant to this Rule, and will be notified of any action taken by the Exchange with respect to its trading activity. A Participant may revoke responsibility allocated to its clearing member pursuant to this paragraph at any time, if designated in a manner prescribed by the Exchange.”

⁴ 17 CFR 240.15c3–5.

⁵ See SEC Division of Trading and Markets, Responses to Frequently Asked Questions Concerning Risk Management Controls for Brokers or Dealers with Market Access (Apr. 15, 2014), available at <https://www.sec.gov/rules-regulations/staff-guidance/trading-markets-frequently-asked-questions/divisionsmarketregfaq-0>.

⁶ See Securities Exchange Act Release No. 91058 (Feb. 4, 2021), 86 FR 8966 (Feb. 10, 2021), at 8969 (File No. SR–Phlx–2021–04) (Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Relocate Its PSX Equity and General Rules From Its Current Rulebook Into Its New Rulebook Shell and Make Other Changes to the Phlx Rules).

³ The term “PSX Participant” has the meaning set forth in PHLX Equity 1, Section 1(c).

adjust the risk levels. The proposal will permit a clearing member with whom a PSX Participant has entered into a clearing arrangement to better monitor and manage the potential risks assumed by the clearing member, thereby providing the clearing member with greater control and flexibility over setting its own risk tolerance and exposure and aiding the clearing member in complying with the requirements of the Act.

The Exchange also believes that the proposed amendment will assist PSX Participants and clearing members in managing their financial exposure which, in turn, could enhance the integrity of trading on the securities markets and help to ensure the stability of the financial system. Moreover, a PSX Participant may revoke responsibility allocated to its clearing member at any time.

The Exchange believes that the proposed rule change does not unfairly discriminate among PSX Participants because the use of the risk settings under PHLX Equity 6, Section 5 would be available to all PSX Participants and their clearing members, if authorized. In addition, because all orders on the Exchange pass through the Exchange's risk checks, there would be no difference in the latency experienced by PSX Participants who have opted to use the risk settings versus those who have not opted to use them.¹¹

Additionally, the Exchange believes that relabeling PHLX Equity 6, Section 4(a) as PHLX Equity 6, Section 4(a) (Sharing Risk Settings), and correcting the reference to the "commentary" in that rule to its current location in PHLX Equity 6, Section 5, are consistent with the Act because they make PHLX Equity 6, Section 4 easier to understand and navigate, which should aid all PSX Participants in following the rules of the Exchange.

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 designed to provide PSX Participants and their clearing members with additional means to monitor and control risk. The proposed rule may increase confidence in the proper functioning of the markets and contribute to additional competition among trading venues and

broker-dealers. Rather than impede competition, the proposal is designed to facilitate more robust risk management by PSX Participants and clearing members, which, in turn, could enhance the integrity of trading on the securities markets and help to ensure the stability of the financial system. Additionally, the changes to PHLX Equity 6, Section 4(a) will not have any impact on competition, as they are merely technical in nature.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act¹² and subparagraph (f)(6) of Rule 19b-4 thereunder.¹³

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule 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:

¹² 15 U.S.C. 78s(b)(3)(A)(iii).

¹³ 17 CFR 240.19b-4(f)(6). 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.

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-PHLX-2025-70 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-PHLX-2025-70. 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 filing 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-PHLX-2025-70 and should be submitted on or before January 13, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁴

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-23658 Filed 12-22-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235-0554]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension: Rule 6a-4, Form 1-N

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 (SEC or "Commission") is soliciting comments on the proposed collection of information provided for in Rule 6a-4

¹¹ All Exchange orders pass through basic risk checks regardless of whether a PSX Participant opts into a risk setting.

¹⁴ 17 CFR 200.30-3(a)(12).

and Form 1–N, summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval. The Code of Federal Regulation citation to this collection of information is 17 CFR 240.6a–4 and 17 CFR 249.10 under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (the “Act”).

Section 6 of the Act¹ sets out a framework for the registration and regulation of national securities exchanges. Under the Commodity Futures Modernization Act of 2000, a futures market may trade security futures products by registering as a national securities exchange. Rule 6a–4² sets forth these registration procedures and directs futures markets to submit a notice registration on Form 1–N.³ Form 1–N calls for information regarding how the futures market operates, its rules and procedures, corporate governance, its criteria for membership, its subsidiaries and affiliates, and the security futures products it intends to trade. Rule 6a–4 also requires entities that have submitted an initial Form 1–N to file: (1) amendments to Form 1–N in the event of material changes to the information provided in the initial Form 1–N; (2) periodic updates of certain information provided in the initial Form 1–N; (3) certain information that is provided to the futures market’s members; and (4) a monthly report summarizing the futures market’s trading of security futures products. The information required to be filed with the Commission pursuant to Rule 6a–4 is designed to enable the Commission to carry out its statutorily mandated oversight functions and to ensure that registered and exempt exchanges continue to be in compliance with the Act.

The respondents to the collection of information are futures markets.

The Commission estimates that the total annual burden for all respondents to provide periodic amendments to keep the Form 1–N accurate and up to date as required under Rule 6a–4(b)(1) would be 45 hours (15 hours/respondent per year × 3 respondents) and \$327 of miscellaneous clerical expenses. The Commission estimates that the total annual burden for all respondents to provide annual amendments under Rule 6a–4(b)(3) would be 45 hours (15 hours/respondent/year × 3 respondents) and \$327 of miscellaneous clerical expenses. The Commission estimates that the total annual burden for all respondents to

provide three-year amendments under Rule 6a–4(b)(4) would be 20 hours (20 hours/respondent × 1 respondents per year) and \$145 in miscellaneous clerical expenses. The Commission estimates that the total annual burden for the filing of the supplemental information and the monthly reports required under Rule 6a–4(c) would be 18 hours (6 hours/respondent per year × 3 respondents) and \$196.20 of miscellaneous clerical expenses. Thus, the Commission estimates the total annual burden for complying with Rule 6a–4 is 128 hours and \$995.20 in miscellaneous clerical expenses.

Compliance with Rule 6a–4 is mandatory. Information received in response to Rule 6a–4 shall not be kept confidential; the information collected is public information.

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.

Please direct your written comments on this 60-Day Collection Notice to Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Tanya Ruttenberg via email to PaperworkReductionAct@sec.gov by February 23, 2026. There will be a second opportunity to comment on this SEC request following the **Federal Register** publishing a 30-Day Submission Notice.

Dated: December 19, 2025.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025–23737 Filed 12–22–25; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. PA–63; File No. S7–2025–05]

Privacy Act of 1974; System of Records

AGENCY: Securities and Exchange Commission.

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act of 1974 and Office of Management and Budget (“OMB”) Circular A–108, the Securities and Exchange Commission (“Commission” or “SEC”) is proposing a modification to its system of records notice (SORN), SEC–06, SEC’s Financial and Acquisition Management System (“SEC–06”). This proposed update introduces a new routine use to comply with Executive Order (E.O.) 14249, Protecting America’s Bank Account Against Fraud, Waste, and Abuse. The change supports enhanced efforts to safeguard federal financial systems and ensure responsible stewardship of public funds. The modified SORN does not change the categories of individuals, the record collection process, the authorities, or the purpose of collection. It also does not affect individuals’ rights to access or amend their records under the Privacy Act.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this notice is effective upon publication, subject to a 30-day period in which to comment on the routine use, described below. Comments may be submitted on or before January 22, 2026.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the SEC’s internet comment form (<http://www.sec.gov/rules/other.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number S7–2025–05 on the subject line.

Paper Comments

- Send paper comments to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number S7–2025–05. 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 of submission. The Commission will post all comments on

¹ 15 U.S.C. 78f.

² 17 CFR 240.6a–4.

³ 17 CFR 249.10.

the Commission's website (<http://www.sec.gov/rules/other.shtml>). 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.

FOR FURTHER INFORMATION CONTACT:

Ronnette McDaniel, Branch Chief, Privacy and Information Assurance Branch, 202-551-7200 or privacyhelp@sec.gov.

SUPPLEMENTARY INFORMATION: On March 25, 2025, Executive Order 14249 was issued to modernize federal financial oversight, strengthen controls over U.S. General Fund transactions, and combat fraud, waste, and abuse. It consolidates payment systems, mandates electronic transactions, and enhances accountability in government financial operations. The E.O. requires federal agencies to overhaul their financial practices by modernizing payment systems, instituting robust pre-certification for all payment transactions, and increasing data sharing with the Department of Treasury ("Treasury") to prevent fraud and improper payments. In support of this effort, OMB Memorandum M-25-32 requires agencies to review and update their System of Records Notices (SORNs) under the Privacy Act, as relevant and necessary, to include a new routine use clause that allows for the sharing of records with the Treasury to review payment and award eligibility through the Do Not Pay Working System. To ensure compliance with the review and update requirements outlined in Executive Order 14249 and OMB Memorandum M-25-32, the Commission conducted a comprehensive review of its SORN inventory to identify and implement necessary modifications. The proposed modification to add a new routine use to the identified SORN, SEC-06, aligns with the Privacy Act and incorporates the new requirements introduced by OMB Memorandum M-25-32. Accordingly, the Commission is proposing to modify SEC-06 to add new routine use number 14 as follows:

"To the U.S. Department of the Treasury when disclosure of the information is relevant to review payment and award eligibility through the Do Not Pay Working System for the purposes of identifying, preventing, or recouping improper payments to an applicant for, or recipient of, Federal funds, including funds disbursed by a state (meaning a state of the United

States, the District of Columbia, a territory or possession of the United States, or a federally recognized Indian tribe) in a state-administered, federally funded program."

The remaining routine uses were previously published.

In accordance with 5 U.S.C. 552a(r), we have provided a report to OMB and Congress on the proposal to modify the system of records.

SYSTEM NAME AND NUMBER:

SEC-06: SEC's Financial and Acquisition Management System.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

1. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549. Files may also be maintained in the Commission's Regional Offices.

2. Federal Aviation Administration, Mike Monroney Aeronautical Center, AMZ-740, 6500 S. MacArthur Blvd., Headquarters Bldg. 1, Oklahoma City, OK 73169.

SYSTEM MANAGER(S):

Chief Financial Officer, Office of Financial Management, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-6041.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

31 U.S.C. 3501, *et seq.* and 31 U.S.C. 7701(c). Where the employee identification number is the social security number, collection of this information is authorized by Executive Order 9397.

PURPOSE(S) OF THE SYSTEM:

Serves as the core financial system and integrates program, financial and budgetary information. Records are collected to ensure that all obligations and expenditures other than those in the pay and leave system are in conformance with laws, existing rules and regulations, and good business practice, and to maintain subsidiary records at the proper account and/or organizational level where responsibility for control of costs exists.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

SEC employees, contractors, vendors, interns, customers and members of the public.

CATEGORIES OF RECORDS IN THE SYSTEM:

Employee personnel information: Limited to SEC employees, and includes name, address, Social Security number (SSN); Business-related information:

Limited to contractors/vendors and customers, and includes name of the company/agency, point of contact, telephone number, mailing address, email address, contract number, CAGE code, vendor number (system unique identifier), DUNS number, and TIN, which could be a SSN in the case of individuals set up as sole proprietors; and financial information, this includes financial institution name, lockbox number, routing transit number, deposit account number, account type, debts (e.g., unpaid bills/invoices, overpayments, etc.), and remittance address.

RECORD SOURCE CATEGORIES:

The information maintained in Department of Transportation (DOT)/Enterprise Service Center (ESC): Purchase orders, vouchers, invoices, contracts, and electronic records; Department of Interior (DOI)/Federal Personnel Payroll System (FPPS): travel applications, disgorgement information, or other paper records submitted by employees, vendors, and other sources, including claims filed by witnesses in SEC actions; Delphi-Prism: Fed Traveler, Department of the Interior (DOI) Payroll System, Bureau of Public Debt, and EDGAR Financial Management System (EFMS).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records; (2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. In any legal proceeding where the federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity, and the SEC has determined that information from this system of records is relevant and necessary to the litigation and compatible with the purpose for which the records were collected.

4. To a federal, state, local, tribal, foreign, or international agency, if necessary to obtain information relevant to the SEC's decision concerning the hiring or retention of an employee; the issuance of a security clearance; the letting of a contract; or the issuance of a license, grant, or other benefit.

5. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

6. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

7. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records must agree to comply with the provisions of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

8. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

9. To members of Congress or others charged with monitoring the work of the Commission or conducting records management inspections.

10. To a commercial contractor in connection with benefit programs administered by the contractor on the Commission's behalf, including, but not

limited to, supplemental health, dental, disability, life and other benefit programs.

11. To the OMB in connection with the review of private relief legislation as set forth in OMB Circular A-19 at any stage of the legislative coordination and clearance process as set forth in that circular.

12. To the Treasury or other appropriate agencies to provide appropriate audit documentation.

13. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

14. To the U.S. Department of the Treasury when disclosure of the information is relevant to review payment and award eligibility through the Do Not Pay Working System for the purposes of identifying, preventing, or recouping improper payments to an applicant for, or recipient of, Federal funds, including funds disbursed by a state (meaning a state of the United States, the District of Columbia, a territory or possession of the United States, or a federally recognized Indian tribe) in a state-administered, federally funded program.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records and data are stored in electronic media via a configuration of government servers. Physical records are maintained in hard-copy, paper format in secure filing cabinets, office spaces, and storage locations, including Federal Records Centers.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by a name of employee, social security number (SSN) for employees, SSN/Tax Identification Number (TIN) for vendors doing business with the SEC, Name for both employees and vendors, Central Index Key (CIK) (system unique) for both employees and vendors, DUNS/DUNS + 4.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which

time they will be retired or destroyed in accordance with records schedules of the United States Securities and Exchange Commission and as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: restricting access to authorized personnel who have a "need to know"; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may submit a request online at www.sec.gov or contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-2736.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be requested online at www.sec.gov or directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-2736.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 40 FR 39253 (August 27, 1975). Subsequent notices of revision can be found at the following citations:

—41 FR 5318 (February 5, 1976)
 —41 FR 11631 (March 19, 1976)
 —41 FR 41550 (September 22, 1976)
 —42 FR 36333 (July 14, 1977)
 —46 FR 63439 (December 31, 1981)
 —59 FR 27626 (May 27, 1994)
 —62 FR 47884 and 47885 (September 11, 1997)
 —63 FR 11938 (March 11, 1998)
 —77 FR 16569 (March 21, 2012)
 —85 FR 85440 (January 27, 2021)

By the Commission.

Dated: December 19, 2025.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025–23771 Filed 12–22–25; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–104444; File No. SR–NASDAQ–2025–102]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Enhance the Designated Liquidity Provider Program and Add a New Market Quality Supporter Program

December 18, 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 December 11, 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 (i) enhance the Designated Liquidity Provider (as defined below) program in Equity 7, Section 114(f), and (ii) add a new Market Quality Supporter (as defined

below) program in Equity 7, Section 114(g).

The text of the proposed rule change is available on the Exchange’s website at <https://listingcenter.nasdaq.com/rulebook/nasdaq/rulefilings>, and at the principal office of the Exchange.

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 purpose of the proposed rule change is to (i) enhance the Designated Liquidity Provider³ (“DLP”) program in Equity 7, Section 114(f), and (ii) add a new Market Quality Supporter⁴ (“MQS”) program in Equity 7, Section 114(g).

Together, these proposed changes are intended to create a more scalable, targeted, and effective market quality support structure for Nasdaq-listed exchange-traded products (“ETPs”).

The Exchange initially filed the proposed pricing changes on December 1, 2025 (SR–NASDAQ–2025–097). On December 11, 2025, the Exchange withdrew that filing and submitted this filing.

³ A “Designated Liquidity Provider” or “DLP” is a registered Nasdaq market maker for a Qualified Security that has committed to maintain minimum performance standards. A DLP shall be selected by Nasdaq based on factors including, but not limited to, experience with making markets in exchange-traded products, adequacy of capital, willingness to promote Nasdaq as a marketplace, issuer preference, operational capacity, support personnel, and history of adherence to Nasdaq rules and securities laws. Nasdaq may limit the number of DLPs in a security, or modify a previously established limit, upon prior written notice to members. See Equity 7, Section 114(f)(2).

⁴ As set out in proposed paragraph (g)(2) of Equity 7, Section 114, a “Market Quality Supporter” or “MQS” has committed to maintain minimum performance standards in Low Volume ETPs. An MQS shall be selected by Nasdaq based on factors including, but not limited to, experience with making markets in exchange-traded products, adequacy of capital, willingness to promote Nasdaq as a marketplace, issuer preference, operational capacity, support personnel, and history of adherence to Nasdaq rules and securities laws.

Background

Pursuant to Equity 7, Section 114(f), the Exchange currently maintains a DLP program that is designed to enhance liquidity and market quality in Nasdaq-listed ETPs by providing incentives to the DLP for a Qualified Security.⁵ The DLP program provides tiered rebates to qualifying DLPs based on a combination of performance criteria (*i.e.*, market quality metrics or “MQM”) and trading activity based on average daily volume (“ADV”) in the DLP’s assigned ETP. The MQMs are set out in paragraph (f)(4) of Equity 7, Section 114, and measure:⁶ (1) percentage of time at the national best bid (best offer) (“NBBO”), (2) percentage of time within 5 basis points of NBBO, (3) average notional depth within specified basis points of the NBBO, (4) average spread,⁷ and (5) auction quality.⁸ Primary DLPs may qualify for either a standard DLP rebate by meeting at least 4 of 5 standard MQMs in the assigned ETP or an enhanced DLP rebate by meeting all 5 enhanced MQMs, as specified in Equity 7, Section 114(f)(4). As set out in Section 114(f)(5), a Primary DLP that satisfies the MQMs in Section 114(f)(4) will be eligible to receive the rebates provided in paragraph (A) of Section 114(f)(5) in each of its assigned ETPs for which it qualified. For ETPs with higher ADV (*i.e.*, Tiers 1 and 2), eligible Primary DLPs receive the standard or enhanced rebate for which they qualified for each displayed share that adds liquidity in the ETP. For lower ADV ETPs (*i.e.*, Tiers 3–5), the Primary DLP receives fixed monthly payments for their standard or enhanced rebates, as applicable, which are in addition to any other rebate the Primary DLP is eligible for under Equity 7, Sections 114 and 118. Specifically, Nasdaq currently pays qualifying Primary DLPs in accordance with the following rebate schedule in Section 114(f)(5)(A):

⁵ Under this program, a security may be designated as a “Qualified Security” if it (1) is an ETP listed on Nasdaq pursuant to Rules 5704, 5705, 5710, 5711, 5713, 5715, 5720, 5735, 5745, 5750 or 5760, and (2) has at least one DLP. See Equity 7, Section 114(f)(1).

⁶ These MQMs are measured on average in the DLP’s assigned ETP during regular market hours, except for auction quality requirements that are measured each auction against the metrics. See Equity 7, Section 114(f)(4).

⁷ Average spread is the time weighted average spread in basis points when the DLP has a two-sided quote.

⁸ Auction quality is measured by auction price deviation from first reference price after 30 seconds before the market open (Opening) and 120 before the market close (Closing).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

Tiers	ADV	Standard rebate	Enhanced rebate
Tier 1	ETP with monthly ADV greater than 1 million in the prior month.	\$0.0034 per executed share	\$0.0036 per executed share.
Tier 2	ETP with monthly ADV between 250,001 and 1 million in the prior month.	\$0.0040 per executed share	\$0.0042 per executed share.
Tier 3	ETP with monthly ADV between 150,001 and 250,000 in the prior month.	\$200 per month	\$350 per month.
Tier 4	ETP with monthly ADV between 50,001 and 150,000 in the prior month.	\$225 per month	\$450 per month.
Tier 5	ETP with monthly ADV less than 50,001 in the prior month.	\$300 per month	\$500 per month.

Further, if two DLPs are assigned to a Nasdaq-listed ETP, one may be designated as the Secondary DLP, which may receive rebates if it meets 2 of the enhanced MQMs in Section 114(f)(4) (excluding the auction quality MQM).⁹ Section 114(f)(5)(A) sets forth the rebate schedule for Secondary DLPs. For ETPs with higher ADV (*i.e.*, Tiers 1 and 2), eligible Secondary DLPs receive an additional \$0.0003 per executed share that is in addition to any other rebate the Secondary DLP is eligible for under

Equity 7, Sections 114 and 118. For ETPs with lower ADV (*i.e.*, Tiers 3–5), eligible Secondary DLPs receive an additional \$150 per month that is in addition to any other rebate the Secondary DLP is eligible for under Equity 7, Sections 114 and 118.

Lastly, the DLP program also has an additional Tape C ETP incentive for Primary DLPs based on their quoting performance across their ETP assignments. As set forth in Section 114(f)(4), the Exchange currently

requires that the average time the Primary DLP is at the NBBO for each assigned ETP averages at least 20%, and the average liquidity provided by the Primary DLP for each assigned ETP averages at least 5% of the liquidity provided on Nasdaq in the respective ETP. Qualifying Primary DLPs are then provided incremental rebates for each displayed share that adds liquidity in a Tape C ETP in accordance with the following schedule in Section 114(f)(5)(B):

	Tier 1	Tier 2	Tier 3	Tier 4
Minimum Monthly Average Number of Assigned ETPs as a Primary DLP.	10	25	50	100.
Incremental Tape C ETP Rebate	\$0.0002 per executed share.	\$0.0003 per executed share.	\$0.0004 per executed share.	\$0.0005 per executed share.

Proposal 1: DLP Program

As discussed in detail below, the Exchange proposes to enhance the current DLP program in Equity 7, Section 114(f) by: (1) eliminating the distinction between Primary and Secondary DLPs, eliminating Secondary DLP rebates, and limiting the number of DLPs to one DLP per Qualified Security; (2) replacing the distinction between standard and enhanced MQMs (and associated rebates) with a single set of MQMs (and associated rebates); (3) adding a new “Low Volume”¹⁰ group framework; (4) replacing some of the current MQMs with more detailed MQMs; (5) increasing the fixed monthly DLP rebates for Tiers 3–5; (6) updating the qualifications, eligibility thresholds, and associated rebates for the additional Tape C ETP incentive; and (7) making non-substantive changes throughout proposed Section 114(f) to remove all references to “fees” as the Exchange would only provide incentives under the DLP Program and to add references to “stipends” to refer to the monthly

fixed payments the Exchange would provide to eligible DLPs.¹¹ With the proposed amendments, the Exchange is seeking to enhance market quality and encourage broader DLP participation, including in investment strategies that exhibit wider spreads and lower trading volume.

As described above, the DLP program currently provides separate rebates for eligible Primary and Secondary DLPs. Primary DLPs are also eligible for standard or enhanced rebates based on whether they meet the relevant standard or enhanced MQMs. The Exchange now proposes to remove the distinction between Primary and Secondary DLPs, and eliminate the Secondary DLP rebates (and associated qualifications) under Equity 7, Section 114(f)(4) and (5). The Exchange also proposes to eliminate the standard and enhanced rebates (and associated qualifications) under Equity 7, Section 114(f)(4) and (5). Under this proposal, and as further described below, any DLP may qualify for one set of tiered rebates if it meets

specified MQMs applicable to their assigned ETP.

The Exchange also proposes in Section 114(f) to limit the number of DLPs in a Qualified Security so that as proposed, there may only be one DLP per Qualified Security. This is to better align the rule text to current practice where issuers only have one DLP per Qualified Security. Accordingly, the Exchange will make corresponding changes in paragraphs (f)(1)(B) and (f)(2) to make clear that only one DLP will be assigned per Qualified Security. Specifically in the definition of Qualified Security in paragraph (f)(1)(B), the Exchange proposes to remove the reference to “at least” one DLP so that it will be clear the Qualified Security has only one DLP. Also in paragraph (f)(2), the Exchange proposes to remove the last sentence, which currently provides that Nasdaq may limit the number of DLPs in a security, or modify a previously established limit, upon prior written notice to members. This language will no longer be relevant once

⁹ The Secondary DLP is determined by using the same factors for DLPs in Section 114(f)(2), including, but not limited to, experience with making markets in exchange-traded products, adequacy of capital, willingness to promote Nasdaq as a marketplace, issuer preference, operational

capacity, support personnel, and history of adherence to Nasdaq rules and securities laws.

¹⁰ As discussed below, “Low Volume” will mean ETPs with a monthly ADV of 1 million shares or less in the prior month. This ADV volume threshold equates to the ADV volume threshold for Tiers 2–

5 under the current DLP rebate program in Equity 7, Section 114(f)(5)(A). The Exchange is not proposing to amend the DLP program’s ADV volume thresholds under this proposal.

¹¹ The term “rebates” would therefore refer to the incentives that are provided per executed share.

the Exchange limits the number of DLPs in a Qualified Security to just one.

The Exchange also proposes to make clear how the DLP program will interact with the MQS program by providing in paragraph (f) that a DLP that is designated as a MQS of a Qualified Security may also be eligible to receive the MQS stipend in proposed Section 114(g), provided that the DLP meets the Market Quality Metrics in the DLP program as specified in Section 114(f)(4)(B) as well as the Market Quality Metrics for the MQS program as specified in proposed Section 114(g).

In proposed Section 114(f)(4)(A), the Exchange proposes to add a new Low

Volume group framework. As used in the DLP program, the term “High Volume” ETPs will mean ETPs with a monthly ADV of more than 1 million shares in the prior month (*i.e.*, Tier 1). The term “Low Volume” ETPs will mean ETPs with a monthly ADV of 1 million shares or less in the prior month, which equates to the ADV volume threshold for Tiers 2–5 under the current DLP rebate program in Section 114(f)(5)(A). The Exchange will further segment Low Volume ETPs into Investment Strategy Groups A–C, which will be different ETP investment strategies segmented by their average

NBBO spread in basis points, over the prior two calendar years. The Exchange would look at the NBBO continuously throughout the regular trading hours of the day and take the average of the NBBO across all of those times. That average would be the NBBO for the day, which is then taken and averaged across two calendar years to determine the Investment Strategy group.

These Investment Strategy Groups will be checked by the Exchange each calendar year to ensure the investment strategy’s average NBBO spread remains within its respective Investment Strategy Group.

Investment strategy group	Average NBBO spread in basis points
A ¹²	15 or less.
B ¹³	16–28.
C ¹⁴	29 or more.

Group A includes ETP investment strategies that have relatively low trading volumes but exhibit relatively tighter NBBO spreads compared to Groups B and C, which include relatively low trading volume investment strategies with increasingly wider NBBO spreads. Each Nasdaq-listed ETP will be assigned an Investment Strategy Group, which will be publicly available and updated to

reflect any changes to the assigned group.¹⁵

As discussed in detail below, the Investment Strategy Groups will be used to tailor the MQMs that DLPs will need to meet in their assigned ETPs to qualify for DLP rebates. The proposed Investment Strategy Group framework is intended to more precisely calibrate the DLP incentives to the liquidity profile of the investment strategy that the DLP’s assigned ETP falls under. The proposed

framework is also intended to incentivize market makers to become DLPs in ETPs, particularly ETPs that have lower trading volume and are less liquid.

Proposed Section 114(f)(4)(B) will set forth the MQM thresholds that the DLP must meet based on which Investment Strategy Group or High Volume (*i.e.*, Tier 1) ETP¹⁶ they are assigned, as follows:

Market quality metrics	High volume ETPs	Investment strategy Group A ETPs	Investment strategy Group B ETPs	Investment strategy Group C ETPs
Time at the NBBO with a minimum notional size of \$5,000	40%	45%	45%	45%
Average Notional Depth within 25 basis points of the NBBO	\$75,000	\$40,000	\$30,000	\$20,000
Average Spread in basis points	25	35	60	100
Auction Reference Price Difference (Opening) of first reference price within 30 seconds prior to the market open must be within basis points	150	150	150	150
Auction Reference Price Difference (Closing) of first reference price within 120 seconds prior to the market close must be within basis points	50	50	50	50
Auction Spread in basis points with \$37,500 notional depth (Opening)	75	105	180	300
Auction Spread in basis points with \$75,000 notional depth (Closing)	25	35	60	100

The proposed MQMs are similar to the current MQMs except the Exchange is proposing to refine some of the existing MQMs (*e.g.*, adding that time at the NBBO must be with a minimum

notional size of \$5,000). The Exchange also proposes to delete the existing MQM that requires the DLP to be a certain percentage of time within 5 basis

points of the NBBO, and add the new auction spread MQMs described above.

To be eligible for the proposed DLP rebates and stipends in paragraph (5)(A) of Section 114(f), DLPs will need to

¹² Investment Strategy Group A will currently consist of the following investment strategies: government fixed income, North American or USD denominated developed market fixed income, developed market equities, and currencies.

¹³ Investment Strategy Group B will currently consist of the following investment strategies: micro- to small-cap developed market equities, multi asset strategies other than absolute returns,

commodities tracking, international fixed income, and derivatives.

¹⁴ Investment Strategy Group C will currently consist of the following investment strategies: emerging market equities, emerging market fixed income, multi asset absolute return strategies, commodities strategies and exchange-traded notes (“ETNs”).

¹⁵ The list of investment strategies in Investment Strategy Groups A–C will be publicly available on Nasdaq’s website and updated to ensure the investment strategy’s average NBBO spread remains within its respective Investment Strategy Group.

¹⁶ As currently set forth in Equity 7, Section 114(f)(5)(A), Tier 1 ETPs have a monthly ADV greater than 1 million in the prior month.

meet 5 of the 7 MQMs described above, including auction spread (both opening and closing),¹⁷ in the assigned ETP as measured by Nasdaq. The Exchange is requiring DLPs meet the two auction spread metrics because the opening and the closing auctions are important parts of the day as these auctions set the benchmark prices. The Exchange also wants to ensure that there is ample liquidity during this vital part of the trading day.

Proposed Section 114(f)(4)(B) will also provide that for leveraged and inverse ETPs, the average spread, auction spread, and auction reference

price difference metrics will be multiplied by the absolute value of the leverage factor of the ETP. Because leveraged and inverse ETPs often exhibit higher price volatility relative to standard, non-leveraged and non-inverse ETPs, the DLP is often taking on higher risk and costs to take on these products. Adjusting these MQMs by the absolute value of the ETP's leverage factor aligns the rebate structure with the DLP's cost of taking these products on. These MQMs will be measured on average in the assigned ETP during regular market hours, except for the auction price difference and auction

spread metrics that are measured at and directly before each auction, respectively, against the metrics and averaged for the monthly period.

Proposed Section 114(f)(4)(C) will provide the new qualifications for the additional Tape C ETP incentives for DLPs. Specifically, to be eligible for the rebates in proposed paragraph (5)(B) of Section 114(f), a DLP must meet the same average notional depth and average spread metrics as described above for proposed paragraph (4)(B) of Section 114(f). Specifically those metrics are as follows:

Market quality metrics	High volume ETPs	Investment strategy Group A ETPs	Investment strategy Group B ETPs	Investment strategy Group C ETPs
Average Notional Depth within 25 basis points of the NBBO	\$75,000	\$40,000	\$30,000	\$20,000
Average Spread in basis points	25	35	60	100

DLPs will need to meet the above additional Tape C incentive MQMs in order to be eligible for the additional Tape C incentives in paragraph (5)(B) of Section 114(f).

Proposed section 114(f)(5) will provide that a DLP that satisfies the MQMs above will be eligible to receive the rebates and stipends provided in paragraph (A) below in each of its assigned ETPs for which it qualified, and the rebates provided in paragraph (B) in any Tape C ETP that meets the criteria of paragraph (1)(A) above.¹⁸ As is the case today, rebates and stipends in paragraph (A) below will be in lieu of or in addition to, as specified, other rebates or fees provided under Equity 7, Sections 118 and 114. The rebates in paragraph (B) below will be in addition to other rebates or fees provided under Equity 7, Sections 118 and 114, including those in Section 114(f)(5)(A) (*i.e.*, the proposed DLP incentives) and Section 114(g) (*i.e.*, the proposed MQS stipend, as discussed below). The

Exchange also proposes that the DLP will automatically be eligible to receive the relevant rebate or stipend in one of the following scenarios: (1) for the month of December 2025; or (2) for the current month of a new DLP allocation of a symbol (*i.e.*, in the context of a listing transfer from another exchange or switching DLPs on a symbol). New launches will automatically get the Tier 5 incentive for the current month. The Exchange will not have trading volume data for a newly-launched ETP for its first month, so it is proposing to automatically provide the DLP of the newly-launched ETP with the base Tier 5 rebate in the first month. For listing transfers or DLP allocations, where there is trading volume data for these ETPs, that trading volume data would be applied to determine which Tier rebate or stipend the DLP would receive for the current month of the transfer or allocation. After the first month, the DLP will need to satisfy the MQMs relevant to their assigned ETP, as set

forth in proposed Section 114(f)(4). DLPs would likewise receive the applicable Tier rebate or stipend for the first month of the proposed incentive program (*i.e.*, December 2025) based on the relevant ETP trading volume data only because the Exchange seeks to encourage greater participation in the new program and allow DLPs to have adequate time to transition to the MQMs. After December 2025, DLPs will need to satisfy the MQMs relevant to their assigned ETP, as set forth in proposed Section 114(f)(4).

Proposed paragraph (A) of Section 114(f)(5) will set forth the amended DLP rebates and stipends. As discussed above, the Exchange is eliminating the distinction between standard and enhanced rebates, and removing the Secondary DLP rebates in paragraph (A). Instead, the Exchange will pay DLP rebates and stipends according to the following schedule:

Tiers	ADV	Rebate/stipend
Tier 1	ETP with monthly ADV greater than 1 million in the prior month	\$0.0034 per executed share.
Tier 2	ETP with monthly ADV between 250,001 and 1 million in the prior month	\$0.0040 per executed share.
Tier 3	ETP with monthly ADV between 150,001 and 250,000 in the prior month	\$350 per month.
Tier 4	ETP with monthly ADV between 50,001 and 150,000 in the prior month	\$450 per month.
Tier 5	ETP with monthly ADV less than 50,001 in the prior month	\$500 per month.

In particular, the Exchange proposes to increase the fixed monthly payments (*i.e.*, stipends) in Tiers 3–5 from \$200 to \$350 (Tier 3), \$225 to \$450 (Tier 4), and

\$300 to \$500 (Tier 5). Tier 1–2 rebates will remain at the same levels currently provided for the standard DLP rebates. The proposed changes are intended to

better incentivize DLPs to quote in lower volume and less liquid ETPs, recognizing that there may be higher costs to do so. The Exchange also

¹⁷ Specifically, the MQMs are Auction Spread in basis points with \$37,500 notional depth (Opening) and Auction Spread in basis points with \$75,000 notional depth (Closing).

¹⁸ Paragraph (1)(A) of Section 114(f) provides the list of Nasdaq-listed ETPs that are included in the DLP program as Qualified Securities, provided it has at least one DLP. Specifically, these are ETPs

listed pursuant to Rules 5704, 5705, 5710, 5711, 5713, 5715, 5720, 5735, 5745, 5750, or 5760.

proposes to clarify in paragraph (5)(A) of Section 114(f) that the Tiers 1–2 rebates will be in lieu of any other rebate the DLP is eligible for under Equity 7, Sections 114 and 118. This is current practice today, but the Exchange is adding this language for transparency and to avoid potential confusion.¹⁹ Unlike the Tiers 3–5 DLP stipends,

which are additive, the Tiers 1 and 2 DLP rebates are not because the Exchange is trying to greater incentivize DLPs to quote in lower volume and less liquid ETPs.

Proposed paragraph (B) of Section 114(f)(5) will set forth the amended additional Tape C incentives. As proposed, this will be provided to all

eligible DLPs (and removing the references around Primary DLPs which is currently the case) that add liquidity in a Tape C ETP and will clarify that the DLP needs to meet the two DLP MQMs specified in proposed paragraph (4)(C) above. Specifically, the Exchange proposes to provide DLPs rebates in accordance with the following schedule:

	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5
Minimum Monthly Average Number of Assigned ETPs as a DLP and meeting the Average Notional Depth and Average Spread metrics in paragraph (4)(B).	20	35	75	135	200.
Incremental Tape C ETP Rebate	\$0.00025 per executed share.	\$0.00035 per executed share.	\$0.0004 per executed share.	\$0.00045 per executed share.	\$0.00055 per executed share.

As proposed, the Exchange will increase the minimum monthly average number of assigned Tape C ETPs needed to qualify for each rebate tier, increase the rebates in Tiers 1–2 and decrease the rebate in Tier 4. The Exchange will also add a new Tier 5 rebate. The proposed changes reflect the growing number of ETPs listed on the Exchange, and are designed to expand liquidity support in Tape C ETPs and ensure that DLPs contributing to market quality in these ETPs are appropriately incentivized.

Specifically, new Section 114(g) will provide that the following stipend discussed in this section shall apply to transactions in a Qualified Security (as defined below) by up to three MQSs associated with its MQS program MPID.²⁰ The Exchange notes that a DLP (*i.e.*, registered market maker) can also be designated as the MQS of a Qualified Security and be eligible to receive the MQS stipend proposed herein,²¹ but an MQS is not required to be a registered market maker. These members are simply supporters who are trading in the ETP and have subsequently been designated as an MQS, but they are not subject to the same obligations as the DLP that is, in essence, the registered market maker (*i.e.*, lead market maker), nor are they required to meet the registered market maker obligations in the ETP, as set forth in Equity 2, Section 5. The Exchange believes that allowing any member to participate in the MQS Program (instead of limiting it just to registered market makers) would fortify participation in the proposed MQS Program, and enhance market quality in lower volume ETPs.

114(f)(4)(B) described above as well as the MQS Market Quality Metrics as specified in this proposed Section 114(g). The term ADV shall mean the total consolidated volume reported to all consolidated transaction reporting plans, for each individual security, by all exchanges and trade reporting facilities during a month divided by the number of trading days during the month. If a security is not listed for a full month, the number of trading days will only include the days which the security is listed.²²

Proposal 2: MQS Program

The Exchange proposes to establish a new MQS program in new Section 114(g) of Equity 7. The new MQS program is designed to complement the DLP program in Section 114(f) by allowing up to three members (*i.e.*, MQSs) per ETP to participate in market quality improvement by providing liquidity for lower volume ETPs. The Exchange believes that allowing up to three MQSs will work to further support market quality in lower volume ETPs and increase resiliency in market quality performance. By incentivizing more than one MQS to meet the MQS Market Quality Metrics described below, lower volume ETPs would have more members that are incentivized to provide quote quality and layering of notional depth, which can enhance the market quality in an ETP overall.

Proposed Section 114(g)(1) will set forth the definition of Qualified Security, which will be defined for purposes of the MQS program in proposed Section 114(g)(1) as an ETP listed on Nasdaq pursuant to Nasdaq Rules 5704, 5705, 5710, 5711, 5713, 5715, 5720, 5735, 5745, 5750, or 5760, and has at least one MQS. The proposed definition will be identical to the current definition in the DLP program in Section 114(f)(1).

Proposed Section 114(g)(2) will set forth the definition of MQS, which will be a market participant that has committed to maintain minimum performance standards in Low Volume ETPs.²³ An MQS shall be selected by Nasdaq based on factors including, but not limited to, experience with making markets in exchange-traded products, adequacy of capital, willingness to promote Nasdaq as a marketplace, issuer

¹⁹ The Exchange notes that paragraph (5)(A) already specifies that for Tiers 3–5, the DLP will be eligible to receive a fixed payment per month in addition to any other rebate the DLP is eligible for under Equity 7, Sections 114 and 118.

²⁰ The term “market participant identifier” or “MPID” means a unique four-letter mnemonic assigned to each Participant in the Nasdaq Market Center. A Participant may have one or more than one MPID. See Equity 1, Section 1(a)(11).

²¹ As discussed below, the Exchange is proposing identical qualifications as a DLP for selecting an

MQS. Specifically, an MQS shall be selected by Nasdaq based on factors including, but not limited to, experience with making markets in exchange-traded products, adequacy of capital, willingness to promote Nasdaq as a marketplace, issuer preference, operational capacity, support personnel, and history of adherence to Nasdaq rules and securities laws. See proposed Equity 7, Section 114(g)(2).

²² See Equity 7, Section 114(f) for substantially similar provisions in the DLP program. The Exchange is not adopting the DLP program’s

language around the incentive only being applied for executions \$1 per share and above because this is only applicable to rebates provided per executed share and not a fixed monthly stipend.

²³ “Low Volume” ETPs will have the same meaning in the MQS program as proposed in the DLP program, and shall mean ETPs with a monthly ADV of 1 million shares or less in the prior month. See proposed Equity 7, Section 114(g)(4)(A).

preference, operational capacity, support personnel, and history of adherence to Nasdaq rules and securities laws. The proposed definition will be similar to the definition of DLP in Section 114(f)(2) and the MQS will be selected using the same evaluation criteria as a DLP, except an MQS will not be required to be a registered market maker in the Qualified Security for the reasons discussed above.²⁴

Proposed Section 114(g)(3) will provide that if an MQS does not meet the performance measurements under paragraph (4) in this section for a given month, fees and credits will revert to the normal schedule under Sections 118(a) and 114. An MQS must provide 5 days written notice if it wishes to withdraw its registration in a Qualified Security,

unless it is also withdrawing as a market maker in the Qualified Security, as applicable.²⁵

In proposed Section 114(g)(4)(A), the Exchange proposes to add a new Investment Strategy group framework, which will be identical to the framework proposed for the DLP program in Section 114(f)(4)(A) above. The Exchange will segment the Low Volume ETPs into Investment Strategy groups A–C in the same way as proposed for the DLP program and will bucket the same investment strategies into groups A–C based on the average NBBO spread in the same way as proposed in the DLP program:²⁶

Investment strategy group	Average NBBO spread in basis points
A	15 or less.
B	16–28.
C	29 or more.

Same as proposed in the DLP program, these Investment Strategy groups will be checked by the Exchange each calendar year to ensure the investment strategy's average NBBO spread remains within its respective Investment Strategy group.

Proposed Section 114(g)(4)(B) will set forth the MQM thresholds that MQSs will need to meet based on which Investment Strategy group ETP they are assigned.

Market quality metrics	Investment strategy group A ETPs	Investment strategy group B ETPs	Investment strategy group C ETPs
Average Notional Depth within 75 basis points of the NBBO	\$125,000	\$75,000	\$50,000
Average Spread in basis points	35	60	100
Auction Spread in basis points with \$37,500 notional depth (Opening)	105	180	300
Auction Spread in basis points with \$75,000 notional depth (Closing)	35	60	100

The Exchange proposes that to be eligible for the stipend in paragraph (5) below, MQSs will need to meet the above MQMs in the assigned ETP as measured by Nasdaq. For leveraged and inverse ETPs, the average spread and auction spread metrics are multiplied by the absolute value of the leverage factor of the ETP. Because leveraged and inverse ETPs often exhibit higher price volatility relative to standard, non-leveraged ETPs, the MQS is often taking on higher risk and costs to take on these products. Adjusting these MQMs by the absolute value of the ETP's leverage factor aligns the rebate structure with the MQS's cost of taking these products on. These MQMs are measured on average in the assigned ETP during regular market hours, except for the auction spread metric that is measured directly before each auction against the metrics and averaged for the period. The Exchange also proposes that an MQS that is also designated as the DLP in a Qualified Security will need to meet the MQMs as set out in Section 114(f)(4) above to receive the MQS stipend.

Proposed Section 114(g)(5) will provide that an MQS that satisfies the MQMs in paragraph (4) above will be eligible to receive the MQS stipend of

\$175 per month in each of its assigned ETPs for which it qualified. The MQS stipend will be a fixed payment per month in addition to other rebates or fees for which the MQS is eligible and provided under Equity 7, Sections 118 and 114. This stipend will only apply to the MPID where a member is an MQS. Similar to the proposed DLP program, the Exchange proposes that the MQS will be automatically eligible to receive the MQS stipend in one of the following scenarios: (1) for the month of December 2025; (2) for the current month following the new MQS allocation of a symbol (*i.e.*, in the context of a listing transfer from another exchange or switching MQSs on a symbol); or (3) for the current month of new launches. After the first month, the MQS will need to satisfy the MQMs relevant to their assigned ETP, as set forth in Section 114(g)(4)(B).

Proposal 3: Technical Amendments

The Exchange proposes technical amendments to reflect the addition of new Section 114(g). Specifically, the Exchange proposes to renumber current Sections 114(g)–(k) as Sections 114(h)–(l). The Exchange also proposes to update the cross-cite to current Section

114(g) within the definition of “Designated Retail Order” in Equity 7, Section 118(a).

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,²⁷ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,²⁸ 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 Exchange notes that its ETP listing business operates in a highly-competitive market in which market participants, which include both ETP issuers and ETP market makers, can readily transfer their listings or opt not to participate, respectively, if they deem fee levels, liquidity incentive programs, or any other factor at a particular venue to be insufficient or excessive. The proposed rule change reflects a competitive pricing structure designed to incentivize issuers to list new products and transfer existing products to the Exchange, and market

²⁴ A registered market maker has certain quoting obligations on Nasdaq to provide two-sided quotes in the security at all times within certain percentages from the NBBO. See Equity 2, Section 5.

²⁵ See Equity 7, Section 114(f)(3) for substantially similar provisions in the DLP program except the Exchange is adding “as applicable” herein to clarify that a MQS does not have to be a registered market maker.

²⁶ See *supra* notes 15–17 for the specific investment strategies within each Investment Strategy group.

²⁷ 15 U.S.C. 78f(b).

²⁸ 15 U.S.C. 78f(b)(4) and (5).

participants to enroll and participate as ETP market makers on the Exchange, which will enhance market quality in listed ETPs on the Exchange.

Proposal 1: DLP Program

The Exchange believes that the proposed changes to the DLP program are reasonable, equitable, and not unfairly discriminatory for the reasons that follow. As a general matter, the Exchange must from time to time assess the effectiveness of the incentives it provides to market participants in return for the beneficial behavior required to receive the incentive. In this case, the Exchange is proposing to enhance the current DLP program in Equity 7, Section 114(f) by: (1) eliminating the distinction between Primary and Secondary DLPs, eliminating Secondary DLP rebates, and limiting the number of DLPs to one DLP per Qualified Security; (2) replacing the distinction between standard and enhanced MQMs (and associated rebates) with a single set of MQMs (and associated rebates); (3) adding a new Low Volume group framework; (4) replacing some of the current MQMs with more detailed MQMs; (5) increasing the fixed monthly DLP rebates for Tiers 3–5; (6) updating the qualifications, eligibility thresholds, and associated rebates for the additional Tape C ETP incentive; and (7) making non-substantive changes throughout proposed Section 114(f) to remove all references to “fees” as the Exchange would only provide incentives under the DLP Program and to add references to “stipends” to refer to the monthly fixed payments the Exchange would provide to eligible DLPs. Taken together, the proposed enhancements to the DLP program are intended to help the Exchange compete as a listing venue for ETPs, including with respect to Low Volume ETPs. Further, the Exchange notes that the proposed incentives are based on achieving certain objective MQMs. The revised MQMs are designed to encourage DLPs to uphold better quality markets in Nasdaq-listed ETPs and also ensure a scalable business model to support new and incubating ETPs that often trade less on a daily basis and exhibit less liquidity. The Exchange believes that providing incentives that are based on the quality of the market in individual ETPs, including those that generally have lower volumes and wider spreads, will incentivize DLPs to provide tight and deep markets in those securities. The proposed changes to the DLP program reflects a competitive pricing structure designed to incentivize market participants to direct their order flow to

the Exchange and enhance market quality in Nasdaq-listed ETPs.

The Exchange further believes that the proposed changes to add a Low Volume group framework in the manner discussed above is reasonable because the proposed framework is intended to more precisely calibrate the DLP rebate/stipend qualifications in proposed Section 114(f)(4)(B) and additional Tape C incentive qualifications in proposed Section 114(f)(4)(C) to the liquidity profile of the investment strategy that the DLP’s assigned ETP falls under. In other words, segmenting Low Volume ETPs into three groups based on 2-year average NBBO spread is intended to better align the DLP’s performance expectations to the nature of the ETP’s investment strategy and structure. The Exchange believes that the proposed framework will encourage tighter spreads and more liquidity in investment strategies that may typically be less actively traded or exhibit wider spreads. The Exchange notes that other equity exchanges distinguish between different ETP investment strategies in their fee schedules to incentivize enhanced market quality in those ETPs, or have incentives in place to encourage greater market quality in lower volume ETPs.²⁹

The Exchange similarly believes that the proposed changes to increase the fixed monthly payments in Tiers 3–5 in the manner described above will incentivize DLPs to provide tight and deep markets in ETPs that generally have lower volume and wider spreads. The Exchange also believes that automatically providing the DLP the relevant tiered rebate or stipend for the current month of a new DLP allocation of a symbol, or of a new launch, automatically providing them the Tier 5 stipend for the current month, is reasonable because the Exchange is providing the DLP with clear visibility into their rebate/stipend earnings at the time of the ETP’s launch or allocation. This approach is critical as ETPs may launch or be allocated a new DLP at various points throughout the month, potentially complicating the DLP’s ability to meet the monthly performance criteria proposed above and making it unclear on what rebates/stipends the DLP may expect. Furthermore, enabling

the DLP to receive the rebate/stipend during the current month ensures they have sufficient runway to quote the product and maintain liquidity in the subsequent month as the first month of a new DLP allocation or new launch is often one where the ETP is more thinly traded and liquidity standards may be more difficult to meet. The Exchange also believes that automatically providing DLPs the applicable tiered rebate or stipend and waiving the MQM requirements for the first month of the new incentive program (*i.e.*, December 2025) is reasonable because the Exchange seeks to encourage greater participation in the new program and allow DLPs to have adequate time to transition to the MQMs.

The Exchange also believes that its proposal to amend the additional Tape C incentives by increasing the monthly average number of assigned Tape C ETPs needed to qualify for each rebate tier and to add a new Tier 5 rebate are reasonable because these modifications reflect the growing number of ETPs listed on Nasdaq. The Exchange also believes that the proposed rebates are set at appropriate levels, and will continue to incentivize DLPs to add liquidity in Tape C ETPs in order to qualify for these rebates.

The Exchange also believes that the proposed enhancements to the DLP program, as described above, are equitable and not unfairly discriminatory because the Exchange will apply the amended program uniformly to all registered market makers that are DLPs. The Exchange does not believe it is unfairly discriminatory to only offer the program to market makers because of their unique role in the markets, including their obligation to provide liquidity in the securities in which they are registered. Thus, the DLP program is a further extension of the market maker’s role in providing liquidity in specific securities, to the benefit of all market participants. Further, as discussed above, the Exchange is proposing to waive the MQM requirements in specified scenarios for a limited period of time such that DLPs would automatically receive the relevant DLP rebate or stipend.³⁰ The Exchange believes this proposal is equitable and

²⁹ See *e.g.*, Cboe BZX Equities Fee Schedule for market quality incentive program for “LEP Securities,” which are single-stock ETFs determined by Cboe BZX for inclusion in the program; and NYSE Arca Equities Schedule of Fees and Charges for market quality incentive programs for leveraged ETPs and “Less Active” ETPs (defined as ETPs that have a CADV in the prior calendar quarter that is the greater of either less than 100,000 shares or less than 0.013% of Consolidated Tape B ADV), including Less Active leveraged ETPs.

³⁰ As discussed in detail above, the Exchange is proposing to waive the MQM requirements and automatically provide the applicable DLP rebate/stipend based on the trading volume of the relevant ETP in one of the following scenarios: (1) for the month of December 2025; or (2) for the current month of a new DLP allocation of a symbol. Further, the Exchange is proposing to waive the MQM requirements and automatically provide the Tier 5 stipend for the current month of a new launch.

not unfairly discriminatory because the waiver would apply to all DLPs. As discussed above, enabling the DLP to receive the rebate during the current month ensures they have sufficient runway to quote the product and maintain liquidity in the subsequent month as the first month of a new DLP allocation or new launch is often one where the ETP is more thinly traded and liquidity standards may be more difficult to meet. As it relates to the proposed waiver for December 2025, the Exchange is seeking to encourage greater participation in the new DLP program and allow DLPs to have adequate time to transition to the MQMs. Further, this will be strictly limited to the first month of trading under the new program, after which the DLP must meet the MQMs set out in proposed Section 114(f)(4)(B) in order to qualify for the DLP rebates.

Ultimately, the Exchange believes that all of the changes proposed for the enhanced DLP program, taken together, will promote price discovery and market quality in Nasdaq-listed securities and further, that the tightened spreads and increased liquidity from the proposal will benefit all market participants and investors by deepening the Exchange's liquidity pool (including in lower volume and less liquid ETPs), offering additional flexibility for all investors to enjoy cost savings, supporting the quality of price discovery, enhancing quoting competition across exchanges, promoting market transparency, and improving investor protection. Accordingly, the Exchange believes that the proposal is reasonable, equitably allocated, and non-discriminatory because it would enhance market quality to the benefit of all market participants and investors.

Proposal 2: MQS Program

The Exchange believes that the new MQS program is reasonable because the program is designed to attract additional market makers to provide depth and tighter spreads in Nasdaq-listed ETPs that have lower volume and are less liquid. As discussed above, the Exchange is introducing a supplemental liquidity incentive framework focused on enhancing market quality in Low Volume ETPs.

The Exchange believes that allowing up to three MQSs per Qualified Security is reasonable because it will further support market quality and increase resiliency by increasing coverage in Nasdaq-listed ETPs that have lower trading volume and wider spreads. Similar to the proposed DLP program discussed above, the Exchange believes that the proposed changes to add a Low

Volume group framework in the manner discussed above is reasonable because the proposed framework is intended to more precisely calibrate the MQS rebate qualifications in proposed Section 114(g)(4) to the liquidity profile of the investment strategy that the MQS's assigned ETP falls under. In other words, segmenting Low Volume ETPs into three groups based on 2-year average NBBO spread is intended to better align the MQS's performance expectations to the nature of the ETP's investment strategy and structure. The Exchange believes that the proposed framework will encourage tighter spreads and more liquidity in investment strategies that may typically be less actively traded or exhibit wider spreads across all exchanges. The Exchange notes that other equity exchanges distinguish between different ETP investment strategies in their fee schedules to incentivize enhanced market quality in those ETPs, or have incentives in place to encourage greater market quality in lower volume ETPs.³¹

The Exchange believes that the proposed MQMs for the MQS program are reasonable as they are intended to enhance market quality by encouraging MQSs to provide depth, tighter quoted spreads, and better auction spreads in the open and close. The Exchange also believes that it is reasonable to require an MQS that is also designated as the DLP of the Qualified Security to meet the MQMs from the DLP program as specified to qualify for the MQS rebate. This change is intended to ensure that market makers earning incentives under both programs are delivering comprehensive market quality. Since DLPs would already be eligible to receive rebates under the DLP program, the Exchange believes that the additional MQS rebate should be reserved for DLPs meeting the requisite MQMs in proposed Section 114(f)(4)(B) and providing sufficient value under the DLP program.

The Exchange believes that the flat monthly payment of \$175 is set at an appropriate level to incentivize MQSs to enhance market quality in Low Volume ETPs. In addition, providing a flat stipend (as opposed to a per-executed share rebate) would provide for a more reliable business model for MQSs that choose to participate in this program, particularly in lower volume and less liquid ETPs. The Exchange also believes that automatically providing the MQS the stipend for the current month following the new MQS allocation of a symbol or following new launches is reasonable because the Exchange is

providing the MQS with clear visibility into their stipend earnings at the time of the ETP's launch or new MQS allocation. This approach is critical as ETPs may launch or get allocated to a new MQS at various points throughout the month, potentially complicating the MQS's ability to meet the monthly performance criteria proposed above. Furthermore, enabling the MQS to receive the rebate during the current month ensures they have sufficient runway to quote the product and maintain liquidity in the subsequent month as the first month of a new MQS allocation or new launch is often one where the ETP is more thinly traded and liquidity standards may be more difficult to meet. In addition, the Exchange believes that automatically providing the MQS stipend and waiving the MQM requirements for the first month of the new incentive program (*i.e.*, December 2025) is reasonable because the Exchange seeks to encourage greater participation in the new program and allow MQSs to have adequate time to transition to the MQMs.

The Exchange also believes that the proposed MQS program is equitable and not unfairly discriminatory because the Exchange will apply the MQS program uniformly to all members that choose to participate as MQSs. Further, as discussed above, the Exchange is proposing to waive the MQM requirements in specified scenarios for a limited period of time such that MQSs would automatically receive the MQS stipend.³² The Exchange believes this proposal is equitable and not unfairly discriminatory because the waiver would apply to all MQSs. As discussed above, enabling the MQS to receive the stipend during current month ensures they have sufficient runway to provide market quality in the product and maintain market quality for the subsequent month as the first month of a new MQS allocation or new launch is often one where the ETP is more thinly traded and market quality standards may be more difficult to meet. As it relates to the proposed waiver for December 2025, the Exchange is seeking to encourage greater participation in the new MQS program and allow MQSs to have adequate time to transition to the new MQMs. Further, this will be strictly limited to the first month of trading under the new program, after which the

³² As discussed in detail above, the Exchange is proposing to waive the MQM requirements and automatically provide the MQS stipend in one of the following scenarios: (1) for the month of December 2025; (2) for the current month of a new MQS allocation of a symbol; or (3) for the current month of a new launch.

³¹ See *supra* note 30.

MQS must meet the MQMs as specified in proposed Section 114(g)(4)(B) in order to qualify for the MQS stipend.

Further, the Exchange believes that the proposed MQS program will promote price discovery and market quality in Nasdaq-listed securities and further, that the tightened spreads and increased liquidity from the proposal will benefit all market participants and investors by deepening the Exchange's liquidity pool (particularly in lower volume and less liquid ETPs), offering additional flexibility for all investors to enjoy cost savings, supporting the quality of price discovery, enhancing quoting competition across exchanges, promoting market transparency, and improving investor protection. Accordingly, the Exchange believes that the proposal is reasonable, equitably allocated, and non-discriminatory because it would enhance market quality to the benefit of all market participants and investors.

Proposal 3: Technical Amendments

The Exchange believes that the technical amendments to reflect the addition of new Section 114(g) are reasonable, equitable, and not unfairly discriminatory. Specifically, the Exchange proposes to renumber current Sections 114(g)–(k) as Sections 114(h)–(l). The Exchange also proposes to update the cross-cite to current Section 114(g) within the definition of “Designated Retail Order” in Equity 7, Section 118(a). The proposed changes will bring clarity and avoid potential confusion in Exchange's Pricing Schedule to the benefit of all market participants and investors.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed changes consisting of the introduction of the DLP program enhancements and adoption of the MQS program will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Rather, the Exchange believes that the proposed changes, taken together, will enhance competition by improving the market quality in Nasdaq-listed ETPs, which will benefit all market participants through additional trading opportunities, tighter spreads, and enhanced price discovery.

In terms of intra-market competition, as it relates to the DLP and MQS programs, the Exchange notes the respective programs will be applied uniformly to all similarly situated market participants that are DLPs and MQSs, as applicable. The Exchange

does not believe it is unfairly discriminatory to only offer the DLP program to registered market makers because of their unique role in the markets, including their obligation to provide liquidity in the securities in which they are registered. Thus, the DLP program is a further extension of the registered market maker's role in providing liquidity in specific ETPs, to the benefit of all market participants.

The Exchange further believes that waiving the MQM requirements and automatically providing the applicable DLP or MQS rebate or stipend in the scenarios specified above (*i.e.*, for December 2025, for the current month of a new DLP or MQS allocation of a symbol, or for the current month of a new launch) do not impose an undue burden on intra-market competition because the waiver would apply to all DLPs and MQSs. As discussed above, enabling the DLP or MQS to receive the rebate during the current month ensures they have sufficient runway to provide market quality in the product and maintain market quality in the subsequent month, as the first month of a new launch or new DLP/MQS allocation is often one where the ETP is more thinly traded and liquidity standards may be more difficult to meet. As it relates to the proposed waiver for December 2025, the Exchange is seeking to encourage greater participation in the new DLP and MQS programs, and allow participants to have adequate time to transition to the new MQMs. Further, this will be strictly limited to the first month of trading under the DLP and MQS programs, after which the DLP and MQS must meet all of the relevant MQMs in order to qualify for the applicable rebates or stipends.

In terms of inter-market competition, 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 to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. In sum, if the changes proposed herein are unattractive to market

participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

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.³³

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–2025–102 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–2025–102. 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/>

³³ 15 U.S.C. 78s(b)(3)(A)(ii).

rules/sro.shtml). Copies of the filing 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-2025-102 and should be submitted on or before January 13, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁴

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-23669 Filed 12-22-25; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235-0507]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension: Rule 19b-5 and Form PILOT

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 ("PRA") (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("SEC") is soliciting comments on the proposed collection of information provided for in Rule 19b-5 (17 CFR 240.19b-5) and Form PILOT (17 CFR 249.821) under the Securities Exchange Act of 1934 ("Exchange Act") (15 U.S.C. 78a *et seq.*). The SEC plans to submit this existing collection of information to the Office of Management and Budget ("OMB") for extension and approval.

Rule 19b-5 provides a temporary exemption from the rule-filing requirements of Section 19(b) of the Exchange Act (15 U.S.C. 78s(b)) to self-regulatory organizations ("SROs") wishing to establish and operate pilot trading systems. Rule 19b-5 permits an SRO to develop a pilot trading system and to begin operation of such system shortly after submitting an initial report on Form PILOT to the SEC. During operation of any such pilot trading system, the SRO must submit quarterly reports of the system's operation to the SEC, as well as timely amendments

describing any material changes to the system. Within two years of operating such pilot trading system under the exemption afforded by Rule 19b-5, the SRO must submit a rule filing pursuant to Section 19(b)(2) of the Exchange Act (15 U.S.C. 78s(b)(2)) to obtain permanent approval of the pilot trading system from the SEC.

The collection of information is designed to allow the SEC to maintain an accurate record of all new pilot trading systems operated by SROs and to determine whether an SRO has properly availed itself of the exemption afforded by Rule 19b-5, is operating a pilot trading system in compliance with the Exchange Act, and is carrying out its statutory oversight obligations under the Exchange Act.

The respondents to the collection of information are national securities exchanges and national securities associations.

There are 29 SROs which could avail themselves of the exemption under Rule 19b-5 and the use of Form PILOT. The SEC estimates that approximately one of these SROs each year will file on Form PILOT one initial report (*i.e.*, 1 report total, for an estimated annual burden of 24 hours total), four quarterly reports (*i.e.*, 4 reports total, for an estimated annual burden of 12 hours total (3 hours per report)), and two amendments (*i.e.*, 2 reports total, for an estimated annual burden of 6 hours total (3 hours per report)). Thus, the estimated annual time burden resulting from Form PILOT is 42 hours for the estimated sole SRO respondent. The SEC estimates that the aggregate annual internal cost of compliance for the sole SRO respondent is approximately \$15,890 (42 hours at an average of \$378.33 per hour). In addition, the SEC estimates that the sole SRO respondent will incur, in the aggregate, printing, supplies, copying, and postage expenses of \$2,516 per year for filing initial reports, \$1,256 per year for filing quarterly reports, and \$628 per year for filing notices of material systems changes, for a total annual cost burden of \$4,400.

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.

Please direct your written comments on this 60-Day Collection Notice to Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Tanya Ruttenberg via email to PaperworkReductionAct@sec.gov by February 23, 2026. There will be a second opportunity to comment on this SEC request following the **Federal Register** publishing a 30-Day Submission Notice.

Dated: December 19, 2025.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-23736 Filed 12-22-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104443; File Nos. SR-NASDAQ-2025-080; SR-BX-2025-024; SR-GEMX-2025-27; SR-MRX-2025-23; SR-PHLX-2025-56; SR-ISE-2025-31]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Nasdaq BX, Inc.; Nasdaq GEMX, LLC; Nasdaq MRX, LLC; Nasdaq PHLX LLC; Nasdaq ISE, LLC; Order Approving Proposed Rule Change To Amend the Amended and Restated Certificate of Incorporation and By-Laws of Parent Corporation, Nasdaq, Inc.

December 18, 2025.

I. Introduction

On September 26, 2025, each of The Nasdaq Stock Market LLC ("NASDAQ Exchange"); Nasdaq BX, Inc. ("BX"); Nasdaq GEMX, LLC ("GEMX"); Nasdaq MRX, LLC ("MRX"); Nasdaq PHLX LLC ("PHLX"); and Nasdaq ISE, LLC ("ISE" and, collectively, the "Exchanges"), 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 proposed rule changes (the "Proposals") with respect to the Amended and restated Certificate of Incorporation ("Certificate") and By-Laws ("By-Laws") of their parent corporation, Nasdaq, Inc. ("Nasdaq"). The Proposals amend the Certificate to align with certain amendments to the Delaware General Corporation Law

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³⁴ 17 CFR 200.30-3(a)(12).

(“DGCL”) passed in 2022 and update the By-Laws to reflect recent changes in law and best practices. The Proposals were published for comment in the **Federal Register** on October 1, 2025.³ On November 3, 2025, pursuant to Section 19(b)(2) of the Act,⁴ the Commission designated a longer period within which to approve the proposed rule changes, disapprove the proposed rule changes, or institute proceedings to determine whether to disapprove the proposed rule changes.⁵ The Commission did not receive any comment letters on the Proposals. This order approves the Proposals.

II. Description of the Proposals

The Exchanges propose amendments to the Certificate to exculpate covered officers from monetary liability for breach of fiduciary duty, similar to the existing treatment of directors.⁶ As discussed more fully in the Notices, the Exchanges state that the proposed amendments would update the Certificate to reflect amendments to the DGCL that enable companies to limit the liability of certain officers in narrow circumstances.⁷

The Exchanges also propose amendments to the following provisions of the By-Laws: Articles III (Meetings of Stockholders);⁸ IV (Board of Directors);⁹ VII (Officers, Agents, and Employees);¹⁰ VIII (Indemnification);¹¹ IX (Capital Stock);¹² X (Miscellaneous Provisions);¹³ XI (Amendments and Emergency By-Laws);¹⁴ and XIII (Forum Selection);¹⁵ as well as other non-

substantive changes.¹⁶ These amendments are summarized below and discussed more fully in the Notices.

Proposed Amendments to Article III

- Specify the scope of information that may be requested in connection with a stockholder nominee for director to provide that Nasdaq may require any other information to determine whether the proposed nominee is qualified under the Certificate, the By-Laws, and other applicable rules, laws, and regulations.

- Amend the information requirements for notices to Nasdaq from a Proposing Person¹⁷ regarding nominations or other business to be considered at an annual meeting of stockholders. Such notices require “a description of any agreement, arrangement or understanding with respect to the nomination or proposal between and among such stockholder and/or such beneficial owners, any of their respective affiliates or associates, and *any others acting in concert with any of the foregoing*” (emphasis added).¹⁸ The amendments remove the references to others “acting in concert.”¹⁹

- Add a requirement that a Proposing Person’s notice must include a representation as to whether the Proposing Person intends, or is part of a group which intends, “to solicit proxies or votes in support of any proposed nominee in accordance with Rule 14a–19²⁰ promulgated under the Act.”²¹

- Limit the number of nominees that a Proposing Person may nominate for election at the annual meeting in certain instances to the number of directors to be elected at such annual meeting.

- Remove a reference to the binding nature of the Board’s²² determination with respect to whether a special meeting request is in proper form, which aligns the By-Laws with current Delaware corporate practices.²³

- Require that the chairman who presides over stockholder meetings shall be an officer or director of Nasdaq.

Proposed Amendments to Article IV

- Provide Nasdaq with greater flexibility to include “Issuer Directors” on the Board by removing the current restriction that the Board may not include more than two such directors.²⁴
- Amend the Board quorum and voting provisions to clarify how a quorum is calculated and the process for the adjournment of meetings.

- Amend how notice of meetings may be given to, or waived by, directors (e.g., eliminate outdated forms of communication, such as telegram, telefax, cable, and radio).

- Specify that Nasdaq is opting into Section 141(c)(2) of the DGCL, which provides Nasdaq greater flexibility with respect to the formation and powers of Board committees, including, for example, allowing greater delegations of authority.²⁵

- Remove limitations on the ability of Board committees to take certain actions, such as the authorization of preferred stock designations.

- Remove the one-year limitation on the terms of committee members.²⁶

proxy rule would apply. *See, e.g.*, NASDAQ Exchange Notice, *supra* note 3, at 47421; proposed By-Laws Section 3.3(a) (relating to when Nasdaq would disregard nominees proposed by a stockholder under the universal proxy rule, if the stockholder has failed to comply with the rule).

²² “Board” is defined in Article I(c) of the By-Laws as the Board of Directors of Nasdaq.

²³ The Exchanges propose similar deletions of references to the decisions made in the “sole discretion” of the Board or to the finality or “binding” nature of decisions by the Board (or persons authorized by the Board), any committees thereof, or the chairman of a meeting thereof throughout the proposed amendments.

²⁴ “Issuer Director” is defined in Article I(o) of the By-Laws.

²⁵ *See, e.g.*, NASDAQ Exchange Notice, *supra* note 3, at 47421–23.

²⁶ *See, e.g.*, NASDAQ Exchange Notice, *supra* note 3, at 47423. The Proposals also remove the requirement that the chair of Nasdaq’s Audit Committee must be a Public Director (as defined in Article I of the By-Laws). *See id.* The Exchanges state that the chair of the Audit Committee must still satisfy prescribed independence standards. *See id.* With respect to the Audit Committee, the Proposals would amend the By-Laws to provide flexibility for such committee to be renamed from

³ Securities Exchange Act Release Nos. 104108 (September 26, 2025), 90 FR 47418 (SR–NASDAQ–2025–080) (“NASDAQ Exchange Notice”), 104110 (September 26, 2025), 90 FR 47428 (SR–BX–2025–024), 104118 (September 29, 2025), 90 FR 47444 (SR–GEMX–2025–27), 104120 (September 29, 2025), 90 FR 47373 (SR–MRX–2025–23), 104109 (September 26, 2025), 90 FR 47401 (SR–Phlx–2025–56); 104115 (September 29, 2025), 90 FR 47461 (SR–ISE–2025–31) (collectively, “Notices”).

⁴ 15 U.S.C. 78s(b)(2).

⁵ *See* Securities Exchange Act Release No. 104173, 90 FR 51424 (designating December 30, 2025, as the date by which the Commission shall either approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule changes).

⁶ *See, e.g.*, NASDAQ Exchange Notice, *supra* note 3, at 47419.

⁷ *See, e.g., id.* (discussing related corporate governance trends under Delaware law and the potential consequences to Nasdaq from failing to adopt the proposed changes). *See also infra* notes 38 and 39 and accompanying text.

⁸ *See* NASDAQ Exchange Notice, *supra* note 3, at 47419–22.

⁹ *See id.* at 47422–24.

¹⁰ *See id.* at 47424–25.

¹¹ *See id.* at 47425.

¹² *See id.* at 47425–26.

¹³ *See id.* at 47426.

¹⁴ *See id.*

¹⁵ *See id.*

¹⁶ *See id.* at 47426–27. These changes are either typographical corrections or otherwise administrative or clarifying changes (such as changing a reference to “shareholder” to “stockholder” to more closely reflect terminology of the By-Laws).

¹⁷ Section 3.1(c) of the By-Laws defines “Proposing Person” as (i) the stockholder providing the notice of business or the notice of the nomination, as applicable, proposed to be brought before an annual meeting, (ii) any beneficial owner or beneficial owners, if different, on whose behalf such business is proposed to be brought before the meeting or the notice of the nomination proposed to be made at the meeting is made, as applicable, and (iii) any affiliate or associate (each within the meaning of Rule 12b–2 under the Act for purposes of these By-Laws) of such stockholder or beneficial owner.

¹⁸ *See* NASDAQ Exchange Notice, *supra* note 3, at 47420; proposed By-Laws Section 3.1(b)(iii)(C).

¹⁹ The Exchanges propose a similar amendment to By-Law Section 3.2(a), which addresses requirements for requesting a special meeting of the stockholders, including procedures for determining the requisite percentage of stockholders necessary to support a special meeting request. *See* NASDAQ Exchange Notice, *supra* note 3, at 47421.

²⁰ 17 CFR 240.14a–9 (referred to as the “universal proxy rule”).

²¹ *See, e.g.*, NASDAQ Exchange Notice, *supra* note 3, at 47421; proposed By-Laws Section 3.1(b)(iii)(O)(3). Other amendments to the By-Laws under the Proposals also clarify when the universal

- Remove duplicative language in the By-Laws that specifies that members of the Nominating & Governance Committee may be removed by “majority vote of” the Board, because the By-Laws already separately provide the voting standards for all decisions of the Board.²⁷

- Modify the quorum requirement for Board committees to specify that a majority of the members of a committee *then serving in office*, rather than a majority of total members on the committee, as is currently the case, shall constitute a quorum.²⁸

Proposed Amendments to Article VII

- Delete outdated references to Nasdaq’s corporate structure, including references to having one President that is a director, or that has executive authority over the entire company, and add provisions that contemplate more than one president.

- Make the specified list of officers to be elected by the Board permissive rather than mandatory.

- Modify the process and authority for appointing Vice Presidents and providing that each Vice President shall have all powers and duties usually incident to the office of a Vice President, except as specifically limited.

- Modify who may assign powers and duties to Presidents, Vice Presidents, the Secretary, and the Treasurer.²⁹

- Clarify that the obligation to pay claims or expenses related to the indemnification of directors, officers, employees, and agents is limited to those claims and expenses not prohibited by applicable law.³⁰

Proposed Amendments to Article IX

- Broaden the scope of officers authorized to sign stock certificates.

- Provide that applicable law will control whether Nasdaq is able to treat stockholders of record as shown on the stock ledgers as owners thereof and as the persons entitled to vote such shares and to receive notices, as well as when Nasdaq is bound to recognize any equitable claim to, or interest in, any shares on the part of any other person.

time to time or for any successor of such committee delegated with similar duties to be known as the respective committee. *See, e.g.,* NASDAQ Exchange Notice, *supra* note 3, at 47423–24; proposed By-Law Article I(p) and Section 4.13(g). The Proposals make similar changes with respect to the Nominating & Governance Committee. *See* proposed By-Law Article I(p).

²⁷ *See, e.g.,* NASDAQ Exchange Notice, *supra* note 3, at 47424.

²⁸ *See, e.g.,* NASDAQ Exchange Notice, *supra* note 3, at 47424.

²⁹ *See id.*

³⁰ *See, e.g.,* NASDAQ Exchange Notice, *supra* note 3, at 47425.

- Provide that Nasdaq shall be authorized, rather than the Board or an authorized committee thereof, to take certain actions with respect to lost, stolen, or destroyed certificates.

Proposed Amendments to Article X

- Replace an existing provision regarding the authority for the execution of contracts and other documents with a provision that more closely reflects Nasdaq’s current policies and procedures on signatory authority.

- Replace an existing provision regarding the required form of records with a provision that conforms to updated Delaware law.³¹

Proposed Amendments to Article XI

- Amend the By-Laws to reflect changes to the emergency by-law provisions of the DGCL.³²

Proposed Amendments to Article XIII

- Provide a new forum selection provision.³³

III. Discussion and Commission’s Findings

After careful review, the Commission finds that the Proposals are consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.³⁴ Specifically, the Commission finds that the Proposals are consistent with Section 6(b) of the Act³⁵ in general, and, in particular, with the requirement of Section 6(b)(1)³⁶ that a national securities exchange be so organized and have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulations thereunder, and the rules of the exchange. The Commission also finds that the Proposals are consistent, in particular, with the requirement of 6(b)(5) that the rules of a national securities exchange are designed, in general, to protect investors and the public interest.³⁷

The Commission finds that the Proposals are designed to help to ensure

that the Exchanges are so organized and have the capacity to be able to carry out the purposes of the Act, and to protect investors and the public interest. The Exchanges state that the proposed changes to the Certificate are in the public interest as they would update it consistent with developments in DGCL that enable companies incorporated in Delaware to limit the liability of certain of their officers in narrow circumstances. As discussed in the Notices, the Exchanges also state that such amendments are increasingly common for public companies; that the number of stockholder proposals calling for such amendments have continued to increase since 2022 when the DGCL was amended; and that the majority of these proposals have been approved by wide margins.³⁸ The Exchanges state that failing to adopt such amendments could potentially expose Nasdaq to higher litigation expenses and impact its recruitment and retention of officer candidates.³⁹

The Commission also finds that proposed amendments to the By-Laws are consistent with the Act. With respect to the proposed changes to the By-Laws, the Exchanges state that:

- the proposed changes to Article III are in the public interest as they would update the By-Laws and conform them to current practices and developments in DGCL;

- the proposed changes to Article IV are either clarifying in nature or otherwise purport to refine governance practices by providing Nasdaq with greater flexibility with respect to such matters as the qualifications of directors, quorum and voting, or otherwise update such provisions to make them more consistent with current governance practices as well as the policies and procedures of Nasdaq;

- the proposed changes to Articles VII through XIII are in the public interest and consistent with the protection of investors as they are designed to accomplish several objectives, including updating the By-Laws to conform with current practices or recent developments in Delaware law, aligning the By-Laws with current Nasdaq policies and procedures, and enhancing the clarity of the By-Laws, thus facilitating their proper application and use; and

- the remaining changes can be characterized as non-substantive, because they are designed to either correct typographical errors, conform

³¹ *See id.*

³² *See id.*

³³ *See id.* The Exchanges note that the by-laws of Cboe Global Markets, Inc., as well as those of CME Group, Inc., contain forum selection provisions similar to those proposed by the Exchanges. *See id.* at 47426, n.75.

³⁴ Additionally, in approving the Proposals, the Commission has considered the proposed rules’ impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

³⁵ 15 U.S.C. 78f(b).

³⁶ 15 U.S.C. 78f(b)(1).

³⁷ 15 U.S.C. 78f(b)(5).

³⁸ *See, e.g.,* NASDAQ Exchange Notice, *supra* note 3, at 47419, n. 3, and accompanying text.

³⁹ *See, e.g.,* NASDAQ Exchange Notice, *supra* note 3, at 47419.

Nasdaq governance documents to terminology in the By-Laws, remove obsolete text, or otherwise make non-substantive revisions to the By-Laws to make them clearer and easier to use.⁴⁰

The Commission finds that the proposed changes are designed to update the By-Laws for conformance with DGCL and litigation and corporate governance trends, conform the By-Laws with Nasdaq's corporate structure and policies and procedures, or make other clarifying and non-substantive changes. With respect to the proposed changes to Nasdaq's Audit Committee structure,⁴¹ the Exchanges states that such committee must, in any event, satisfy other applicable independence standards.⁴² Certain of the proposed amendments would also clarify when the universal proxy rule would apply.⁴³ Similar to the Exchanges' proposed amendments to the Certificate, the proposed amendments to the By-Laws should help to ensure that the Exchanges are so organized and have the capacity to be able to carry out the purposes of the Act, and are designed to protect investors and the public interest.⁴⁴

IV. Conclusion

For the foregoing reasons, the Commission finds that the Proposals are consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,⁴⁵ that the Proposals (SR-NASDAQ-2025-080; SR-BX-2025-024; SR-GEMX-2025-27; SR-MRX-2025-23; SR-Phlx-2025-56; SR-ISE-2025-31) be, and hereby are, approved.

⁴⁰ See, e.g., NASDAQ Exchange Notice, *supra* note 3, at 47427.

⁴¹ See *supra* note 26.

⁴² See, e.g., NASDAQ Exchange Notice, *supra* note 3, at 47423. By-Laws Section 4.13(g), currently and as proposed, requires that Nasdaq's Audit Committee be comprised of three or more directors, each of whom shall be an independent director within the meaning of the rules of the NASDAQ Stock Market and Section 10A of the Act.

⁴³ See, e.g., NASDAQ Exchange Notice, *supra* note 3, at 47421-22.

⁴⁴ The Commission has previously stated that certain provisions in the Nasdaq governing documents are designed to ensure that each self-regulatory subsidiary can carry out its regulatory obligations. See, e.g., Securities Exchange Act Release No. 78119 (June 21, 2016) 81 FR 41611 (approving proposed rule changes by ISE, GEMX, and MRX relating to their acquisition by Nasdaq) at 41613. Such provisions are not impacted by the Proposals.

⁴⁵ 15 U.S.C. 78s(b)(2).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴⁶

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-23668 Filed 12-22-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104446; File No. SR-GEMX-2025-34]

Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Options 7, Sections 3 and 4 Regarding the Crossing Fee Cap

December 18, 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 December 15, 2025, Nasdaq GEMX, LLC ("GEMX" 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 Options 7, Section 3, Regular Order Fees and Rebates, and Options 7, Section 4, Other Options Fees and Rebates.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/gemx/rulefilings>, and at the principal office of the Exchange.

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

GEMX proposes to amend Options 7, Section 3, Regular Order Fees and Rebates, and Options 7, Section 4, Other Options Fees and Rebates with respect to the Crossing Fee Cap.

Options 7, Section 4

The Exchange currently offers a Crossing Fee Cap at Options 7, Section 4.C. By way of background, Crossing Orders³ are contracts that are submitted as part of a Facilitation, Solicitation, Price Improvement Mechanism, Block or Qualified Contingent Cross Order. The Crossing Fee Cap is \$85,000 per month, per Member on all Firm Proprietary⁴ transactions that are part of the originating or contra side of a Crossing Order. All eligible volume from affiliated Members is aggregated for purposes of the Crossing Fee Cap, provided there is at least 75% common ownership between the Members as reflected on each Member's Form BD, Schedule A. Fees charged by the Exchange for Responses to Crossing Orders are not included in the calculation of the monthly fee cap. Surcharge fees charged by the Exchange for licensed products and the fees for index options as set forth in Options 7, Section 3 are not included in the calculation of the monthly fee cap. A service fee of \$0.00 per side applies to all order types that are eligible for the fee cap. The service fee applies once a Member has reached the fee cap level and would apply to every contract side above the fee cap. A Member who did not reach the monthly fee cap is not charged the service fee. Once the fee cap is reached, the service fee applies to eligible Firm Proprietary orders in all Nasdaq GEMX products. The service fee is not calculated in reaching the cap. For purposes of the Crossing Fee Cap, the Exchange attributes eligible volume to the GEMX Member on whose behalf the Crossing Order was executed.

³ "Crossing Order" is an order executed in the Exchange's Facilitation Mechanism, Solicited Order Mechanism, Price Improvement Mechanism or submitted as a Qualified Contingent Cross order. For purposes of this Pricing Schedule, orders executed in the Block Order Mechanism are also considered Crossing Orders. See Options 7, Section 1(c).

⁴ A "Firm Proprietary" order is an order submitted by a member for its own proprietary account. See Options 7, Section 1(c).

⁴⁶ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

At this time, the Exchange proposes to remove the Crossing Fee Cap from its Pricing Schedule in Options 7, Section 4.C. The Exchange also proposes to remove note 8 at Options 7, Section 3 that refers to the Crossing Fee Cap. Note 8 of Options 7, Section 3 states, "Firm Proprietary contracts traded are subject to the Crossing Fee Cap, as provided in Options 7, Section 4C." Finally, the Exchange proposes to remove references to note 8 in the tables in Options 7, Section 3.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁵ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,⁶ 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 proposed changes to the Pricing Schedule are reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for order flow, which constrains its pricing determinations. The fact that the market for order flow is competitive has long been recognized by the courts. In *NetCoalition v. Securities and Exchange Commission*, the D.C. Circuit stated, "[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'. . . ."⁷

Numerous indicia demonstrate the competitive nature of this market. For example, clear substitutes to the Exchange exist in the market for options transaction services. The Exchange is only one of eighteen options exchanges to which market participants may direct their order flow. Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing

venues in response to changes in their respective pricing schedules. Within the foregoing context, the proposal represents a reasonable attempt by the Exchange to attract additional order flow to the Exchange and increase its market share relative to its competitors.

The Exchange's proposal to remove the Crossing Fee Cap of \$85,000 within Options 7, Section 4.C and note 8 in Options 7, Section 3 is reasonable because the Exchange no longer seeks to incentivize Members for executing a high volume of Firm Proprietary Crossing Orders on the Exchange. While the Exchange's Crossing Fee Cap could have potentially lowered transaction fees for Members providing liquidity on the Exchange, the program did not attract Members. While the Exchange believed the Crossing Fee Cap would provide additional opportunities for market participants to interact with this Crossing Order Flow, contributing to a robust and competitive market, the Exchange notes that the fee [sic] did not achieve those goals and therefore the Exchange seeks to remove the fee [sic].

The Exchange's proposal to remove the Crossing Fee Cap of \$85,000 in Options 7, Section 4.C and note 8 in Options 7, Section 3 is equitable and not unfairly discriminatory as no Member would be eligible for the Crossing Fee Cap.

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.

Intermarket Competition

The Exchange believes its proposal remains competitive with other options markets, and will offer market participants with another choice of venue to transact options. 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. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

Intramarket Competition

The Exchange's proposal to remove the Crossing Fee Cap of \$85,000 in

Options 7, Section 4.C and note 8 in Options 7, Section 3 does not impose an undue burden on competition as no Member would be eligible for the Crossing Fee Cap.

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.⁸ 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-GEMX-2025-34 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-GEMX-2025-34. 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 filing will be available for inspection and copying at the principal office of the Exchange.

⁵ See 15 U.S.C. 78f(b).

⁶ See 15 U.S.C. 78f(b)(4) and (5).

⁷ See *NetCoalition*, 615 F.3d at 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782-83 (December 9, 2008) (SR-NYSEArca-2006-21)).

⁸ 15 U.S.C. 78s(b)(3)(A)(ii).

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–GEMX–2025–34 and should be submitted on or before January 13, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁹

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025–23671 Filed 12–22–25; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–104461; File No. SR–CboeBZX–2025–165]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 11.9(c)(8) To Clarify Pegged Order Operation and To Align BZX Rule 11.9(c)(8) With the Corresponding Rule of Its Affiliate Exchanges, Cboe EDGA Exchange, Inc. (“EDGA”) and Cboe EDGX Exchange, Inc. (“EDGX”)

December 18, 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 December 16, 2025, Cboe BZX Exchange, Inc. (the “Exchange” or “BZX”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a “non-controversial” proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³ and Rule 19b–4(f)(6) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (“BZX” or the “Exchange”) is filing with the

Securities and Exchange Commission (the “Commission”) a proposed rule change to amend Rule 11.9(c)(8) to clarify Pegged Order operation and to align BZX Rule 11.9(c)(8) with the corresponding rule of its affiliate exchanges, Cboe EDGA Exchange, Inc. (“EDGA”) and Cboe EDGX Exchange, Inc. (“EDGX”). The text of the proposed rule changes is in Exhibit 5.

The text of the proposed rule change is also available on the Commission’s website (<https://www.sec.gov/rules/sro.shtml>), the Exchange’s website (https://www.cboe.com/us/equities/regulation/rule_filings/bzx/), and at the principal office of the Exchange.

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 11.9(c)(8) to clarify Pegged Order operation and to align BZX Rules with the rules of its affiliate exchanges in order to provide consistency amongst the Exchange and its affiliates. The Exchange notes that the proposed rule text is based on EDGA/EDGX Rule 11.6(j) and is different only to the extent necessary to conform to the Exchange’s current rules.⁵ The proposed amendment does not propose to implement new or unique functionality that has not been previously filed with the Commission or is not available on EDGA or EDGX.

By way of background, Exchange Rule 11.9, Orders and Modifiers, lists and describes the types of orders Users⁶

may enter into the System,⁷ including Pegged Orders as described in Exchange Rule 11.9(c)(8). A Pegged Order⁸ is a limit order that after entry into the System, the price of the order is automatically adjusted by the System in response to changes in the NBBO.⁹ A Pegged Order will peg to the NBB or NBO or a certain amount away from the NBB¹⁰ or NBO,¹¹ as described in Exchange Rules 11.9(c)(8)(A) and 11.9(c)(8)(B). Pegged Orders are not eligible for routing pursuant to Exchange Rule 11.13(b).¹² A new time stamp is created for a Pegged Order each time it is automatically adjusted.¹³

A Pegged Order may be a Primary Pegged Order or a Market Pegged Order.¹⁴ A Primary Pegged Order will have its price pegged by the System to the NBB, for a buy order, or the NBO for a sell order.¹⁵ A User may, but is not required to, specify that such order’s price will offset the inside quote on the same side of the market by an amount set by the User (the “Primary Offset Amount”).¹⁶ A Primary Pegged Order is eligible to be displayed or non-displayed, however, the Primary Offset Amount for a displayed Primary Pegged Order must result in the price of such order being inferior to or equal to the inside quote on the same side of the market.¹⁷ A displayed Primary Pegged Order with a Primary Offset Amount shall only include a time-in-force of RHO,¹⁸ or if entered during Regular

authorized to obtain access to the System pursuant to Rule 11.3.

⁷ See Exchange Rule 1.5(aa). The “System” is defined as “the electronic communications and trading facility designated by the Board through which securities orders of Users are consolidated for ranking, execution and, when applicable, routing away.”

⁸ See Rule 11.9(c)(8).

⁹ See Rule 1.5(o). The term “NBBO” shall mean the national best bid or offer.

¹⁰ See Rule 1.5(o). The term “NBB” shall mean the national best bid.

¹¹ See Rule 1.5(o). The term “NBO” shall mean the national best offer.

¹² See Rule 11.9(c)(8).

¹³ *Id.*

¹⁴ *Id.*

¹⁵ See Rule 11.9(c)(8)(A).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ See Rule 11.9(b)(7). A time-in-force of Regular Hours Only (“RHO”) may be applied to a limit or market order that is designated for execution only during Regular Trading Hours, which includes the Opening Auction, the Closing Auction, and IPO/Halt Auctions for BZX listed securities and the Opening Process for non-BZX-listed securities (as such terms are defined in Rule 11.23 and 11.24). Any portion of a market RHO order will be cancelled immediately following any auction in which it is not executed.

⁹ 17 CFR 200.30–3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴ 17 CFR 240.19b–4(f)(6).

⁵ To the extent a proposed rule change is based on existing EDGA and EDGX Rules, the language of the EDGA, EDGX, and Exchange Rules may differ to extent necessary to conform with existing Exchange rule text or to account for details or descriptions included in the Exchange Rules but not currently included in EDGA and EDGX Rules based on the current structure of such rules.

⁶ See Exchange Rule 1.5(cc). A “User” is defined as “any Member or Sponsored Participant who is

Trading Hours,¹⁹ a time-in-force of Day.²⁰

A Market Pegged Order has its price pegged by the System to the NBB, for a sell order, or the NBO, for a buy order.²¹ A User entering a Market Pegged Order can specify that such order's price will offset the inside quote on the contra side of the market by an amount set by the User (the "Offset Amount").²² A Market Pegged Order is not eligible to be displayed on the Exchange.²³

Now, the Exchange proposes to amend the description of a Pegged Order under Rule 11.9(c)(8) to align with EDGA/EDGX Rule 11.6(j) and to clarify that a Pegged Order will not be eligible for execution where the NBB or NBO, as applicable, is no longer available. Further, the proposed rule text will provide that a new timestamp is created for an order that has been ineligible for execution and again becomes eligible for execution because the NBB or NBO it is pegged to becomes available.

Currently, when the NBB or NBO becomes unavailable, a Pegged Order is cancelled back to the User. As proposed, instead of being cancelled back to the User, a Pegged Order will remain on the BZX Book. When the NBB or NBO that the Pegged Order is pegged to becomes available again, the order will receive a new time stamp and be eligible for execution. The proposed rule change provides additional detail with regard to the operation of Pegged Orders when the NBB or NBO, as applicable, is unavailable, that is currently not included in Exchange Rule 11.9(c). This proposed rule change does not propose to implement new or unique functionality that has not been previously filed with the Commission or is not available on EDGA or EDGX.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the "Act") and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.²⁴ Specifically,

the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)²⁵ 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)²⁶ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed rule change is designed to support the principles of Section 11A(a)(1)²⁷ of the Act in that it seeks to assure fair competition among brokers and dealers and among exchange markets.

The proposed rule change is intended to more thoroughly describe Pegged Order operation and to align BZX Rules with the rules of its affiliate exchanges in order to provide consistent offerings amongst the Exchange and its affiliates, which the Exchange believes is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, thereby protecting investors and the public interest. Consistency amongst the rules of the Exchange and its affiliates, in turn, will promote rule compliance for Users of the Exchange that are also participants on EDGA and/or EDGX. The proposed rule change does not propose to implement new or unique functionality that has not been previously filed with the Commission or is not described in the rules of its affiliate exchanges. By aligning BZX Rules with the rules of EDGA and EDGX, the Exchange believes the proposed rule change will remove impediments to the mechanism of a free and open market and protect investors by providing investors with increased transparency regarding rules that reflect the behavior of Pegged Order on the Exchange when the NBB or NBO, as applicable, becomes unavailable. As a result, the Exchange's proposal will 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. Additionally, the proposal does not permit unfair discrimination among customers, brokers, or dealers because the proposed Pegged Order behavior will apply to all Users equally in that any User's Pegged Order will become non-executable in the event that the NBB or NBO, as applicable, becomes unavailable and a Pegged Order will receive a new timestamp when the NBB or NBO becomes available and the order again becomes eligible for execution.

As described above, the proposed amendment is designed to ensure clarity in the Exchange's rulebook with respect to the operation of Pegged Orders in the event that the NBB or NBO, as applicable, becomes unavailable. The Exchange notes that the proposed amendment is based on EDGA/EDGX Rule 11.6(j) and is different only to the extent necessary to conform to the Exchange's current rules. Thus, the proposed amendment to Rule 11.9(c)(8) is directly targeted at removing impediments to and perfecting the mechanism of a free and open market and national market system, as well as to assure fair competition among brokers and dealers and among exchange markets.

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 amendment to clarify Pegged Order behavior will provide consistent offerings amongst the Exchange and its affiliates. The Exchange does not believe the proposed change will have any impact on intermarket competition as the proposal is not being made for competitive reasons, but rather to align the text of BZX Rule 11.9(c)(8) with the corresponding rule text of its affiliate exchanges. In addition, the Exchange believes the proposed rule change will benefit all Users in that Users will have a more complete understanding of Pegged Order behavior when the NBB or NBO, as applicable, becomes unavailable. The proposed rule change will apply equally to all Users of Pegged Orders.

The Exchange does not believe that the proposed amendments will impose any burden on intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange provides services in a highly competitive market in which participants may avail themselves of a wide variety of order types and order operations offered by self-regulatory

¹⁹ See Rule 1.5(w). The term "Regular Trading Hours" means the time between 9:30 a.m. and 4:00 p.m. Eastern Time.

²⁰ See Rule 11.8(b)(2). A time-in-force of Day may be applied to a limit order to buy or sell, which, if not executed, expires at the end of Regular Trading Hours. Any Day Order entered into the System before the opening of business on the Exchange as determined pursuant to Rule 11.1, or after the closing of Regular Trading Hours, will be rejected.

²¹ See Rule 11.9(c)(8)(B).

²² *Id.*

²³ *Id.*

²⁴ 15 U.S.C. 78f(b).

²⁵ 15 U.S.C. 78f(b)(5).

²⁶ *Id.*

²⁷ 15 U.S.C. 78k-1(a)(1).

organizations, other broker-dealers, market participants' own proprietary routing systems, and service bureaus. In such an environment, more detailed descriptions of the types of orders Users may enter into the System, such as the changes proposed in this rule filing do not burden competition, because they can succeed in attracting order flow to the Exchange only if they offer investors higher quality and better value than services offered by others. The Exchange reiterates that the proposed rule change to clarify Pegged Order behavior is being proposed in an effort to add consistency to offerings across the Exchange and its affiliates.

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 comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

- A. significantly affect the protection of investors or the public interest;
- B. impose any significant burden on competition; and

C. become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act²⁸ and Rule 19b-4(f)(6)²⁹ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-CboeBZX-2025-165 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-CboeBZX-2025-165. 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 filing 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-CboeBZX-2025-165 and should be submitted on or before January 13, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁰

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-23661 Filed 12-22-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104450; File No. SR-NASDAQ-2025-068]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Modify Certain Initial Listing Requirements

December 18, 2025.

I. Introduction

On September 4, 2025, the Nasdaq Stock Market LLC ("Exchange" or "Nasdaq") 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 modify certain initial and continued listing requirements in Nasdaq Listing Rules 5405, 5505, 5810, and 5815. The proposed rule change was published for comment in the **Federal Register** on September 19, 2025.³ On September 25, 2025, pursuant to Section 19(b)(2) of the Act,⁴ the Commission designated a longer period within which to take action on the proposed rule change.⁵ On December 11, 2025, the Exchange filed Amendment No. 1 to the proposed rule change, which superseded the original proposed rule change in its entirety.⁶ The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No. 1, from interested persons and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. Description of the Proposed Rule Change, as Modified by Amendment No. 1⁷

Nasdaq Listing Rules require that a company applying for initial listing on the Exchange must have a minimum Market Value of Unrestricted Publicly Held Shares ("MVUPHS").⁸ For initial

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 103982 (Sept. 16, 2025), 90 FR 45280 ("Notice"). Comments received on the Notice are available at: <https://www.sec.gov/comments/sr-nasdaq-2025-068/srnasdaq2025068.htm>.

⁴ 15 U.S.C. 78s(b)(2).

⁵ See Securities Exchange Act Release No. 104057, 90 FR 47028 (Sept. 30, 2025). The Commission designated December 18, 2025, as the date by which the Commission shall approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change. See *id.*

⁶ Amendment No. 1 to the proposed rule change revised the proposal by: (1) removing the proposed modifications to Nasdaq Rules 5810 and 5815 that would have accelerated suspension and delisting of any company that becomes non-compliant with certain quantitative listing requirements and has a market value of listed securities of less than \$5 million for a period of 10 consecutive business days ("Accelerated Suspension and Delisting Proposal"); (2) providing additional description and support for certain aspects of the proposal; and (3) making other technical and non-substantive changes for readability. The full text of Amendment No. 1 can be found on the Commission's website at: <https://www.sec.gov/comments/sr-nasdaq-2025-068/srnasdaq2025068-683867-2114774.pdf>.

⁷ All capitalized terms not otherwise defined in this order shall have the meanings set forth in the Nasdaq Listing Rules.

⁸ Unrestricted Publicly Held Shares are shares that are not held by an officer, director, or 10% shareholder of the company and which are not subject to resale restrictions of any kind. See Nasdaq Rule 5005(a)(46). See also Nasdaq Rules 5005(a)(23), 5005(a)(35), 5005(a)(38), and 5005(a)(47) for the definitions of "Market Value," "Publicly Held Shares," "Restricted Securities,"

²⁸ 15 U.S.C. 78s(b)(3)(A).

²⁹ 17 CFR 240.19b-4(f)(6).

³⁰ 17 CFR 200.30-3(a)(12).

listing on the Nasdaq Global Market, a company must have a minimum MVUPHS of \$8 million under the Income Standard, \$18 million under the Equity Standard, and \$20 million under either the Market Value or Total Assets/Total Revenue Standards.⁹ For initial listing on the Nasdaq Capital Market, a company must have a minimum MVUPHS of \$5 million under the Net Income Standard, and \$15 million under either the Equity or Market Value of Listed Securities Standards.¹⁰

The Exchange recently modified the liquidity requirements for the initial listing of companies listing in conjunction with an IPO such that shares registered for resale are no longer counted for purposes of satisfying the minimum MVUPHS requirement.¹¹ As a result, a new company listing in connection with an IPO must meet the MVUPHS requirement based on shares being sold in the offering.¹² The Exchange states that, following this change, it has observed an increase in the number of companies applying for initial listing based on Nasdaq's net income-based requirements, which require a lower MVUPHS than the other standards.¹³ The Exchange states that it has observed problematic trading in companies with low public floats and liquidity, and the Exchange is concerned that companies initially listing with just \$5 million or \$8 million

and "Unrestricted Securities." The Exchange states that, like other liquidity requirements, the MVUPHS standard is meant to ensure that there is sufficient liquidity to provide price discovery and support an efficient and orderly market for the company's securities. *See* Notice, *supra* note 3, at 45281.

⁹ *See* Nasdaq Rules 5405(b)(1)(C), 5405(b)(2)(C), 5405(b)(3)(B), and 5405(b)(4)(B).

¹⁰ *See* Nasdaq Rules 5505(b)(1)(B), 5505(b)(2)(C), and 5505(b)(3)(C). For a Company listing in connection with an initial public offering ("IPO"), including through the issuance of American Depositary Receipts, these requirements must be satisfied from the offering proceeds. *See* Nasdaq Rules 5405(b)(1)(C), 5405(b)(2)(C), 5405(b)(3)(B), 5405(b)(4)(B), 5505(b)(1)(B), 5505(b)(2)(C), and 5505(b)(3)(C).

¹¹ *See* Securities Exchange Act Release No. 102622 (Mar. 12, 2025), 90 FR 12608 (Mar. 18, 2025) (SR-NASDAQ-2024-084) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Modify Certain Initial Listing Requirements).

¹² The Exchange states that when it made this change, it did not increase any of the numeric requirements for MVUPHS under any of the listing standards. *See* Notice, *supra* note 3, at 45281.

¹³ *See id.* The Exchange states that, prior to the new rule taking effect, less than one-third of companies on the Nasdaq Capital Market listed under the Net Income Standard. *See id.* at 45281, n.7. Since March 2025, when the change requiring companies to satisfy the MVUPHS requirement by proceeds of the IPO took effect, nearly three-quarters of companies listing on the Nasdaq Capital Market have listed under the Net Income Standard. *See* Amendment No. 1, *supra* note 6, at 6, n.11.

MVUPHS on the Nasdaq Capital or Global Market, respectively, may not trade in a manner supportive of price discovery.¹⁴

Accordingly, the Exchange proposes to modify Nasdaq Rule 5505(b)(3)(C) to increase the minimum MVUPHS for companies listing under the Net Income Standard on the Nasdaq Capital Market from \$5 million to \$15 million.¹⁵ The Exchange also proposes to modify Nasdaq Rule 5405(b)(1)(C) to increase the minimum MVUPHS for companies listing under the Income Standard on the Nasdaq Global Market from \$8 million to \$15 million.¹⁶ The Exchange states that it believes that these proposed changes will help ensure that there is a sufficient initial pool of liquidity available to support liquid trading on the Exchange.¹⁷

The Exchange states that the proposed change will become operative 30 days after approval by the Commission.¹⁸

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.¹⁹ In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act,²⁰ which requires, among other things, 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 remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The development and enforcement of meaningful listing standards²¹ for an exchange is of critical importance to

financial markets and the investing public. Among other things, such listing standards help ensure that exchange-listed companies will have sufficient public float, investor base, and trading interest to provide the depth and liquidity to promote fair and orderly markets. Meaningful listing standards also are important given investor expectations regarding the nature of securities that have achieved an exchange listing, and the role of an exchange in overseeing its market and assuring compliance with its listing standards.²²

The Exchange has proposed to make more rigorous certain of its initial listing standards for the Nasdaq Global Market and Nasdaq Capital Market to address recent market observations²³ and help ensure that an adequate level of liquidity exists for securities that are listing on the Exchange. As discussed above, the Exchange's proposal will align the initial listing standards for minimum MVUPHS on the Nasdaq Capital Market by increasing the requirement for companies listing under the Net Income Standard from \$5 million to \$15 million.²⁴ The Exchange's proposal will also increase the minimum MVUPHS under the Income Standard on the Nasdaq Global Market from \$8 million to \$15 million, thus ensuring that the net income-based standard on the Nasdaq Global Market is not lower than the standard on the Nasdaq Capital Market.²⁵

According to the Exchange, companies listing under different initial

²² *See, e.g.*, Securities Exchange Act Release Nos. 88716 (Apr. 21, 2020), 85 FR 23393 (Apr. 27, 2020) (SR-NASDAQ-2020-001) (Order Approving a Proposed Rule Change To Modify the Delisting Process for Securities With a Bid Price at or Below \$0.10 and for Securities That Have Had One or More Reverse Stock Splits With a Cumulative Ratio of 250 Shares or More to One Over the Prior Two-Year Period); 88389 (Mar. 16, 2020), 85 FR 16163 (Mar. 20, 2020) (SR-NASDAQ-2019-089) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Amend Rule 5815 To Preclude Stay During Hearing Panel Review of Staff Delisting Determinations in Certain Circumstances). *See also* Securities Exchange Act Release No. 81856 (Oct. 11, 2017), 82 FR 48296, 48298 (Oct. 17, 2017) (SR-NYSE-2017-31) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Amend the Listed Company Manual To Adopt Initial and Continued Listing Standards for Subscription Receipts) (stating that "[a]dequate standards are especially important given the expectations of investors regarding exchange trading and the imprimatur of listing on a particular market" and that "[o]nce a security has been approved for initial listing, maintenance criteria allow an exchange to monitor the status and trading characteristics of that issue . . . so that fair and orderly markets can be maintained").

²³ *See supra* note 13 and accompanying text.

²⁴ *See supra* note 15 and accompanying text.

²⁵ *See supra* note 16 and accompanying text.

¹⁴ *See* Notice, *supra* note 3, at 45281.

¹⁵ The Exchange states that this change will align the MVUPHS requirement across all of the initial listing standards on the Nasdaq Capital Market. *See id.*

¹⁶ The Exchange states that this change will avoid having a lower standard on the Nasdaq Global Market than on the Nasdaq Capital Market. *See id.*

¹⁷ *See id.*

¹⁸ *See id.* at 45282.

¹⁹ In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

²⁰ 15 U.S.C. 78f(b)(5).

²¹ The Commission notes that this reference to "listing standards" is referring to both initial and continued listing standards.

listing requirements that meet the \$15 million MVUPHS requirement are less likely to be subject to volatile trading than similarly situated companies that meet the lower requirement for companies listing under the net income-based standard.²⁶ The Exchange states that the MVUPHS is an indicator of sufficient liquidity to help provide price discovery and reduce volatility.²⁷ However, based on observed problems with the trading of smaller companies, the Exchange states that it no longer believes it is appropriate to require such a significantly lower liquidity threshold for companies simply because they have a minimum level of net income, as opposed to companies that qualify for initial listing based on an equity or market value standard.²⁸

The Exchange's proposal is reasonably designed to enhance its initial listing standards, particularly those involving issuers with low public float and liquidity, thereby protecting investors and the public interest. The proposal reasonably addresses a gap in the Exchange's liquidity requirements for initial listing that potentially allows issuers that may not have sufficient levels of liquidity to list on the Exchange. Accordingly, the proposal should help to ensure that the Exchange lists only securities with a sufficient public float, investor base, and trading interest to provide the depth and liquidity to promote fair and orderly markets.²⁹ For these reasons, the

²⁶ See Notice, *supra* note 3, at 45282.

²⁷ See Amendment No. 1, *supra* note 6, at 6.

²⁸ See Notice, *supra* note 3, at 45282. See also *supra* note 8. One commenter stated that the proposal should be approved and that it supported the proposed change to initial listing requirements "directionally insofar as it closes a loophole." Letter from Jeffrey Starr, Managing Director, Head of Operations, Charles Schwab & Co., dated Dec. 16, 2025 ("Schwab Letter"). This commenter stated that the Exchange should raise the initial listing criteria for listing on the Nasdaq Capital Market and adjust the minimum standards for all tiers upwards accordingly. See *id.* at 3. These additional recommendations are not before the Commission in the proposal being considered herein.

²⁹ The Commission also received comment letters addressing the Accelerated Suspension and Delisting Proposal and raising other concerns related to issues in trading exchange-listed low-priced stocks that fail to meet continued listing standards. See Schwab Letter; Letters from Katie Kolchin, CFA, Managing Director, Head of Equity & Options Market Structure, and Gerald O'Hara, Vice President & Assistant General Counsel, SIFMA, dated Nov. 14, 2025; Stephen John Berger, Managing Director, Global Head of Government & Regulatory Policy, Citadel Securities, dated Dec. 3, 2025. See also Letter from Kenneth E. Bentsen Jr., President & CEO, SIFMA, dated Sept. 18, 2025, at 4, n.13. The Exchange stated that it is considering the commenters' proposed enhancements to the Accelerated Suspension and Delisting Proposal, and intends to resubmit a proposal to promptly suspend and delist companies that fail to meet minimum

Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act.

IV. Solicitation of Comments on Amendment No. 1 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning 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-NASDAQ-2025-068 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-2025-068. 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 filing 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-2025-068 and should be submitted on or before January 13, 2026.

V. Accelerated Approval of the Proposed Rule Change, as Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as

market value requirements. See Amendment No. 1, *supra* note 6, at 4, n.4. As discussed above, Amendment No. 1 removed the Accelerated Suspension and Delisting Proposal from the proposed rule change. See *supra* note 6. Thus, the areas of concern raised by the commenters are not before the Commission in the proposal being considered herein. In approving this proposal, the Commission is finding the proposal before us consistent with the Act.

modified by Amendment No. 1, prior to the thirtieth day after the date of publication of notice of the filing of Amendment No. 1 in the **Federal Register**. Amendment No. 1 narrows the scope of the proposed rule change and sets forth additional support and detail regarding the proposal. These changes include (1) removing the Accelerated Suspension and Delisting Proposal; (2) providing additional description and support for certain aspects of the proposal; and (3) making other technical and non-substantive changes for readability. Amendment No. 1 does not alter any substantive provisions of the remaining parts of the proposed rule change from what is set forth in the Notice, which was subject to public comment.³⁰

The Commission finds that Amendment No. 1 does not raise any novel regulatory issues that have not previously been subject to comment and is reasonably designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,³¹ to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,³² that the proposed rule change (SR-NASDAQ-2025-068), as modified by Amendment No. 1, be and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³³

Sherry R. Haywood,
Assistant Secretary.

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³⁰ The one commenter that addressed the proposed increase to initial listing requirements supported that aspect of the proposal. See *supra* note 28. The other comments received on the Notice focused on the Accelerated Suspension and Delisting Proposal, which has been removed. See *supra* note 29.

³¹ 15 U.S.C. 78s(b)(2).

³² *Id.*

³³ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–104458; File No. SR–PEARL–2025–49]

Self-Regulatory Organizations; MIAx PEARL, LLC; Notice of Filing of a Proposed Rule Change To Amend Exchange Rule 402, Criteria for Underlying Securities, To List and Trade Options on Commodity-Based Trust Shares

December 18, 2025.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b–4 thereunder,² notice is hereby given that on December 5, 2025, MIAx PEARL, LLC (“MIAx Pearl” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) a proposed rule change as described in Items I and II below, which Items have been prepared by MIAx Pearl. 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 Exchange Rule 402, Criteria for Underlying Securities, to permit options on Commodity-Based Trust Shares. Specifically, the Exchange proposes to amend the rule to (1) redefine Commodity-Based Trust; (2) require additional qualifying criteria, based on the criteria outlined by the primary listing market to list options on a Commodity-Based Trust; and (3) require that the crypto asset held by the Commodity-Based Trust have a comprehensive surveillance sharing agreement. This filing also defines a crypto asset. Additionally, this filing proposes to amend Exchange Rule 403(g) to update the relevant citations to Exchange Rule 402, which are revised pursuant to this filing.

The text of the proposed rule change is available on the Exchange’s website at <https://www.miaxglobal.com/markets/us-equities/pearl-equities/rule-filings> and at MIAx Pearl’s principal office.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, MIAx Pearl 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. MIAx Pearl has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its listing rules at Exchange Rule 402, Criteria for Underlying Securities.³ Specifically, the Exchange proposes to amend the criteria for listing options on Exchange-Traded Fund Shares (“ETFs”) at Exchange Rule 402(i). This is a competitive filing substantively identical to the proposal submitted by Nasdaq ISE, LLC (“ISE”) to the Securities and Exchange Commission (the “Commission”), which was recently deemed approved.⁴

The Exchange initially filed SR–PEARL–2025–08, as Modified by Partial Amendment Nos. 1 and 2, a proposed rule change to amend its listing rules at Exchange Rule 402, Criteria for Underlying Securities, to allow the listing and trading of options on interests in a Commodity-Based Trust on March 5, 2025, which was published in the Federal Register [sic] on March 19, 2025.⁵ On April 25, 2025, the Commission issued a notice designating a longer period for Commission action, which designated June 17, 2025, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove the filing.⁶ On

³ The Exchange notes that its affiliate options exchanges, Miami International Securities Exchange, LLC (“MIAx”) and MIAx Sapphire, LLC (“MIAx Sapphire”), submitted (or will submit) substantively similar proposals. The Exchange notes that the rules of Chapter IV of MIAx, including Exchange Rule 402, are incorporated by reference into the MIAx Emerald, LLC (“MIAx Emerald”) rulebook.

⁴ See Securities Exchange Act Release No. 102465 (February 7, 2025), 90 FR 10740 (February 26, 2025) (SR–ISE–2025–08) (Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, to Adopt Listing Criteria for Options on a Commodity-Based Trust) [sic].

⁵ See Securities Exchange Act Release No. 102659 (March 5, 2025), 90 FR 12876 (March 19, 2025) (SR–PEARL–2025–08) (Self-Regulatory Organizations; Notice of Filing of a Proposed Rule Change, as Modified by Partial Amendment Nos. 1 and 2, by MIAx PEARL, LLC To Amend Exchange Rule 402, Criteria for Underlying Securities, To List and Trade Options on Commodity-Based Trust Share).

⁶ See Securities Exchange Act Release No. 102929 (April 25, 2025), 90 FR 18718 (May 1, 2025) (SR–

PEARL–2025–08) (Self-Regulatory Organizations; MIAx PEARL, LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change, as Modified by Partial Amendment Nos. 1 and 2, To Amend Exchange Rule 402, Criteria for Underlying Securities, To List and Trade Options on Commodity-Based Trust Shares).

⁷ See Securities Exchange Act Release No. 103283 (June 17, 2025), 90 FR 26634 (June 23, 2025) (SR–PEARL–2025–08) (Self-Regulatory Organizations; Miami International Securities Exchange, LLC; MIAx PEARL, LLC; MIAx Sapphire, LLC; Order Instituting Proceedings To Determine Whether To Approve or Disapprove Proposed Rule Changes, as Modified by Partial Amendments Thereto, To Amend Rule 402, Criteria for Underlying Securities, To List and Trade Options on Commodity-Based Trust Shares).

⁸ See Securities Exchange Act Release No. 103903 (September 8, 2025), 90 FR 44123 (September 11, 2025) (SR–PEARL–2025–08) (Self-Regulatory Organizations; Miami International Securities Exchange, LLC; MIAx PEARL, LLC; MIAx Sapphire, 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 Partial Amendments Thereto, To Amend Rule 402, Criteria for Underlying Securities, To List and Trade Options on Commodity-Based Trust Shares).

⁹ See Securities Exchange Act Release No. 104210 (November 18, 2025), 90 FR 52727 (November 21, 2025) (SR–PEARL–2025–08) (Self-Regulatory Organizations; BOX Exchange LLC, Cboe Exchange, Inc., Cboe BYX Exchange, Inc., Cboe BZX Exchange, Inc., Cboe EDGX Exchange, Inc., Miami International Securities Exchange, LLC, MIAx PEARL, LLC, MIAx Sapphire, LLC, Nasdaq ISE, LLC, New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE National, Inc., and NYSE Texas, Inc.; Notice of Deemed Approval of Various Proposed Rule Changes).

The Exchange proposes to amend Rule 402 to adopt new listing criteria in

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

subparagraph (i)(6) to permit the listing and trading of options on a Commodity-Based Trust that meets the generic listing standards for Commodity-Based Trust Shares of the applicable primary listing market, except that the Commodity-Based Trust holds a single crypto asset.¹⁰

On September 17, 2025, the Commission approved proposals by The Nasdaq Stock Market LLC, Cboe BZX Exchange, Inc. and NYSE Arca, Inc., to Adopt Generic Listing Standards for Commodity-Based Trusts.¹¹ In the approval order, the Commission noted that each of the exchanges proposed to adopt substantially identical “generic” listing standards for Commodity-Based Trusts. Those generic listing standards define the term shares of a “Commodity-Based Trust” as a security¹² that:

(1) is issued by a trust, limited liability company, partnership, or other similar entity (“Trust”) that, if applicable, is operated by a registered commodity pool operator pursuant to the Commodity Exchange Act (“CEA”), and is not registered as an investment company pursuant to the Investment Company Act of 1940, or series or class thereof;

(2) is designed to reflect the performance of one or more reference assets or an index of reference assets;

(3) in order to reflect the performance, is issued by a Trust that holds (a) one or more commodities or commodity-based assets, and (b) in addition to such commodities or commodity-based assets, may hold securities, cash, and cash equivalents;

(4) is issued by such Trust in a specified aggregate minimum number in return for a deposit of (a) a specified quantity of the underlying commodities, commodity-based assets, securities, cash, and/or cash equivalents or (b) a cash amount with a value based on the next determined net asset value per Trust share; and

(5) when aggregated in the same specified minimum number, may be redeemed at a holder’s request by such Trust which will deliver to the redeeming holder (a) the specified quantity of the underlying commodities, commodity-based assets, securities, cash, and/or cash equivalents or (b) a cash amount with a value based on the next determined net asset value per Trust share.

The Exchange proposes to amend Exchange Rule 402(i) to create a new subparagraph (6)(iii) that states,¹³

Additionally, with respect to a Commodity-Based Trust that meets the requirements of Exchange Rule 402(i)(6), the following requirements are satisfied: (A) the total global supply of the underlying crypto a held by the Commodity-Based Trust has an average daily market value of at least \$700 million over the last 12 months; and (B) the crypto asset held by the Commodity-Based Trust underlies a derivatives contract that trades on a market with which the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in the Intermarket Surveillance Group. For purposes of this rule the term “crypto asset” means an asset that is generated, issued and/or transferred using a blockchain or similar distributive ledger technology network, including but not limited to, assets known as “tokens,” “digital assets,” “virtual currencies,” and “coins” and that relies on cryptographic protocols.

The proposed additional criteria would require a Commodity-Based Trust to: (1) meet the generic criteria for Commodity-Based Trust Shares of the applicable primary listing market and hold only a single crypto asset; (2) meet

the criteria and guidelines set forth in Exchange Rule 402(a)¹⁴ and (b),¹⁵ or Exchange Rule 402(i)(6)(i)(B);¹⁶ and meet the requirements in 402(i)(6)(iii) prior to listing options on the Commodity-Based Trust.

As proposed, Exchange Rule 402(i)(6)(iii) requires Commodity-Based Trust that meets the requirements of 402(i)(6) to also satisfy the following requirements: (A) the total global supply of the underlying crypto asset held by the Commodity-Based Trust has an average daily market value of at least \$700 million over the last 12 months; and (B) the crypto asset held by the Commodity-Based Trust underlies a derivatives contract that trades on a market with which the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in the Intermarket Surveillance Group (“ISG”).

The Exchange defines a “crypto asset” at Exchange Rule 402(i)(6)(iii) to mean, for purposes of this rule, an asset that is generated, issued and/or transferred using a blockchain or similar distributive ledger technology network, including but not limited to, assets known as “tokens,” “digital assets,” “virtual currencies,” and “coins” and that relies on cryptographic protocols.

The market value of the underlying crypto asset will be calculated by taking the total global supply of the particular crypto asset multiplied by the token price.¹⁷ Total supply of crypto assets includes all crypto assets currently

¹⁰ For example, a multi-coin ETF would not be subject to Exchange Rule 402(i)(6). For purposes of this rule the term “crypto asset” means an asset that is generated, issued and/or transferred using a blockchain or similar distributive ledger technology network, including but not limited to, assets known as “tokens,” “digital assets,” “virtual currencies,” and “coins” and that relies on cryptographic protocols. See definition at proposed Exchange Rule 402(i)(6)(iii).

¹¹ See Securities Exchange Act Release No. 103995 (Sept. 17, 2025), 90 FR 45414 (Sept. 22, 2025) (Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Cboe BZX Exchange, Inc.; NYSE Arca, Inc.; Order Granting Accelerated Approval of Proposed Rule Changes, as Modified by Amendments Thereto, To Adopt Generic Listing Standards for Commodity-Based Trust Shares) (SR-NASDAQ-2025-056; SR-CboeBZX-2025-104; SR-NYSEARCA-2025-54) (“Generic Listing Standards for Commodity-Based Trust Shares Approval”). The Exchange believes that it is appropriate to rely on the generic listing standards outlined by the primary listing market due to the potential proliferation of new primary listing markets and the Commission’s acknowledgment that the definition of shares of a Commodity-Based Trust across those primary listing markets is substantially identical.

¹² Shares of the applicable Commodity-Based Trust trade as equity securities. See Securities Exchange Act Release No. 50603 (Oct. 28, 2004), 69 FR 64614, 64619 (Nov. 5, 2004) (SR-NYSE-2004-22) (approving the listing and trading of streetTRACKS Gold Shares) (“Spot Gold Approval Order”) and ETP Request for Comments, *infra* note 20, at 34731. See also Nasdaq Rule 5711(d)(ii); proposed BZX Rule 14.11(e)(4)(B); proposed NYSE Arca Rule 8.201-E(b) (Generic) (stating that Commodity-Based Trust Shares are included within the definition of a “security” as such term is used in the Exchanges’ rules and are subject to the Exchanges’ existing rules governing the trading of equity securities).

¹³ The Exchange proposes to renumber current Exchange Rules 402(i)(5)(i) and 402(i)(5)(ii) to Exchange Rules 402(i)(6)(i) and 402(i)(6)(ii) for ease of reference, clarity, and consistency of the Rulebook.

¹⁴ Exchange Rule 402(a) provides that a security (which includes an ETF) on which options may be listed and traded on the Exchange must be a security registered (with the Commission) and be an NMS stock (as defined in Rule 600 of Regulation NMS under the Act), and the security shall be characterized by a substantial number of outstanding shares that are widely held and actively traded.

¹⁵ Exchange Rule 402(b) provides criteria and guidelines when evaluating potential underlying securities for the listing of options.

¹⁶ Exchange Rule 402(i)(6)(i)(B) provides that the Exchange-Traded Fund Shares are available for creation or redemption each business day from or through the issuing trust, investment company, commodity pool or other entity in cash or in kind at a price related to net asset value, and the issuer is obligated to issue Exchange-Traded Fund Shares in a specified aggregate number even if some or all of the investment assets and/or cash required to be deposited have not been received by the issuer, subject to the condition that the person obligated to deposit the investment assets has undertaken to deliver them 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 of the Exchange-Traded Fund Shares, all as described in the Exchange-Traded Fund Shares’ prospectus.

¹⁷ The market supply information can be obtained from publicly available sources such as coingecko.com or coinmarketcap.com.

issued and does not include unissued crypto assets.¹⁸

Further, the Exchange has specified in proposed Exchange Rule 402(i)(6)(iii) that the crypto asset held by the Commodity-Based Trust must underlie a derivatives contract that trades on a market with which the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in ISG.¹⁹ The Exchange will be required to ensure that this requirement is met prior to listing options on a Commodity-Based Trust pursuant to proposed Exchange Rule 402(i)(6).

As a result of this filing, the proposed listing criteria would permit a Commodity Based Trust that is generically listed on the applicable primary listing market and holds a single crypto asset to qualify for the listing of options on that ETF, provided Exchange Rule 402(i)(6)(iii) has also been met, as well as the listing criteria in Exchange Rule 402(a) and (b), or Exchange Rule 402(i)(6)(i)(B).

Similar to options on any ETF, an option on a Commodity-Based Trust that meets the requirements of Exchange Rule 402(i)(6) would also be subject to the Exchange's continued listing standards for options on ETFs set forth in Exchange Rule 403(g). Pursuant to Exchange Rule 403(g), ETFs approved for options trading pursuant to Exchange Rule 402(i) will not be deemed 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 ETFs, if the ETFs are delisted from trading pursuant to Exchange Rule 403(b)(4),²⁰ are halted or suspended from trading in their primary market.²¹ Additionally, options on ETFs

may be subject to the suspension of opening transactions in any of the following circumstances:²²

(1) in the case of options covering ETFs approved for trading under Exchange Rule 402(i)(6)(i)(A), in accordance with the terms of paragraphs (b)(1), (2), and (3) of Exchange Rule 403;²³

(2) in the case of options covering ETFs approved for trading under Exchange Rule 402(i)(6)(i)(B), following the initial twelve-month period beginning upon the commencement of trading in the ETFs on a national securities exchange and are defined as an NMS stock, there are fewer than 50 record and/or beneficial holders of such ETFs 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 ETFs 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.

Consistent with current Exchange Rule 404, which governs the opening of options series on a specific underlying security (including ETFs), the Exchange will open at least one expiration month²⁴ for options on a Commodity-

Rule 403(g) to reflect the changes in numbering proposed herein for Exchange Rule 402(i).

²² See *id.*

²³ Exchange Rule 403(b)(1) through (3) provides, if: (1) there are fewer than 6,300,000 shares of the underlying security held by persons other than those who are required to report their security holdings under Section 16(a) of the Act, (2) there are fewer than 1,600 holders of the underlying security, (3) the trading volume (in all markets in which the underlying security is traded) has been less than 1,800,000 shares in the preceding twelve (12) months.

²⁴ See Exchange Rule 404(b). The monthly expirations are subject to certain listing criteria for underlying securities described within Exchange Rule 404 and its Interpretations and Policies. 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 Exchange Rule 404(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

Based Trust that are approved subject to Exchange Rule 402(i)(6) and may also list series of options on Commodity-Based Trust Share for trading on a weekly,²⁵ monthly,²⁶ or quarterly²⁷ basis. The Exchange may also list long-term equity option series ("LEAPS") that expire from 12 to 39 months from the time they are listed.²⁸

Pursuant to Exchange Rule 404, Interpretation and Policy .06, which governs strike prices of series of options on ETFs, the interval between strike prices of series of options on ETFs approved for options trading pursuant to Exchange Rule 402(i) shall be fixed at a price per share which is reasonably close to the price per share at which the underlying security is traded in the primary market at or about the same time such series of options is first open for trading on the Exchange, or at such intervals as may have been established on another options exchange prior to the initiation of trading on the Exchange. With respect to the Short Term Options Series or Weekly Program, during the month prior to expiration of an option class that is selected for the Short Term Option Series Program, the strike price intervals for the related non-Short Term Option ("Related non-Short Term Option") shall be the same as the strike price intervals for the Short Term Option.²⁹ Specifically, the Exchange may open for trading Short Term Option Series at strike price intervals of (i) \$0.50 or greater where the strike price is less than \$100, and \$1 or greater where the strike price is between \$100 and \$150 for all option classes that participate in the Short Term Options Series Program; (ii) \$0.50 for option classes that trade in one dollar increments and are in the Short Term Option Series Program; or (iii) \$2.50 or greater where the strike price is above \$150.³⁰ Additionally, the Exchange may list series of options pursuant to the \$1

from the initial exercise price or prices. Pursuant to Exchange Rule 404(e), 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.

²⁵ See Exchange Rule 404, Interpretation and Policy .02.

²⁶ See Exchange Rule 404, Interpretation and Policy .13.

²⁷ See Exchange Rule 404, Interpretation and Policy .03.

²⁸ See Exchange Rule 406.

²⁹ See Exchange Rule 404, Interpretation and Policy .02(e).

³⁰ *Id.*

¹⁸ For example, if Bitcoin were the underlying crypto asset, the Exchange would consider the total supply of all Bitcoin currently issued instead of the maximum supply, which would be currently issued as well as unmined Bitcoin. As of September 12, 2025, Bitcoin's total supply was 19,919,915 (the maximum supply was 21,000,000). See <https://www.coingecko.com/en/coins/bitcoin>. The Exchange would calculate market value by utilizing the total supply number multiplied by the Bitcoin price on that day.

¹⁹ For a list of the current members and affiliate members [sic] of ISG, see <https://isgportal.org/publicmembers>.

²⁰ Exchange Rule 403(b)(5) provides, if an underlying security is approved for options listing and trading under the provisions of Rule 402(c), the trading volume of the Original Equity Security (as therein defined) prior to but not after the commencement of trading in the Restructure Security (as therein defined), including "when-issued" trading, may be taken into account in determining whether the trading volume requirement of subparagraph (3) is satisfied.

²¹ See Exchange Rule 403(g). With this filing the Exchange is also proposing to amend Exchange

Strike Price Interval Program,³¹ the \$0.50 Strike Program,³² and the \$2.50 Strike Price Program.³³ Pursuant to Exchange Rule 510, where the price of a series of options on a Commodity-Based Trust 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 \$0.10³⁴ consistent with the minimum increments for options on other ETFs listed on the Exchange. Any and all new series of a [sic] Commodity-Based Trust options that the Exchange lists will be consistent and comply with the expirations, strike prices, and minimum increments set forth in Rules 404 and 510, as applicable.

Further, options on a [sic] Commodity-Based Trusts that are approved subject to Exchange Rule 402(i)(6) would trade in the same manner as options on other ETFs on the Exchange. The Exchange Rules that currently apply to the listing and trading of all options on ETFs on the Exchange, including, for example, Rules that govern listing criteria, expirations, exercise prices, minimum increments, position and exercise limits, margin requirements, customer accounts and trading halt procedures would apply to the listing and trading of options on Commodity-Based Trusts that are approved subject to Exchange Rule 402(i)(6) in the same manner.

Position and exercise limits for options on Commodity-Based Trusts that are approved pursuant to Exchange Rule 402(i)(6) would be determined pursuant to Exchange Rules 307 and 309, respectively, as is the case for other options on other ETFs. Position and exercise limits for options on ETF vary according to the number of outstanding shares and the trading volumes of the underlying ETF over the past six months, where the largest in capitalization and the most frequently traded ETFs have an option position and exercise limits of 250,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market; and smaller capitalization ETFs have position and exercise limits of 200,000, 75,000, 50,000 or 25,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market. Further, Exchange Rule 1502, which governs margin requirements applicable to trading on the Exchange, including options on

ETFs, will also apply to the trading of options on a [sic] Commodity-Based Trusts listed pursuant to Exchange Rule 402(i)(6).

The Exchange represents that the same surveillance procedures applicable to all other options on other ETFs currently listed and traded on the Exchange will apply to the trading of options on Commodity-Based Trusts that are approved subject to Exchange Rule 402(i)(6).³⁵ The Exchange represents that it has the necessary systems capacity to support the new option series. The Exchange believes that its existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior which might potentially arise from listing and trading options on ETFs, including the listing of options on Commodity-Based Trusts that are approved subject to Exchange Rule 402(i)(6). Also, the Exchange may obtain information from designated contract markets that are members of the ISG related to a financial instrument that is based, in whole or in part, upon an interest in or performance of a crypto asset, as applicable. The Exchange has specified in proposed Exchange Rule 402(i)(6) that the crypto asset held by the Commodity-Based Trust must underlie a derivatives contract that trades on a market with which the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in ISG.³⁶ The Exchange will be required to ensure that this requirement is met prior to listing options on a Commodity-Based Trust listed pursuant to proposed Exchange Rule 402(i)(6).

Additionally, the Exchange has also analyzed its capacity and represents that it believes the Exchange and the Options Price Reporting Authority or "OPRA" have the necessary systems capacity to handle the additional traffic associated with the listing of new series of ETFs, including options on a [sic] Commodity-Based Trusts, that are approved subject to Exchange Rule 402(i)(6), up to the number of expirations currently permissible under the Exchange Rules.

Finally, today, the Exchange lists and trades options on ETFs that would

qualify for listing as an option on a Commodity-Based Trust under proposed Exchange Rule 402(i)(6),³⁷ and it has not identified any issues with the listing and trading of options on those ETFs.

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.³⁸ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)³⁹ 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)⁴⁰ 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 its proposal to establish new listing criteria at Exchange Rule 402(i)(6) with respect to options on Commodity-Based Trusts, without the need for additional approvals, 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 it would allow the Exchange to immediately list and trade qualifying options on Commodity-Based Trusts, provided the initial listing criteria has been met, without any additional approvals from the Commission.

Specifically, the Exchange's proposal to adopt Exchange Rule 402(i)(6) to allow the listing and trading of options on units that represent interests in Commodity-Based Trusts that meet the generic listing standards for

³⁷ The following ETFs currently have options listed on them on the Exchange: iShares Bitcoin Trust, the Fidelity Wise Origin Bitcoin Fund, the ARK21Shares Bitcoin ETF, the Grayscale Bitcoin Trust (BTC), the Grayscale Bitcoin Mini Trust BTC, and the Bitwise Bitcoin ETF. See Exchange Rule 402(i)(4). The Exchange filed rule proposals and received the appropriate regulatory notice or approval to list the aforementioned options on the ETFs.

³⁸ 15 U.S.C. 78f(b).

³⁹ 15 U.S.C. 78f(b)(5).

⁴⁰ *Id.*

³¹ See Exchange Rule 404, Interpretation and Policy .01.

³² See Exchange Rule 404, Interpretation and Policy .04.

³³ See Exchange Rule 404(f).

³⁴ See Exchange Rule 510.

³⁵ The surveillance program includes real-time patterns for price and volume movements and post-trade surveillance patterns (e.g., spoofing, marking the close, ping, phishing).

³⁶ There are a number of futures contracts on digital asset commodities that are listed and trading on the CME and Coinbase Derivatives, both of which are ISG members. See <https://www.cmegroup.com/markets/cryptocurrencies.html#products>. See also <https://www.coinbase.com/derivatives>.

Commodity-Based Trust Shares of the applicable primary listing market,⁴¹ and hold a single crypto asset, is consistent with the Act because it will permit the Exchange to offer options on Commodity-Based Trusts soon after the listing of the ETF on the primary listing market, provided that all the generic listing standards for that Commodity-Based Trust on that primary listing market have been met. Listing these options will avail market participants of the opportunity to hedge their positions in the Commodity-Based Trusts in a timely manner, thereby providing investors with the ability to hedge their exposure to the underlying Commodity-Based Trust. Options on Commodity-Based Trusts benefits investors, similar to the listing of any other option on an ETF, by providing investors with a relatively lower-cost risk management tool to manage their positions and associated risk in their portfolios more easily in connection with exposure to the price of a crypto asset. Additionally, listing options on Commodity-Based Trusts provides investors with the ability to transact in such options on a listed market as opposed to the OTC options market, which increases market transparency and enhances the process of price discovery to the benefit of all investors.

Also, this proposal would permit options on Commodity-Based Trusts to be listed on the Exchange in the same manner as all other securities that are subject to the current listing criteria in Exchange Rule 402. The Exchange notes that the majority of ETFs are able to list and trade options once the initial listing criteria have been met without the need for additional approvals. The proposed rule change would allow options on certain Commodity-Based Trusts to likewise list and trade options once the initial listing criteria on the primary listing market have been met without the need for additional approvals.

As proposed, the Exchange would list options in a Commodity-Based Trust that met the generic criteria of the applicable primary listing market, provided the Commodity-Based Trust held only a single crypto asset. Further, these options on Commodity-Based Trusts would also be required to satisfy the conditions in proposed Exchange Rule 402(i)(6)(iii). Specifically, a Commodity-Based Trust that met the requirements of proposed Exchange Rule 402(i)(6) would also have to satisfy the following requirements in proposed Exchange Rule 402(i)(6)(iii): (A) the total global supply of the underlying crypto asset held by the Commodity-Based

Trust has an average daily market value of at least \$700 million over the last 12 months; and (B) the crypto asset held by the Commodity-Based Trust underlies a derivatives contract that trades on a market with which the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in the ISG.

These requirements are consistent with the Act and the protection of investors as they should ensure that the underlying ETF has sufficient liquidity prior to listing options, which will serve to prevent disruption to the underlying market. The Exchange believes that market supply serves as a good measure of liquidity to prevent the addition of options trading on the Commodity-Based Trust from disrupting the market for the underlying security. Requiring the underlying crypto asset to have a requisite amount of deliverable supply, in addition to all the other criteria the ETF is required to have under the applicable primary listing market rules, should ensure adequate liquidity prior to listing. Further, ensuring the crypto asset held by the Commodity-Based Trust underlies a derivatives contract that trades on a market with which the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in the ISG, will provide the Exchange with information to adequately surveil options on qualifying Commodity-Based Trusts. Today, the Exchange has a comprehensive surveillance sharing agreement in place with both the CME and Coinbase Derivatives through its common membership in ISG. This facilitates the sharing of information that is available to the CME and Coinbase Derivatives through their surveillance of their respective markets, including their surveillance of their respective digital asset futures markets.

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. Options on qualifying Commodity-Based Trusts must satisfy the initial listing standards and continued listing standards currently in the Exchange Rules applicable to options on all ETFs, including ETFs that hold other crypto assets already deemed appropriate for options trading on the Exchange in addition to the proposed criteria. Options on qualifying Commodity-Based Trusts would trade in the same manner as any other ETF options—the same Exchange Rules that

currently govern the listing and trading of all ETF options, including permissible expirations, strike prices and minimum increments, and applicable position and exercise limits and margin requirements, will govern the listing and trading of options on qualifying Commodity-Based Trusts.

The Exchange represents that it has the necessary systems capacity to support the listing and trading of options on qualifying Commodity-Based Trusts. 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 of these options on Commodity-Based Trust, particularly in light of the additional requirement that the crypto asset held by the Commodity-Based Trust underlies a derivatives contract that trades on a market with which the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in ISG.

Finally, today, the Exchange lists and trades options on ETFs that would qualify for listing as an option on a Commodity-Based Trust under proposed Exchange Rule 402(i)(6),⁴² and it has not identified any issues with the listing and trading of options on those ETFs.

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. In this regard and as indicated above, the Exchange notes that the rule change is being proposed as a competitive response to the filing submitted by ISE.⁴³

The Exchange does not believe that the proposal to amend the listing criteria at Exchange Rule 402(i)(6), with respect to ETFs, to adopt new criteria to permit the listing and trading of options on certain Commodity-Based Trusts that hold a single crypto asset and that were listed pursuant to the generic listing standards for Commodity-Based Trust Shares of the applicable primary listing market, without the need for additional approvals, will impose any burden on

⁴² The following ETFs currently have options listed on them on the Exchange: iShares Bitcoin Trust, the Fidelity Wise Origin Bitcoin Fund, the ARK21Shares Bitcoin ETF, the Grayscale Bitcoin Trust (BTC), the Grayscale Bitcoin Mini Trust BTC, and the Bitwise Bitcoin ETF. See Exchange Rule 402(i)(4). The Exchange filed rule proposals and received the appropriate regulatory notice or approval to list the aforementioned options on the ETFs.

⁴³ See *supra* note 4.

⁴¹ See *supra* note 11.

intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Options on qualifying Commodity-Based Trusts would need to satisfy the initial listing standards set forth in the Exchange Rules in the same manner as any other ETF before the Exchange could list options on them. Additionally, options on qualifying Commodity-Based Trusts will be equally available to all market participants who wish to trade such options. The Exchange Rules currently applicable to the listing and trading of options on ETFs on the Exchange will apply in the same manner to the listing and trading of all options on qualifying Commodity-Based Trusts.

Additionally, the Exchange notes that listing and trading options on qualifying Commodity-Based Trusts 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 in a timely manner.

The Exchange does not believe that the proposal to adopt new listing criteria at Exchange Rule 402(i)(6) to permit the listing and trading of certain options on a Commodity-Based Trust, without the need for additional approvals, will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Other options exchanges are free to amend their applicable rules to permit them to list and trade options on Commodity-Based Trusts.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant

burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act⁴⁴ and subparagraph (f)(6) of Rule 19b-4 thereunder.⁴⁵

A proposed rule change filed under Rule 19b-4(f)(6)⁴⁶ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),⁴⁷ the Commission may designate a shorter time if such action is consistent with protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. The Commission believes that waiving 30-day operative delay is consistent with the protection of investors and the public interest because the proposal seeks to amend the Exchange's rules to be consistent with an amendment filed by the Exchange during a government shutdown, and which would have replaced the proposed rule change that did become effective if the Commission could have received amendments during the pendency of the government shutdown.⁴⁸ The proposal also aligns the rule text relating to Commodity-Based Trust Shares with the rule text of other exchanges and does not introduce any novel regulatory issues.⁴⁹ Accordingly, the Commission designates the proposed rule change to be operative upon filing.⁵⁰

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such

action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule 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-PEARL-2025-49 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-PEARL-2025-49. 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 filing 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-PEARL-2025-49 and should be submitted on or before January 13, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁵¹

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-23665 Filed 12-22-25; 8:45 am]

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⁴⁴ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴⁵ 17 CFR 240.19b-4(f)(6). 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 Commission is waiving this requirement.

⁴⁶ 17 CFR 240.19b-4(f)(6).

⁴⁷ 17 CFR 240.19b-4(f)(6)(iii).

⁴⁸ See *supra* Section II.A.1.

⁴⁹ See e.g., Nasdaq ISE, LLC, Options Rules, Options 4, Section 3(h); Cboe Exchange, Inc. Rule 4.3(a).

⁵⁰ For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

⁵¹ 17 CFR 200.30-3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–104445; File No. SR–EMERALD–2025–22]

Self-Regulatory Organizations; MIAX Emerald, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the MIAX Emerald Options Exchange Fee Schedule

December 18, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on December 10, 2025, MIAX Emerald, LLC (“MIAX Emerald” or “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the 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 MIAX Emerald Options Exchange Fee Schedule (the “Fee Schedule”) to establish alternative Simple Maker (as defined below) rebates for options transactions in Penny classes and non-Penny classes (as defined below) in Tier 4 for executed Priority Customer³ orders when the contra-side is an

Affiliated⁴ Market Maker⁵ and certain volume thresholds are met.

The text of the proposed rule change is available on the Exchange’s website at <https://www.miaxglobal.com/markets/us-options/miax-options/rule-filings>, and at the Exchange’s principal office.

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.

⁴ “Affiliate” means (i) an affiliate of a Member of at least 75% common ownership between the firms as reflected on each firm’s Form BD, Schedule A, or (ii) the Appointed Market Maker of an Appointed EEM (or, conversely, the Appointed EEM of an Appointed Market Maker). An “Appointed Market Maker” is a MIAX Emerald Market Maker (who does not otherwise have a corporate affiliation based upon common ownership with an EEM) that has been appointed by an EEM and an “Appointed EEM” is an EEM (who does not otherwise have a corporate affiliation based upon common ownership with a MIAX Emerald Market Maker) that has been appointed by a MIAX Emerald Market Maker, pursuant to the following process. A MIAX Emerald Market Maker appoints an EEM and an EEM appoints a MIAX Emerald Market Maker, for the purposes of the Fee Schedule, by each completing and sending an executed Volume Aggregation Request Form by email to membership@miaxglobal.com no later than 2 business days prior to the first business day of the month in which the designation is to become effective. Transmittal of a validly completed and executed form to the Exchange along with the Exchange’s acknowledgement of the effective designation to each of the Market Maker and EEM will be viewed as acceptance of the appointment. The Exchange will only recognize one designation per Member. A Member may make a designation not more than once every 12 months (from the date of its most recent designation), which designation shall remain in effect unless or until the Exchange receives written notice submitted 2 business days prior to the first business day of the month from either Member indicating that the appointment has been terminated. Designations will become operative on the first business day of the effective month and may not be terminated prior to the end of the month. Execution data and reports will be provided to both parties. See the Definitions Section of the Fee Schedule.

⁵ “Market Maker” refers to “Lead Market Maker” (“LMM”), “Primary Lead Market Maker” (“PLMM”) and “Registered Market Maker” (“RMM”), collectively. See the Definitions Section of the Fee Schedule and Exchange Rule 100.

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 Section 1)a)i) of the Fee Schedule to establish alternative Simple Maker (as defined below) rebates for options transactions in Penny classes and non-Penny classes (as defined below) in Tier 4 for executed Priority Customer orders when the contra-side is an Affiliated Market Maker and certain volume thresholds are met. The Exchange initially filed this proposal on December 1, 2025 (SR–EMERALD–2025–19). On December 10, 2025, the Exchange withdrew SR–EMERALD–2025–19 and refiled this proposed rule change.

Background

The Exchange currently provides transaction rebates and assesses transaction fees to all market participants based upon a threshold tier structure (“Tier”) that is applicable to all transactions. Tiers are determined on a monthly basis and are based on three alternative volume calculation methods, as described in Section 1)a)ii) of the Fee Schedule.⁶ Each method is calculated based on the total monthly sides executed by the Member⁷ in all options classes on MIAX Emerald in the relevant origin(s) and/or applicable liquidity (*i.e.*, Priority Customer Maker), not including Excluded Contracts,⁸ (as the numerator) expressed as a percentage of (divided by) Customer Total Consolidated Volume (“CTCV”)⁹

⁶ The three alternative volume calculation methods are as follows. Method 1 is calculated by total Member sides volume as a percentage of CTCV. Method 2 is calculated by total MIAX Emerald Market Maker sides volume as a percentage of CTCV. Method 3 is calculated by total Priority Customer, Maker sides volume as a percentage of CTCV. See Fee Schedule, Section 1)a)ii) (also providing the volume threshold percentages for Tiers 1–4 for each volume calculation method). The Tier applied for a Member and its Affiliates’ Priority Customer origin will solely be determined by Method 3. The Tier applied for a Member and its Affiliates’ Market Maker and other professional origins (non-MIAX Emerald Market Maker, Firm Proprietary/Broker-Dealer, and Non-Priority Customer) will be the highest Tier achieved among the three alternative calculation methods. *Id.*

⁷ “Member” means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed “members” under the Exchange Act. See the Definitions section of the Fee Schedule and Exchange Rule 100.

⁸ “Excluded Contracts” means any contracts routed to an away market for execution. See the Definitions Section of the Fee Schedule.

⁹ “CTCV” means Customer Total Consolidated Volume calculated as the total national volume cleared at The Options Clearing Corporation in the

Continued

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ “Priority Customer” means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). The number of orders shall be counted in accordance with Interpretation and Policy .01 of Exchange Rule 100. See the Definitions section of the Fee Schedule and Exchange Rule 100, including Interpretation and Policy .01.

(as the denominator). The per contract transaction rebates and fees shall be applied retroactively to all eligible volume once the Tier has been reached by the Member. The Exchange aggregates the volume of Members and their Affiliates in the Tiers. Members that place resting liquidity, *i.e.*, orders on the MIAX Emerald System, will be assessed the specified “maker” rebate or fee (each a “Maker”) and Members that execute against resting liquidity will be assessed the specified “taker” fee or rebate (each a “Taker”). Members are also assessed lower transaction fees and provided lower rebates for order executions in standard option classes in the Penny Interval Program ¹⁰ (“Penny classes”) than for order executions in standard option classes which are not in the Penny Interval Program (“non-Penny classes”), for which Members will be assessed higher transaction fees and receive higher rebates.

Proposal

The Exchange proposes to establish alternative Simple Maker rebates for options transactions in Penny classes and non-Penny classes in Tier 4 for executed Priority Customer orders when the contra-side is an Affiliated Market Maker and certain volume thresholds are met. Currently, the Exchange provides Simple Maker rebates of (\$0.53) and (\$1.05) for options transactions in Penny classes and non-Penny classes in Tier 4, respectively, for executed Priority Customer orders when the contra-side is not an Affiliated Market Maker. The Exchange provides reduced Simple Maker rebates of (\$0.37) and (\$0.85) for options transactions in Penny classes and non-Penny classes in Tier 4, respectively, for executed Priority Customer orders when the contra-side is an Affiliated Market Maker. The reduced Simple Maker rebate for Penny classes is denoted by footnote “□” and the reduced Simple

Customer range in those classes listed on MIAX Emerald for the month for which fees apply, excluding volume cleared at the Options Clearing Corporation in the Customer range executed during the period of time in which the Exchange experiences an Exchange System Disruption (solely in the option classes of the affected Matching Engine). The term “Exchange System Disruption” means an outage of a Matching Engine or collective Matching Engines for a period of two consecutive hour or more, during trading hours. See the Definitions Section of the Fee Schedule.

¹⁰ See Securities Exchange Act Release No. 88993 (June 2, 2020), 85 FR 35145 (June 8, 2020) (SR-EMERALD-2020-05) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 510, Minimum Price Variations and Minimum Trading Increments, To Conform the Rule to Section 3.1 of the Plan for the Purpose of Developing and Implementing Procedures Designed To Facilitate the Listing and Trading of Standardized Options).

Maker rebate for non-Penny classes is denoted by footnote “■” following the tables of transaction fees and rebates in Section 1(a)i) of the Fee Schedule.

The Exchange proposes to establish the following alternative Simple Maker rebates for options transactions in Penny classes and non-Penny classes in Tier 4 for executed Priority Customer orders when the contra-side is an Affiliated Market Maker and the Member achieves certain volume thresholds. In particular, the Exchange proposes to add the following sentence to footnote “□”: ¹¹

When the contra is an Affiliated Market Maker and the Member has achieved above 0.90% of total Market Maker sides volume and above 0.60% of total Priority Customer, Maker sides volume, both thresholds as a percentage of CTCV, this Maker rebate for executed Priority Customer Simple Orders will be (\$0.49).

The Exchange also proposes to add the following sentence to footnote “■”:

When the contra is an Affiliated Market Maker and the Member has achieved above 0.90% of total Market Maker sides volume and above 0.60% of total Priority Customer, Maker sides volume, both thresholds as a percentage of CTCV, this Maker rebate for executed Priority Customer Simple Orders will be (\$0.95). ¹²

The purpose of the proposed changes is for business and competitive reasons in order to attract additional Priority Customer volume. The Exchange believes that this may, in turn, encourage Members to submit more Priority Customer orders, leading to increased liquidity on the Exchange to the benefit of all market participants by providing more trading opportunities and tighter spreads. The proposed changes may also provide an incentive

¹¹ The Exchange notes that references to “total Market Maker sides volume” in the proposed new text includes aggregated volume of the Member and its Affiliates. See Fee Schedule, Section 1(a)ii) (explanatory paragraph below the table of “Tiers and their Application”).

¹² In the initial version of this proposal (SR-EMERALD-2025-19), the Exchange used the term “at least” when referring to the minimum alternative volume thresholds that Members would be required to meet (*i.e.*, at least 0.90% of total Market Maker sides volume and at least 0.60% of total Priority Customer, Maker sides volume). The Exchange notes that the term “at least” was inadvertently used when the correct term “above” should have been used when referring to the minimum alternative volume thresholds that Members would be required to meet (*i.e.*, above 0.90% of total Market Maker sides volume and above 0.60% of total Priority Customer, Maker sides volume). These changes were made to the Exhibit 5 for this filing. The Exchange notes that these proposed changes do not impact any Member that has met the alternative Simple Maker rebates described herein at the time of this refiling.

for Market Makers to interact with more Priority Customer liquidity in Penny and non-Penny classes, thereby promoting price discovery and contributing to a deeper and more liquid market, which benefits all market participants and enhances the attractiveness of the Exchange as a trading venue. The Exchange also notes that other equity options exchanges provide for different pricing dependent upon whether the executing buyer and seller are the same market participant, have some form of common ownership, and/or based upon certain volume thresholds in different segments. ¹³

Implementation

The proposed changes are immediately effective.

2. Statutory Basis

The Exchange believes that its proposal to amend the Fee Schedule is consistent with Section 6(b) of the Act ¹⁴ in general, and furthers the objectives of Section 6(b)(4) of the Act, ¹⁵ in that it is an equitable allocation of reasonable dues, fees and other charges among Exchange Members and issuers and other persons using its facilities, and 6(b)(5) of the Act, ¹⁶ in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Commission has repeatedly expressed its preference for competition

¹³ See NYSE Arca, Inc. Options Fees and Charges, page 11, available at https://www.nyse.com/publicdocs/nyse/markets/arca-options/NYSE_Arca_Options_Fee_Schedule.pdf (providing a reduced taker fee of \$0.03 or \$0.02 for Professional Customers and non-Customers removing liquidity that execute at least 0.80% of TCADV from Customer posted interest in all issues, plus executed ADV of 0.30% ADV of U.S. equity market share posted and executed on the equity market of NYSE Arca; however, the \$0.03 discount only applies when the executing buyer and seller are the same OTP Holder or OTP Firm or an Affiliate or Appointed OFP or Appointed MM of that OTP Holder or OTP Firm); see also Nasdaq ISE, Options 7: Pricing Schedule, Section 4, Maker and Taker Fees section, footnote 3, available at <https://listingcenter.nasdaq.com/rulebook/ise/rules/ISE%20Options%207> (providing reduced Taker fee in select symbols for all origins other than Priority Customer when executed against Priority Customer Complex Orders in Select Symbols entered by an Affiliated Member or Affiliated Entity, excluding Complex Orders executed in the Nasdaq ISE Facilitation Mechanism, Solicited Order Mechanism, and Price Improvement Mechanism).

¹⁴ 15 U.S.C. 78f(b).

¹⁵ 15 U.S.C. 78f(b)(4).

¹⁶ 15 U.S.C. 78f(b)(1) and (b)(5).

over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system “has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.”¹⁷

There are currently 18 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange had more than approximately 10.28% of the multiply-listed equity options market share for the month of October 2025.¹⁸ Therefore, no exchange possesses significant pricing power. More specifically, the Exchange had a market share of approximately 3.26% of executed volume of multiply-listed equity options for the month of October 2025.¹⁹ The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can discontinue or reduce use of certain categories of products and services, terminate an existing membership or determine to not become a new member, and/or shift order flow, in response to transaction fee changes.

The Exchange believes its proposal to establish alternative Simple Maker rebates for options transactions in Penny classes and non-Penny classes in Tier 4 for executed Priority Customer orders when the contra-side is an Affiliated Market Maker and certain volume thresholds are met is reasonable, equitable and not unfairly discriminatory. The Exchange believes the changes are reasonable because they may attract additional Priority Customer volume to the Exchange, which may, in turn, encourage Members to submit more Priority Customer orders, leading to increased liquidity on the Exchange to the benefit of all market participants by providing more trading opportunities and tighter spreads. The Exchange further believes the proposed changes are reasonable because they may provide an incentive for Market Makers to interact with more Priority Customer liquidity in Penny and non-Penny classes, thereby promoting price discovery and contributing to a deeper and more liquid market, which benefits

all market participants and enhances the attractiveness of the Exchange as a trading venue. The Exchange also notes that other equity options exchanges provide for different pricing dependent upon whether the executing buyer and seller are the same market participant, have some form of common ownership, and/or based upon certain volume thresholds in different segments. Accordingly, the Exchange believes the proposal is reasonable as other exchanges offer similar pricing structures.²⁰

The Exchange believes the proposal is equitable and not unfairly discriminatory because all similarly situated market participants in the same origin type are subject to the same tiered Maker rebates and Taker fees and access to the Exchange is offered on terms that are not unfairly discriminatory. The Exchange believes it is equitably allocated and not unfairly discriminatory to provide the proposed alternative rebates for Priority Customer orders when the contra-side is an Affiliated Market Maker and certain volume thresholds are met in order to incentivize Market Makers to increase their participation in all options to the benefit of the entire market, which may increase order flow sent to the Exchange, benefiting all market participants through increased participation, leading to tighter markets and order interaction.

The Exchange believes that the proposed volume thresholds for the alternative Simple Maker rebates for options transactions in Penny classes and non-Penny classes in Tier 4 for executed Priority Customer orders when the contra-side is an Affiliated Market Maker are reasonable for business and competitive reasons. The Exchange believes the proposed volume thresholds are reasonable, equitably allocated and not unfairly discriminatory because the thresholds should encourage Members to increase Priority Customer liquidity and Market Maker order interaction, which may increase order flow sent to the Exchange, benefiting all market participants through increased liquidity, tighter markets and order interaction.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

The Exchange does not believe that any of the proposed changes will impose any burden on intra-market competition. Instead, the Exchange believes the proposed changes will promote competition because they will further incentivize Priority Customer orders to the Exchange. The Exchange believes that this may, in turn, encourage Members to submit more Priority Customer orders, leading to increased liquidity on the Exchange to the benefit of all market participants by providing more trading opportunities and tighter spreads.

Inter-Market Competition

The Exchange does not believe that the proposed changes will impose any burden on inter-market competition and 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. There are currently 18 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange had more than approximately 10.28% of the multiply-listed equity options market share for the month of October 2025.²¹ Therefore, no exchange possesses significant pricing power. More specifically, the Exchange had a market share of approximately 3.26% of executed volume of multiply-listed equity options for the month of October 2025.²²

In such an environment, the Exchange must continually adjust its rebates and tiers to remain competitive with other options exchanges. Because competitors are free to modify their own fees and tiers in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. The Exchange believes that the proposed rule changes reflect this competitive environment because they modify the Exchange's rebates in a manner that encourages market participants to continue to provide liquidity and to send order flow to the Exchange.

¹⁷ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

¹⁸ See the “Market Share” section of the Exchange's website, available at <https://www.miaxglobal.com/>.

¹⁹ See *id.*

²⁰ See *supra* note 13.

²¹ See *supra* note 18.

²² See *id.*

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,²³ and Rule 19b-4(f)(2)²⁴ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission 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-EMERALD-2025-22 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-EMERALD-2025-22. 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 filing 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-EMERALD-2025-22 and should be submitted on or before January 13, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁵

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-23670 Filed 12-22-25; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104453; File No. SR-BX-2025-031]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend BX Equity 6, Section 4 (Exchange Sharing of Participant Risk Settings) To Permit the Allocation of Responsibility to Clearing Members

December 18, 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 December 10, 2025, Nasdaq BX, Inc. ("BX" 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 BX Equity 6, Section 4 (Exchange Sharing of Participant Risk Settings) to permit the allocation of responsibility to clearing members.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/bx/rulefilings>, and at the principal office of the Exchange.

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 BX Equity 6, Section 4 to permit the allocation of responsibility to clearing members. Specifically, the Exchange proposes to add a new Section 4(b) (Clearing Member Designation) to allow a Participant that does not self-clear to allocate responsibility for establishing and adjusting its risk levels to a clearing member that clears transactions on behalf of the Participant.³ A clearing member guarantees transactions executed on the Exchange for Participants with whom it has entered into a clearing arrangement, and therefore bears the risk associated with those transactions. Because a clearing member bears the risk on behalf of its associated Participant, the Exchange believes that it is appropriate for the clearing member to have knowledge of what risk settings the Participant may utilize within the Exchange's trading system, as well as the option to set and adjust the risk levels. Therefore, the Exchange proposes to make a Participant's risk settings in BX Equity 6, Section 5 available to a clearing member, as well as the option to set and adjust the risk levels, if authorized by a Participant.

For clarification, the Exchange does not guarantee that these risk controls will be sufficiently comprehensive to meet all of a Participant's needs, nor are the controls designed to be the sole means of risk management, and using these controls will not necessarily meet a Participant's obligations required by Exchange or federal rules—including, without limitation, Rule 15c3-5 under the Act⁴ ("Rule 15c3-5"). Use of the

²³ 15 U.S.C. 78s(b)(3)(A)(ii).

²⁴ 17 CFR 240.19b-4(f)(2).

²⁵ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ The term "Participant" has the meaning set forth in BX Equity 1, Section 1(a)(9).

⁴ 17 CFR 240.15c3-5.

Exchange's risk settings in BX Equity 6, Section 5 will not automatically constitute compliance with Exchange or federal rules, and the responsibility for compliance with all Exchange and federal rules remains with the Participant.⁵

If a Participant chooses to designate responsibility to a clearing member, the Participant may view any risk levels established by the clearing member pursuant to proposed BX Equity 6, Section 4(b). Even if a clearing member is designated, a Participant will continue to be notified by the Exchange of any action taken regarding its trading activity. A Participant may revoke the responsibility it has allocated to a clearing member at any time.

The Exchange also proposes labeling the current rule text at BX Equity 6, Section 4 as BX Equity 6, Section 4(a) (Sharing Risk Settings). The text of this newly labeled provision remains completely unchanged.

The Exchange will announce the implementation date of the change described in this filing in an Equity Trader Alert at least 30 days prior to implementation. At present, the Exchange expects that the functionality described in this filing will be ready for implementation in the first quarter of 2026, although that time frame is subject to change.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁶ in general, and furthers the objectives of Section 6(b)(5) of the Act,⁷ 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.

As a preliminary matter, the Exchange notes that this proposal is not novel. Earlier this year The Nasdaq Stock Market LLC made a parallel change to its rulebook.⁸ The language of Nasdaq

Equity 6, Section 4(b) is substantively identical to the new rule text proposed by the Exchange in the present filing.⁹

The Exchange believes that the proposed amendment to BX Equity 6, Section 4 would provide clearing members, who have assumed certain risks of Participants, greater control over risk tolerance and exposure on behalf of their correspondent Participant, while helping to ensure that both the Participant and its clearing member are aware of developing issues.

A clearing member guarantees transactions executed on Nasdaq for members with whom it has entered into a clearing arrangement, and therefore bears the risk associated with those transactions. The Exchange therefore believes that it is appropriate for a clearing member to have knowledge of what risk settings a Participant may utilize within the Exchange's trading system, as well as the option to set and adjust the risk levels. The proposal will permit a clearing member with whom a Participant has entered into a clearing arrangement to better monitor and manage the potential risks assumed by the clearing member, thereby providing the clearing member with greater control and flexibility over setting its own risk tolerance and exposure and aiding the clearing member in complying with the requirements of the Act.

The Exchange also believes that the proposed amendment will assist Participants and clearing members in managing their financial exposure which, in turn, could enhance the integrity of trading on the securities markets and help to ensure the stability of the financial system. Moreover, a Participant may revoke responsibility allocated to its clearing member at any time.

The Exchange believes that the proposed rule change does not unfairly discriminate among Participants because the use of the risk settings under BX Equity 6, Section 5 would be available to all Participants and their clearing members, if authorized. In

addition, because all orders on the Exchange pass through the Exchange's risk checks, there would be no difference in the latency experienced by Participants who have opted to use the risk settings versus those who have not opted to use them.¹⁰

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 designed to provide Participants and their clearing members with additional means to monitor and control risk. The proposed rule may increase confidence in the proper functioning of the markets and contribute to additional competition among trading venues and broker-dealers. Rather than impede competition, the proposal is designed to facilitate more robust risk management by Participants and clearing members, which, in turn, could enhance the integrity of trading on the securities markets and help to ensure the stability of the financial system.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act¹¹ and subparagraph (f)(6) of Rule 19b-4 thereunder.¹²

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if

⁵ See SEC Division of Trading and Markets, Responses to Frequently Asked Questions Concerning Risk Management Controls for Brokers or Dealers with Market Access (Apr. 15, 2014), available at <https://www.sec.gov/rules-regulations/staff-guidance/trading-markets-frequently-asked-questions/divisionsmarketregfaq-0>.

⁶ 15 U.S.C. 78f(b).

⁷ 15 U.S.C. 78f(b)(5).

⁸ See Securities Exchange Act Release No. 103211 (June 9, 2025), 90 FR 25095 (June 13, 2025) (File No. SR-NASDAQ-2025-043) (Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend Equity 6, Section 4 (Exchange Sharing of Participant Risk Settings) to Permit the Allocation of Responsibility to Clearing Members) ("Nasdaq Filing").

⁹ As adopted in the Nasdaq Filing, this Nasdaq rule reads as follows: "Clearing Member Designation. A Participant that does not self-clear may allocate the responsibility for establishing and adjusting the risk levels identified in Equity 6, Section 5 to a clearing member that clears transactions on behalf of the Participant, if designated in a manner prescribed by the Exchange. A Participant that chooses to allocate responsibility to its clearing member may view any risk levels established by the clearing member pursuant to this Rule, and will be notified of any action taken by the Exchange with respect to its trading activity. A Participant may revoke responsibility allocated to its clearing member pursuant to this paragraph at any time, if designated in a manner prescribed by the Exchange."

¹⁰ All Exchange orders pass through basic risk checks regardless of whether a Participant opts into a risk setting.

¹¹ 15 U.S.C. 78s(b)(3)(A)(iii).

¹² 17 CFR 240.19b-4(f)(6). 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.

it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule 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-BX-2025-031 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-BX-2025-031. 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 filing 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-BX-2025-031 and should be submitted on or before January 13, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-23653 Filed 12-22-25; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235-0461]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension: Rule 602

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 (SEC or "Commission") is soliciting comments on the proposed collection of information provided for in Rule 602 of Regulation NMS (17 CFR 240.602), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget ("OMB") for extension and approval.

Rule 602 of Regulation NMS, Dissemination of Quotations in NMS securities, contains two related collections. The first collection of information is found in Rule 602(a).¹ This third-party disclosure requirement obligates each national securities exchange and national securities association to make available to quotation vendors for dissemination to the public the best bid, best offer, and aggregate quotation size for each "subject security," as defined under the Rule. The second collection of information is found in Rule 602(b).² This disclosure requirement obligates any exchange member and over-the-counter ("OTC") market maker that is a "responsible broker or dealer," as defined under the Rule, to communicate to an exchange or association its best bids, best offers, and quotation sizes for subject securities.³

It is anticipated that 30 respondents, consisting of 29 national securities

exchanges and one national securities association, will collectively respond approximately 1,543,667,886,538 times per year pursuant to Rule 602(a) at 16.20 microseconds per response, resulting in a total annual time burden of approximately 208,410 hours. It is anticipated that no respondents will have a reporting burden pursuant to Rule 602(b).⁴

Thus, the aggregate third-party disclosure burden under Rule 602 is approximately 208,410 hours annually which is comprised of 208,410 hours relating to Rule 602(a) and 0 hours relating to Rule 602(b).

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.

Please direct your written comments on this 60-Day Collection Notice to Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Tanya Ruttenberg via email to PaperworkReductionAct@sec.gov by February 23, 2026. There will be a second opportunity to comment on this SEC request following the **Federal Register** publishing a 30-Day Submission Notice.

Dated: December 19, 2025.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-23683 Filed 12-22-25; 8:45 am]

BILLING CODE 8011-01-P

⁴ For the reporting obligation under Rule 602(b), the respondents are exchange members and OTC market makers. The Commission believes that communication of quotations through an exchange's electronic trading system effectively means that exchange members currently have no reporting burden under Rule 602(b) for these quotations. The Commission also believes that there are presently no OTC market makers that quote other than on an exchange.

¹ 17 CFR 242.602(a).

² 17 CFR 242.602(b).

³ Under Rule 602(b)(5), electronic communications networks ("ECNs") have the option of reporting to an exchange or association for public dissemination, on behalf of customers that are OTC market makers or exchange market makers, the best-priced orders and the full size for such orders entered by market makers on the ECN, to satisfy such market makers' reporting obligation under Rule 602(b). Since this reporting requirement is an alternative method of meeting the market makers' reporting obligation, and because it is directed to nine or fewer persons (ECNs), this collection of information is not subject to OMB review under the Paperwork Reduction Act ("PRA").

¹³ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–104455; File No. SR–ISE–2025–39]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend FLEX Order Fees

December 18, 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 December 10, 2025, Nasdaq ISE, LLC (“ISE” 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 its Pricing Schedule at Options 7, Section 6, D., FLEX Order Fees.³

The text of the proposed rule change is available on the Exchange’s website at <https://listingcenter.nasdaq.com/rulebook/ise/rulefilings>, and at the principal office of the Exchange.

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

ISE proposes to amend its Pricing Schedule at Options 7, Section 6, D.,

FLEX Order Fees, to decrease the FLEX⁴ Order Fees for a FLEX Price Improvement Auction (“FLEX PIM”),⁵ or a FLEX Solicited Order Mechanism (“FLEX SOM”).⁶

FLEX Order Fees

The Exchange proposes to amend Options 7, Section 6, D., FLEX Order Fees. Today, a Member may electronically submit a FLEX Order into an electronic FLEX Auction pursuant to Options 3A, Section 11(b). Today, for the FLEX Auction, the Exchange assesses \$0.10 per contract for Market Makers,⁷ Non-Nasdaq ISE Market Makers (FarMM),⁸ Firm Proprietary/⁹ Broker Dealers,¹⁰ and Professional Customers.¹¹ The Exchange assesses no Fees for FLEX Auctions to Priority Customers.¹²

⁴ FLEX Options are designed to meet the needs of market participants for greater flexibility in selecting the terms of options within the parameters of the Exchange’s rules. Options 3A Rules govern FLEX.

⁵ The FLEX PIM is a paired auction mechanism pursuant to Options 3A, Section 12 through which an Exchange member may electronically submit for execution an order (which may be a simple or complex order) it represents as agent (“Agency Order”) against principal interest or a solicited order(s) (except, if the Agency Order is a simple order, for an order for the account of any FLEX Market Maker with an appointment in the applicable FLEX Option class on the Exchange) (an “Initiating Order”), provided it submits the Agency Order for electronic execution into a FLEX PIM Auction pursuant to Options 3A, Section 12.

⁶ The FLEX SOM is a paired auction mechanism pursuant to Options 3A, Section 13 through which an Exchange member (the “Initiating Member”) may electronically submit for execution an order (which may be a simple or complex order) it represents as agent (“Agency Order”) against a solicited order (“Solicited Order”) if it submits the Agency Order for electronic execution into a FLEX SOM Auction pursuant to Options 3A, Section 13.

⁷ The term “Market Makers” refers to “Competitive Market Makers” and “Primary Market Makers” collectively. See Options 1, Section 1(a)(21).

⁸ A “Non-Nasdaq ISE Market Maker” is a market maker as defined in Section 3(a)(38) of the Securities Exchange Act of 1934, as amended, registered in the same options class on another options exchange. See Options 7, Section 1(c).

⁹ A “Firm Proprietary” order is an order submitted by a member for its own proprietary account. See Options 7, Section 1(c).

¹⁰ A “Broker-Dealer” order is an order submitted by a member for a broker-dealer account that is not its own proprietary account. See Options 7, Section 1(c).

¹¹ A “Professional Customer” is a person or entity that is not a broker/dealer and is not a Priority Customer. See Options 7, Section 1(c).

¹² A “Priority Customer” is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in Nasdaq ISE Options 1, Section 1(a)(38). Unless otherwise noted, when used in this Pricing Schedule the term “Priority Customer” includes “Retail.” A “Retail” order is a Priority Customer order that originates from a natural person, provided that no change is made to the terms of the order with respect to price

Today, a Member may also electronically submit a FLEX Order into a FLEX PIM and FLEX SOM pursuant to Options 3A, Section 12 and Options 3A, Section 13, respectively. For the FLEX PIM and FLEX SOM, today, the Exchange assesses \$0.07 per contract for Market Makers, Non-Nasdaq ISE Market Makers (FarMM), Firm Proprietary/⁹ Broker Dealers, and Professional Customers. The Exchange assesses no FLEX Order Fees for FLEX PIM and FLEX SOM to Priority Customers.

Finally, today, any Member other than an Initiating Member may submit responses to a FLEX PIM and FLEX SOM pursuant to Options 3A, Section 12(c)(5) and Options 3A, Section 13(c)(5), respectively. For responses to a FLEX PIM and FLEX SOM, today, the Exchange assesses \$0.50 per contract for Market Makers, Non-Nasdaq ISE Market Makers (FarMM), Firm Proprietary/⁹ Broker Dealers, Professional Customers, and Priority Customers.

At this time, the Exchange proposes to decrease Non-Priority Customer Fees for FLEX PIM and FLEX SOM from \$0.07 to \$0.06 per contract. The Exchange believes that this decrease will incentivize greater activity in FLEX PIM and FLEX SOM for potential price improvement.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,¹³ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,¹⁴ 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 Exchange’s proposed changes to its Pricing Schedule are reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for options securities transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has long been recognized by the courts. In *NetCoalition v. Securities and Exchange Commission*, the D.C. Circuit stated as follows: “[n]o one disputes that competition for order flow is ‘fierce.’ . . . As the SEC explained, ‘[i]n the U.S. national market system, buyers and sellers of securities,

or side of market and the order does not originate from a trading algorithm or any other computerized methodology. See Options 7, Section 1(c).

¹³ 15 U.S.C. 78f(b).

¹⁴ 15 U.S.C. 78f(b)(4) and (5).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ On December 1, 2025 the Exchange filed SR–ISE–2025–37. On December 12, [sic] 2025, the Exchange withdrew SR–ISE–2025–37 and filed this proposal.

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'. . . ."¹⁵

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."¹⁶

Numerous indicia demonstrate the competitive nature of this market. For example, clear substitutes to the Exchange exist in the market for options security transaction services. The Exchange is only one of eighteen options exchanges to which market participants may direct their order flow. Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules. As such, the proposal represents a reasonable attempt by the Exchange to increase its liquidity and market share relative to its competitors.

FLEX Order Fees

The Exchange's proposal to decrease Non-Priority Customer Fees for FLEX PIM and FLEX SOM from \$0.07 to \$0.06 per contract is reasonable because the fee reduction will incentivize greater activity in FLEX PIM and FLEX SOM for potential price improvement. Further, as proposed, the fees are competitive with market dynamics and consider the price improvement opportunities of the order mechanisms. Priority Customers will continue to be assessed no Fee for FLEX PIM and FLEX SOM.

The Exchange's proposal to decrease Non-Priority Customer Fees for FLEX PIM and FLEX SOM from \$0.07 to \$0.06 per contract is equitable and not

unfairly discriminatory. The Fees for FLEX PIM and SOM will apply in a like manner to all Non-Priority Customers. Priority Customers will continue to be assessed no Fees for FLEX PIM and FLEX SOM. The Exchange believes that it is equitable and not unfairly discriminatory to assess more favorable pricing for Priority Customers. Priority Customer order flow enhances liquidity on the Exchange to the benefit of all market participants by providing more trading opportunities, which in turn attracts Market Makers and other market participants who may interact with this order flow.

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. In terms of intra-market competition, the Exchange does not believe that its proposal will place any category of market participant at a competitive disadvantage.

FLEX Order Fees

The proposed Fees for FLEX PIM and FLEX SOM do not impose an undue burden on competition because the Exchange will apply the same fees to all Non-Priority Customers. Priority Customers will continue to be assessed no Fees for FLEX PIM and FLEX SOM. The Exchange believes that it does not impose an undue burden on competition to assess more favorable pricing for Priority Customers. Priority Customer order flow enhances liquidity on the Exchange to the benefit of all market participants by providing more trading opportunities, which in turn attracts Market Makers and other market participants who may interact with this order flow. Nasdaq does not believe that the proposed fee changes place an unnecessary burden on competition.

In terms of inter-market competition, 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 to remain competitive with other exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. In

sum, if the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

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-ISE-2025-39 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-ISE-2025-39. 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

¹⁵ *NetCoalition v. SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782-83 (December 9, 2008) (SR-NYSEArca-2006-21)).

¹⁶ Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) ("Regulation NMS Adopting Release").

¹⁷ 15 U.S.C. 78s(b)(3)(A)(ii).

post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing 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-ISE-2025-39 and should be submitted on or before January 13, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-23657 Filed 12-22-25; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104441; File No. SR-FINRA-2025-015]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend FINRA Rules 5220, 5320, 6220, 6272, 6279, 6320A, 6320B, and 7620A To Conform to the New Definition of "Round Lot" Adopted by the Commission Under Regulation NMS

December 18, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act" or "Exchange Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on December 3, 2025, the Financial Industry Regulatory Authority, Inc. ("FINRA") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by FINRA. FINRA filed the proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³ and Rule 19b-4(f)(6) thereunder.⁴ 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

FINRA is proposing to amend FINRA Rules 5220, 5320, 6220, 6272, 6279, 6320A, 6320B, and 7620A to conform to the new definition of "round lot" adopted by the Commission under Regulation NMS.

The text of the proposed rule change is available on FINRA's website at <http://www.finra.org> and at the principal office of FINRA.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Background

In 2020, the Commission adopted amendments to Regulation NMS to modernize the information provided within the national market system for NMS stocks.⁵ Prior to the MDI Rule amendments to Regulation NMS, "round lot" was not defined in the Exchange Act or SEC rules. Instead, exchange rules typically defined a round lot as 100 shares, but also allowed the exchange, or the primary listing exchange for the security, discretion to define it otherwise.⁶ Among other things, the MDI Rule amended Rule 600(b) of Regulation NMS to add a new definition of "round lot" that assigns each NMS stock a round lot size based on the stock's average closing price. In light of delays in the implementation of the MDI Rule, including the new definition of "round lot," on September 18, 2024, the Commission adopted further

amendments to Regulation NMS that, among other things, revised and accelerated the implementation of the new round lot definition under Rule 600(b)(93) to implement the new round lot definition on November 3, 2025, the first business day of November 2025.⁷

As adopted under the 2024 NMS Amendments, the new definition of "round lot" in Rule 600(b)(93) of Regulation NMS assigns each NMS stock a round lot size based on the stock's average closing price on the primary listing exchange during the prior Evaluation Period, ranging from 100 shares for NMS stocks priced \$250.00 or less to one share for NMS stocks priced \$10,000.01 or more.⁸

Several FINRA rules use the term "normal unit of trading" as the equivalent to the term "round lot" as used in exchange rules. As described in greater detail below, FINRA is proposing to amend these rules to conform to the new definition of "round lot" for NMS stocks under Regulation NMS.⁹

Conforming Changes to FINRA Rules

FINRA Rule 5220 (Offers at Stated Prices) provides that no member shall make an offer to buy from or sell to any person any security at a stated price unless such member is prepared to purchase or sell, as the case may be, at such price and under such conditions as are stated at the time of such offer to buy or sell. Supplementary Material .01 to Rule 5220 (Firmness of Quotations) discusses the expectations for making a "firm trading market" in a security,

⁷ See Regulation NMS: Minimum Pricing Increments, Access Fees, and Transparency of Better Priced Orders, Securities Exchange Act Release No. 101070 (September 18, 2024), 89 FR 81620 (October 8, 2024) (File No. S7-30-22) (the "2024 NMS Amendments").

⁸ See 17 CFR 242.600(b)(93). The "Evaluation Period," as defined in Rule 600(b)(93)(iii) of Regulation NMS, means (i) all trading days in March for the round lot assigned on the first business day of May and (ii) all trading days in September for the round lot assigned on the first business day of November, during which the average closing price of an NMS stock on the primary listing exchange shall be measured by the primary listing exchange to determine the round lot for each NMS stock. Under Rule 600(b)(93)(iv), the round lot assigned is operative on (i) the first business day of May for the March Evaluation Period and continues through the last business day of October for the calendar year and (ii) the first business day of November for the September Evaluation Period and continues through the last business day of April of the next calendar year. Under Rule 600(b)(93)(ii), any security that becomes an NMS stock during an operative period is assigned a round lot of 100 shares.

⁹ The new definition of "round lot" in Rule 600(b)(93) of Regulation NMS applies only to NMS stocks. The proposed conforming changes to FINRA rules are similarly limited to NMS stocks and do not affect the normal unit of trading as it may be applied to any other type of security.

¹⁸ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴ 17 CFR 240.19b-4(f)(6).

⁵ See Securities Exchange Act Release No. 90610 (December 9, 2020), 86 FR 18596 (April 9, 2021) (File No. S7-03-02) (the "Market Data Infrastructure Rule" or "MDI Rule").

⁶ See 2024 NMS Amendments, *infra* note 7, 89 FR 81620, 81625 n.66. In practice, very few NMS stocks have a round lot size other than 100 shares. See 2024 NMS Amendments, *infra* note 7, 89 FR 81620, 81625 n.67 and accompanying text.

noting that a member “is expected at least to buy or sell a normal unit of trading in the quoted stock at its then prevailing quotations unless clearly designated as not firm or firm for less than a normal unit of trading when supplied by the member.” The proposed rule change would add a new sentence to Supplementary Material .01 to Rule 5220 to clarify that for purposes of Rule 5220, a “normal unit of trading” for an NMS stock means the “round lot” assigned to such NMS stock pursuant to Rule 600(b) of SEC Regulation NMS.

FINRA Rule 5320 (Prohibition Against Trading Ahead of Customer Orders) provides that, except as provided in Rule 5320, a member that accepts and holds an order in an equity security from its own customer or a customer of another broker-dealer without immediately executing the order is prohibited from trading that security on the same side of the market for its own account at a price that would satisfy the customer order, unless it immediately thereafter executes the customer order up to the size and at the same or better price at which it traded for its own account. Among other things, Supplementary Material .05 to Rule 5320 (Odd Lot and Bona Fide Error Transaction Exceptions) provides an exception from these obligations for a member’s proprietary trade that is “to offset a customer order that is in an amount less than a normal unit of trading[.]” The proposed rule change would add a new sentence to Supplementary Material .05 to Rule 5320 to clarify that, for purposes of Rule 5320, a “normal unit of trading” for an NMS stock means the “round lot” assigned to such NMS stock pursuant to Rule 600(b) of SEC Regulation NMS.

The FINRA Rule 6200 Series (Alternative Display Facility) sets forth rules governing the operation of the FINRA Alternative Display Facility (“ADF”), which provides members with a facility for the display of quotations, the reporting of trades, and the comparison of trades in NMS stocks. FINRA Rule 6220 (Definitions) defines specified terms used in the ADF rules, including to define a “normal unit of trading” to mean “100 shares of a security unless, with respect to a particular security, the market where the security is listed determines that a normal unit of trading shall constitute other than 100 shares.” The proposed rule change would amend the definition of “normal unit of trading” in Rule 6220 to mean the “round lot” assigned to a

security pursuant to Rule 600(b) of SEC Regulation NMS.¹⁰

The FINRA Rule 6300 Series (Trade Reporting Facilities) sets forth the rules governing the operation of the FINRA/Nasdaq Trade Reporting Facilities and the FINRA/NYSE Trade Reporting Facility (collectively, the “TRFs”), which provide members with a mechanism for the reporting of transactions in NMS stocks effected otherwise than on an exchange. FINRA Rules 6320(A) (Definitions) and 6320(B) (Definitions) define specified terms used in the FINRA/Nasdaq TRF and FINRA/NYSE TRF rules, respectively, including “normal unit of trading,” which means “100 shares of a security unless, with respect to a particular security, FINRA determines that a normal unit of trading shall constitute other than 100 shares.” The proposed rule change would amend the definitions of “normal unit of trading” in both Rule 6320(A) and Rule 6320(B) to mean the “round lot” assigned to a security pursuant to Rule 600(b) of SEC Regulation NMS.

FINRA Rule 7620A (FINRA/Nasdaq Trade Reporting Facility Reporting Fees) sets forth the charges to be paid by participants for use of the FINRA/Nasdaq TRFs. Under Rule 7620A, participants must complete attestations to qualify for the ATS Market Maker Media/Contra Party Cap and the ATS Market Maker Combined Media Activity Cap. Both attestations include a statement that the participant will “display a quotation size of at least one normal unit of trading (specific for each security)” in each symbol traded on an alternative trading system registered pursuant to Regulation ATS. The proposed rule change would add a new sentence to Supplementary Material .01 to Rule 7620A, which sets forth the definitions of specified terms used in the rule, to clarify that for purposes of Rule 7620A, a “normal unit of trading” means the “round lot” assigned to a security pursuant to Rule 600(b) of SEC Regulation NMS.

FINRA has filed the proposed rule change for immediate effectiveness and has requested that the SEC waive the requirement that the proposed rule

¹⁰ FINRA Rule 6272 (Character of Quotations) includes a duplicative definition of “normal unit of trading.” See Rule 6272(a)(1). For clarity, the proposed rule change would delete the definition in Rule 6272, as the definitions in Rule 6220 apply to the entirety of the Rule 6200 Series. Similarly, FINRA 6279 (Alternative Trading Systems) prohibits the provision of a reserved-size function unless the size of the order displayed through the ADF is “100 shares or greater.” The proposed rule change would amend Rule 6279 to prohibit a reserved-size function unless the size of the order displayed through the ADF is a normal unit of trading or greater.

change not become operative for 30 days after the date of the filing, so FINRA can implement the proposed rule change immediately.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,¹¹ which requires, among other things, that FINRA rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and national market system, and, in general, to protect investors and the public interest, and Section 15A(b)(11) of the Act,¹² which requires among other things that FINRA rules include provisions governing the form and content of quotations relating to securities sold otherwise than on a national securities exchange which may be distributed or published by any member or person associated with a member, and the persons to whom such quotations may be supplied. FINRA believes the proposed rule change will reduce confusion and provide greater clarity to members and the public by conforming the term “normal unit of trading” as used in FINRA rules with respect to NMS stocks to the new definition of “round lot” as adopted by the Commission in Regulation NMS.

B. Self-Regulatory Organization’s Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change conforms FINRA rules to requirements established under Regulation NMS.

Economic Impact Assessment

FINRA has undertaken an economic impact assessment, as set forth below, to analyze the potential economic impacts of the proposed rule change, including anticipated costs, benefits, and distributional and competitive effects, relative to current baseline.

Regulatory Need

The proposed rule change would conform FINRA rules with amendments to the definition of “round lot” under Rule 600(b)(93) of Regulation NMS, minimizing potential confusion and helping industry participants

¹¹ 15 U.S.C. 78o–3(b)(6).

¹² 15 U.S.C. 78o–3(b)(11).

implement the SEC's new definition of "round lot."

Economic Baseline

The economic baseline for the proposed rule change consists of current FINRA Rules 5220, 5320, 6220, 6272, 6279, 6320A, 6320B, and 7620A, as well as the amendments to Rule 600 of Regulation NMS adopted by the SEC.

Economic Impacts

The proposed changes to FINRA rules conform the term "normal unit of trading" as used in FINRA rules with respect to NMS stocks to the new definition of "round lot" as adopted by the SEC in Regulation NMS. The proposed changes do not impose any burdens on industry beyond those that industry must incur to implement the SEC's final rules pertaining to the new definition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

FINRA has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act¹³ and Rule 19b-4(f)(6) thereunder.¹⁴ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁵ and Rule 19b-4(f)(6)(iii) thereunder.¹⁶

A proposed rule change filed under Rule 19b-4(f)(6)¹⁷ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),¹⁸ the

Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. FINRA has asked the Commission to waive the 30-day operative delay so that FINRA can implement the proposed rule change immediately and conform its rules with current federal securities laws and regulations, particularly Rule 600(b)(93) of Regulation NMS, which took effect in November 2025.¹⁹ For these reasons, and because the proposed rule change does not raise any new or novel regulatory issues, the Commission finds that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.²⁰

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings under Section 19(b)(2)(B)²¹ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-FINRA-2025-015 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-FINRA-2025-015. This file

number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of FINRA. 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-FINRA-2025-015 and should be submitted on or before January 13, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²²

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-23666 Filed 12-22-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 35835; File No. 812-15843]

Kayne Anderson Energy Infrastructure Fund, Inc., et al.

December 18, 2025.

AGENCY: Securities and Exchange Commission ("Commission" or "SEC").
ACTION: Notice.

Notice of application for an order under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the "Act") and rule 17d-1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d-1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain business development companies ("BDCs") and closed-end management investment companies to co-invest in portfolio companies with each other and with certain affiliated investment entities.

APPLICANTS: Kayne Anderson Energy Infrastructure Fund, Inc., Kayne Anderson BDC, Inc., Kayne DL 2021, Inc., KA Credit Advisors, LLC, KA Credit Advisors II, LLC, KA Fund Advisors, LLC, Kayne Anderson Capital Advisors, L.P. and certain of their

¹³ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁴ 17 CFR 240.19b-4(f)(6).

¹⁵ 15 U.S.C. 78s(b)(3)(A).

¹⁶ 17 CFR 240.19b-4(f)(6). 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, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. FINRA has satisfied this requirement.

¹⁷ 17 CFR 240.19b-4(f)(6).

¹⁸ 17 CFR 240.19b-4(f)(6)(iii).

¹⁹ See *supra* note 7.

²⁰ 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).

²¹ 15 U.S.C. 78s(b)(2)(B).

²² 17 CFR 200.30-3(a)(12), (59).

affiliated entities as described in Schedule A to the application.

FILING DATES: The application was filed on June 30, 2025, and amended on October 1, 2025, and December 17, 2025.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at Secretarys-Office@sec.gov and serving the Applicants 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 Commission by 5:30 p.m. on January 12, 2026, and should be accompanied by proof of service on the 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 emailing the Commission's Secretary at Secretarys-Office@sec.gov.

ADDRESSES: The Commission: Secretarys-Office@sec.gov. Applicants: Michael O'Neil, Kayne Anderson Capital, moneil@kaynecapital.com and David A. Hearth, Paul Hastings LLP, davidhearth@paulhastings.com.

FOR FURTHER INFORMATION CONTACT: Adam Large, Senior Special Counsel or Laura Solomon, Senior Counsel, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' amendment no. 2 to the application, filed December 17, 2025, which may be obtained via the Commission's website by searching for the file number at the top of this document, 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 the SEC's Office of Investor Education and Advocacy at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025–23651 Filed 12–22–25; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–104454; File No. SR–CboeBZX–2025–161]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the WisdomTree Bitcoin Fund, Shares of Which Were Approved To List and Trade on the Exchange Pursuant to BZX Rule 14.11(e)(4)

December 18, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on December 8, 2025, Cboe BZX Exchange, Inc. (the “Exchange” or “BZX”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a “non-controversial” proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³ and Rule 19b–4(f)(6) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (“BZX” or the “Exchange”) is filing with the Securities and Exchange Commission (“Commission” or “SEC”) a proposed rule change to amend the WisdomTree Bitcoin Fund (the “Fund”), shares (“Fund Shares”) of which have been approved by the Commission to list and trade on the Exchange pursuant to BZX Rule 14.11(e)(4) under an approval order, to permit the Fund to list and trade under the generic listing standards of that rule.

The text of the proposed rule change is also available on the Commission's website (<https://www.sec.gov/rules/sro.shtml>), the Exchange's website (<https://www.cboe.com/us/equities/>

[regulation/rule_filings/bzx/](#)), and at the principal office of the Exchange.

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 Commission has previously approved the listing and trading of shares for the Fund under Rule 14.11(e)(4),⁵ and the Fund currently lists and trades on the Exchange. The Exchange now proposes to transition this Fund to operate under the recently Commission-approved generic listing standards for Commodity-Based Trust Shares pursuant to Rule 14.11(e)(4) (“Amended Rule 14.11(e)(4)”).⁶ The Fund will meet the requirements of Amended Rule 14.11(e)(4) and will be required to comply with the continued listing requirements set forth in such Rule.

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.⁷ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)⁸ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and

⁵ See Securities Exchange Act No. 99306 (January 10, 2024) 89 FR 3008 (January 17, 2024) (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”).

⁶ See Securities Exchange Act No. 103995 (September 17, 2025) 90 FR 45414 (September 22, 2025) (SR–CboeBZX–2025–104) (Order Granting Accelerated Approval of Proposed Rule Changes, as Modified by Amendments Thereto, To Adopt Generic Listing Standards for Commodity-Based Trust Shares).

⁷ 15 U.S.C. 78f(b).

⁸ 15 U.S.C. 78f(b)(5).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴ 17 CFR 240.19b–4(f)(6).

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)⁹ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed rule change is designed to remove impediments to and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest because it would provide for the transition of the Fund from being listed pursuant to the Bitcoin ETP Approval Order to Amended Rule 14.11(e)(4) instead. The proposed change would allow the Fund Shares to continue listing and trading on the Exchange and permit the Fund to operate in reliance on the generic listing standards in Amended Rule 14.11(e)(4) instead of the terms of the Bitcoin ETP Approval Order, thereby facilitating the continued listing and trading of exchange-traded products that will enhance competition among market participants, to the benefit of investors and the marketplace. The Fund will meet the requirements of Amended Rule 14.11(e)(4) and will be required to comply with the continued listing standards set forth in Amended Rule 14.11(e)(4).

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 purpose of the Act. As discussed above, the proposed change is intended to facilitate the continued listing and trading of the Fund on the Exchange, thereby promoting competition among exchange-traded products to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act¹⁰ and Rule 19b-4(f)(6)¹¹ thereunder. Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; or (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act¹² and Rule 19b-4(f)(6)¹³ thereunder.

A proposed rule change filed under Rule 19b-4(f)(6)¹⁴ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),¹⁵ the Commission may designate a shorter time if such action is consistent with protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because it will allow the Exchange to implement the proposed rule change without delay and does not introduce any novel regulatory issues. Accordingly, the Commission designates the proposed rule change to be 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. If the

¹⁰ 15 U.S.C. 78s(b)(3)(A).

¹¹ 17 CFR 240.19b-4(f)(6).

¹² 15 U.S.C. 78s(b)(3)(A).

¹³ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹⁴ 17 CFR 240.19b-4(f)(6).

¹⁵ 17 CFR 240.19b-4(f)(6)(iii).

¹⁶ For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-CboeBZX-2025-161 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-CboeBZX-2025-161. 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 filing 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-CboeBZX-2025-161 and should be submitted on or before January 13, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁷

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-23673 Filed 12-22-25; 8:45 am]

BILLING CODE 8011-01-P

¹⁷ 17 CFR 200.30-3(a)(12) and (59).

⁹ *Id.*

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–104449; File No. SR–NYSE–2025–44]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Price List

December 18, 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 December 5, 2025, New York Stock Exchange LLC (“NYSE” or the “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the 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 definition of “last modified” in the NYSE Price List (“Price List”) applicable to D Orders that execute in the close. The proposed rule change is available on the Exchange’s website at www.nyse.com and at the principal office of the Exchange.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the definition of “last modified” in the Price List applicable to D Orders that execute in the close. The Exchange

proposes to implement the fee change effective December 5, 2025.

Background

Current Market and Competitive Environment

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system “has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.”³

While Regulation NMS has enhanced competition, it has also fostered a “fragmented” market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that “such competition can lead to the fragmentation of order flow in that stock.”⁴ Indeed, cash equity trading is currently dispersed across 16 exchanges,⁵ numerous alternative trading systems,⁶ and broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly-available information, no single exchange currently has more than 20% market share.⁷ Therefore, no exchange possesses significant pricing power in the execution of cash equity order flow. More specifically, the Exchange’s share of executed volume of equity trades in Tapes A, B and C securities is less than 12%.⁸

The Exchange believes that the ever-shifting market share among the exchanges from month to month

demonstrates that market participants can move order flow, or discontinue or reduce use of certain categories of products. While it is not possible to know a firm’s reason for shifting order flow, the Exchange believes that one such reason is because of fee changes at any of the registered exchanges or non-exchange venues to which the firm routes order flow. Accordingly, competitive forces compel the Exchange to use exchange transaction fees and credits because market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

The proposed change responds to the current competitive environment where order flow providers have a choice of where to direct liquidity-providing orders and closing price orders by encouraging all member organizations to enter or modify D Orders as early possible, which the Exchange believes promotes efficient use of Exchange systems in the best interests of member organizations and investors accessing the Exchange.

Proposed Rule Change

The Exchange currently offers fees differentiated by time of entry (or last modification) for D Orders at the close after the first 10,500,000 ADV of the aggregate executions at the close by a member organization. Footnote 10 of the Price List defines “last modified” in this connection as follows:

As used herein, “last modified” means the later of the order’s entry time or the final modification or cancellation time for any D Order designated for the close with the same broker badge, entering firm mnemonic, symbol, and side.

The Exchange proposes to amend this definition to provide that “last modified” would mean the later of the order’s entry time or the final modification for a D Order designated for the close. As proposed, the definition would read as follows:

As used herein, “last modified” means the later of the order’s entry time or the final modification for a D Order designated for the close.

The Exchange is not proposing any changes to the current fees.

The proposed changes are not otherwise intended to address any other issues, and the Exchange is not aware of any problems that member organizations would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (File No. S7–10–04) (Final Rule) (“Regulation NMS”).

⁴ See Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

⁵ See Cboe U.S. Equities Market Volume Summary, available at https://markets.cboe.com/us/equities/market_share. See generally <https://www.sec.gov/fast-answers/divisionsmarketregmr-exchangesshtml.html>.

⁶ See FINRA ATS Transparency Data, available at <https://otctransparency.finra.org/otctransparency/AtsIssueData>. A list of alternative trading systems registered with the Commission is available at <https://www.sec.gov/foia/docs/atslist.htm>.

⁷ See Cboe Global Markets U.S. Equities Market Volume Summary, available at https://markets.cboe.com/us/equities/market_share/.

⁸ See *id.*

Section 6(b) of the Act,⁹ in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,¹⁰ in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,¹¹ in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,¹² in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

As discussed above, the Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system “has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.”¹³ While Regulation NMS has enhanced competition, it has also fostered a “fragmented” market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that “such competition can lead to the fragmentation of order flow in that stock.”¹⁴

The Proposed Change Is Reasonable

The proposed changes to the definition of “last modified” are reasonable. Specifically, the Exchange believes that removing order cancellations and the restriction to D Orders with the same broker badge, entering firm mnemonic, symbol, and

side would result in more D Orders moving to the Early and Mid D Orders buckets in the Price List, *i.e.*, D Orders last modified earlier than 10 minutes before, and from 10 minutes up to but not including 1 minute before, the scheduled close of trading, respectively, rather than the Late D Order bucket, *i.e.*, D Orders last modified in the last 1 minute before the scheduled close of trading. As a result, the Exchange believes that the proposed rule change constitutes a reasonable effort to further encourage all member organizations to enter D Orders as early possible in order to build up liquidity going into the closing auction, and to modify D Orders as early as possible in order to achieve lower fees for modifying the order type.

The Proposal Is an Equitable Allocation of Fees

The Exchange believes the proposal equitably allocates fees and credits among market participants because all member organizations that participate on the Exchange may qualify for lower fees on an equal basis if the member organization enters or modifies D Orders as early possible. The proposal neither targets nor will it have a disparate impact on any particular category of market participant. All member organizations that provide liquidity at the Exchange close would be eligible for lower fees if they enter or modify D Orders as early as possible. The Exchange also believes the proposal equitably allocates its fees and credits among its market participants because the proposed change would encourage greater marketable and other liquidity at the closing auction, which helps to maintain the quality of the Exchange’s closing auctions for the benefit of all market participants. Member organizations derive a substantial benefit from the higher volume of closing executions.

The Proposal Is Not Unfairly Discriminatory

The Exchange believes that the proposal is not unfairly discriminatory. In the prevailing competitive environment, member organizations are free to disfavor the Exchange’s pricing if they believe that alternatives offer them better value.

The proposal does not permit unfair discrimination because the proposed criteria would be applied to all similarly situated member organizations, who would all be eligible for the same lower fees on an equal and non-discriminatory basis. The Exchange also believes that the proposal is not unfairly discriminatory because the proposed changes would equally encourage all

member organizations to provide greater marketable and other liquidity at the closing auction. Finally, the submission of orders to the Exchange is optional for member organizations in that they could choose whether to submit orders to the Exchange and, if they do, the extent of its activity in this regard.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization’s Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,¹⁵ the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for member organizations. As a result, the Exchange believes that the proposed change furthers the Commission’s goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes “more efficient pricing of individual stocks for all types of orders, large and small.”¹⁶

Intramarket Competition. The proposed change is designed to attract additional order flow to the Exchange. The Exchange believes that the proposed changes would continue to incentivize market participants to direct order flow to the Exchange. Greater liquidity benefits all market participants on the Exchange by providing more trading opportunities and encourages member organizations to send orders, thereby contributing to robust levels of liquidity, which benefits all market participants on the Exchange. Lower fees for entering or modifying D Orders would be available to all similarly-situated market participants, and, as such, the proposed change would not impose a disparate burden on competition among market participants on the Exchange. As noted, the proposal would apply to all similarly situated member organizations on the same and equal terms, who would benefit from the changes on the same basis. Accordingly, the proposed change would not impose a disparate burden on competition among market participants on the Exchange.

¹⁵ 15 U.S.C. 78f(b)(8).

¹⁶ See Regulation NMS, 70 FR at 37498–99.

⁹ 15 U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(4) & (5).

¹¹ 15 U.S.C. 78f(b).

¹² 15 U.S.C. 78f(b)(4) & (5).

¹³ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37495, 37499 (June 29, 2005) (S7–10–04) (Final Rule) (“Regulation NMS”).

¹⁴ See Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those 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 and with off-exchange venues. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange does not believe its proposed fee change can impose any burden on intermarket competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to Section 19(b)(3)(A)(ii) of the Act,¹⁷ and Rule 19b-4(f)(2) thereunder¹⁸ the Exchange has designated this proposal as establishing or changing a due, fee, or other charge imposed on any person, whether or not the person is a member of the self-regulatory organization, which renders the proposed rule change effective upon filing. 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-NYSE-2025-44 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.
- All submissions should refer to file number SR-NYSE-2025-44. 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 filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSE-2025-44 and should be submitted on or before January 13, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁹

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-23663 Filed 12-22-25; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104451; File No. SR-MIAX-2025-49]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing of a Proposed Rule Change To Amend Exchange Rule 402, Criteria for Underlying Securities, To Permit Options on Commodity-Based Trust Shares

December 18, 2025.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² notice is hereby given that on December 4, 2025, Miami International Securities Exchange, LLC ("MIAX" or "Exchange") filed with the Securities and Exchange Commission ("Commission") a 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 Exchange Rule 402, Criteria for Underlying Securities, to permit options on Commodity-Based Trust Shares. Specifically, the Exchange proposes to amend the rule to (1) redefine Commodity-Based Trust; (2) require additional qualifying criteria, based on the criteria outlined by the primary listing market to list options on a Commodity-Based Trust; and (3) require that the crypto asset held by the Commodity-Based Trust have a comprehensive surveillance sharing agreement. This filing also defines a crypto asset. Additionally, this filing proposes to amend Exchange Rule 403(g) to update the relevant citations to Exchange Rule 402, which are revised pursuant to this filing.

The text of the proposed rule change is available on the Exchange's website at <https://www.miaxglobal.com/markets/us-options/all-options-exchanges/rule-filings> and at MIAX's principal office.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its listing rules at Exchange Rule 402, Criteria for Underlying Securities.³ Specifically, the Exchange proposes to amend the criteria for listing options on Exchange-Traded Fund Shares ("ETFs") at Exchange Rule 402(i). This is a

³ The Exchange notes that its affiliate options exchanges, MIAX PEARL, LLC ("MIAX Pearl") and MIAX Sapphire, LLC ("MIAX Sapphire"), submitted (or will submit) substantively similar proposals. The Exchange notes that the rules of Chapter IV of MIAX, including Exchange Rule 402, are incorporated by reference into the MIAX Emerald, LLC ("MIAX Emerald") rulebook.

¹⁷ 15 U.S.C. 78s(b)(3)(A)(ii).

¹⁸ 17 CFR 240.19b-4.

¹⁹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

competitive filing substantively identical to the proposal submitted by Nasdaq ISE, LLC (“ISE”) to the Securities and Exchange Commission (the “Commission”), which was recently deemed approved.⁴

The Exchange initially filed SR–MIAX–2025–07, as Modified by Partial Amendment No. 1, a proposed rule change to amend its listing rules at Exchange Rule 402, Criteria for Underlying Securities, to allow the listing and trading of options on interests in a Commodity-Based Trust on March 5, 2025, which was published in the Federal Register [sic] on March 19, 2025.⁵ On April 25, 2025, the Commission issued a notice designating a longer period for Commission action, which designated June 17, 2025, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove the filing.⁶ On June 17, 2025, the Commission issued an order instituting proceedings to determine whether to approve or disapprove the filing.⁷ The Commission did not receive any comments on the proposed rule change. On September 8, 2025, the Commission extended the time period for approving or disapproving the proposed rule changes, as modified by the applicable Partial Amendments, for an additional 60 days, designating November 14, 2025 as the date by which the Commission will

either approve or disapprove the proposed rule change, as modified by the applicable Partial Amendments.⁸ The Commission did not act to either approve or disapprove the proposal on or before November 14, 2025, therefore the proposal, as published in the **Federal Register** on March 5, 2025, was deemed approved as of November 14, 2025.⁹ On November 6, 2025, during the government shutdown, the Exchange submitted Amendment 2 to SR–MIAX–2025–07. The Exchange is now proposing the current change to reiterate the changes proposed in Amendment 2 to SR–MIAX–2025–07 to codify the proposed rule text in the Exchange’s Rulebook.

The Exchange proposes to amend Rule 402 to adopt new listing criteria in subparagraph (i)(6) to permit the listing and trading of options on a Commodity-Based Trust that meets the generic listing standards for Commodity-Based Trust Shares of the applicable primary listing market, except that the Commodity-Based Trust holds a single crypto asset.¹⁰

On September 17, 2025, the Commission approved proposals by The Nasdaq Stock Market LLC, Cboe BZX Exchange, Inc. and NYSE Arca, Inc., to Adopt Generic Listing Standards for Commodity-Based Trusts.¹¹ In the

approval order, the Commission noted that each of the exchanges proposed to adopt substantially identical “generic” listing standards for Commodity-Based Trusts. Those generic listing standards define the term shares of a “Commodity-Based Trust” as a security¹² that:

(1) is issued by a trust, limited liability company, partnership, or other similar entity (“Trust”) that, if applicable, is operated by a registered commodity pool operator pursuant to the Commodity Exchange Act (“CEA”), and is not registered as an investment company pursuant to the Investment Company Act of 1940, or series or class thereof;

(2) is designed to reflect the performance of one or more reference assets or an index of reference assets;

(3) in order to reflect the performance, is issued by a Trust that holds (a) one or more commodities or commodity-based assets, and (b) in addition to such commodities or commodity-based assets, may hold securities, cash, and cash equivalents;

(4) is issued by such Trust in a specified aggregate minimum number in return for a deposit of (a) a specified quantity of the underlying commodities, commodity-based assets, securities, cash, and/or cash equivalents or (b) a cash amount with a value based on the next determined net asset value per Trust share; and

(5) when aggregated in the same specified minimum number, may be redeemed at a holder’s request by such Trust which will deliver to the redeeming holder (a) the specified quantity of the underlying commodities, commodity-based assets, securities, cash, and/or cash equivalents or (b) a cash amount with a value based on the next determined net asset value per Trust share.

The Exchange proposes to amend Exchange Rule 402(i) to create a new subparagraph (6)(iii) that states,¹³

Standards for Commodity-Based Trust Shares)(SR–NASDAQ–2025–056; SR–CboeBZX–2025–104; SR–NYSEARCA–2025–54) (“Generic Listing Standards for Commodity-Based Trust Shares Approval”). The Exchange believes that it is appropriate to rely on the generic listing standards outlined by the primary listing market due to the potential proliferation of new primary listing markets and the Commission’s acknowledgment that the definition of shares of a Commodity-Based Trust across those primary listing markets is substantially identical.

¹² Shares of the applicable Commodity-Based Trust trade as equity securities. See Securities Exchange Act Release No. 50603 (Oct. 28, 2004), 69 FR 64614, 64619 (Nov. 5, 2004) (SR–NYSE–2004–22) (approving the listing and trading of streetTRACKS Gold Shares) (“Spot Gold Approval Order”) and ETP Request for Comments, *infra* note 20, at 34731. See also Nasdaq Rule 5711(d)(ii); proposed BZX Rule 14.11(e)(4)(B); proposed NYSE Arca Rule 8.201–E(b) (Generic) (stating that Commodity-Based Trust Shares are included within the definition of a “security” as such term is used in the Exchanges’ rules and are subject to the Exchanges’ existing rules governing the trading of equity securities).

¹³ The Exchange proposes to renumber current Exchange Rules 402(i)(5)(i) and 402(i)(5)(ii) to Exchange Rules 402(i)(6)(i) and 402(i)(6)(ii) for ease

Continued

⁴ See Securities Exchange Act Release No. 102465 (February 7, 2025), 90 FR 10740 (February 26, 2025) (SR–ISE–2025–08) (Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, to Adopt Listing Criteria for Options on a Commodity-Based Trust) [sic].

⁵ See Securities Exchange Act Release No. 102658 (March 5, 2025), 90 FR 12870 (March 19, 2025) (SR–MIAX–2025–07) (Self-Regulatory Organizations; Notice of Filing of a Proposed Rule Change, as Modified by Partial Amendment No. 1, by Miami International Securities Exchange, LLC To Amend Exchange Rule 402, Criteria for Underlying Securities, To List and Trade Options on Commodity-Based Trust Shares).

⁶ See Securities Exchange Act Release No. 102932 (April 25, 2025), 90 FR 18715 (May 1, 2025) (SR–MIAX–2025–07) (Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change, as Modified by Partial Amendment No. 1, To Amend Exchange Rule 402, Criteria for Underlying Securities, To List and Trade Options on Commodity-Based Trust Shares).

⁷ See Securities Exchange Act Release No. 103283 (June 17, 2025), 90 FR 26634 (June 23, 2025) (SR–MIAX–2025–07) (Self-Regulatory Organizations; Miami International Securities Exchange, LLC; MIAX PEARL, LLC; MIAX Sapphire, LLC; Order Instituting Proceedings To Determine Whether To Approve or Disapprove Proposed Rule Changes, as Modified by Partial Amendments Thereto, To Amend Rule 402, Criteria for Underlying Securities, To List and Trade Options on Commodity-Based Trust Shares).

⁸ See Securities Exchange Act Release No. 103903 (September 8, 2025), 90 FR 44123 (September 11, 2025) (SR–MIAX–2025–07) (Self-Regulatory Organizations; Miami International Securities Exchange, LLC; MIAX PEARL, LLC; MIAX Sapphire, 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 Partial Amendments Thereto, To Amend Rule 402, Criteria for Underlying Securities, To List and Trade Options on Commodity-Based Trust Shares).

⁹ See Securities Exchange Act Release No. 104210 (November 18, 2025), 90 FR 52727 (November 21, 2025) (SR–MIAX–2025–07) (Self-Regulatory Organizations; BOX Exchange LLC, Cboe Exchange, Inc., Cboe BYX Exchange, Inc., Cboe BZX Exchange, Inc., Cboe EDGX Exchange, Inc., Miami International Securities Exchange, LLC, MIAX PEARL, LLC, MIAX Sapphire, LLC, Nasdaq ISE, LLC, New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE National, Inc., and NYSE Texas, Inc.; Notice of Deemed Approval of Various Proposed Rule Changes).

¹⁰ For example, a multi-coin ETF would not be subject to Exchange Rule 402(i)(6). For purposes of this rule the term “crypto asset” means an asset that is generated, issued and/or transferred using a blockchain or similar distributive ledger technology network, including but not limited to, assets known as “tokens,” “digital assets,” “virtual currencies,” and “coins” and that relies on cryptographic protocols. See definition at proposed Exchange Rule 402(i)(6)(iii).

¹¹ See Securities Exchange Act Release No. 103995 (Sept. 17, 2025), 90 FR 45414 (Sept. 22, 2025) (Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Cboe BZX Exchange, Inc.; NYSE Arca, Inc.; Order Granting Accelerated Approval of Proposed Rule Changes, as Modified by Amendments Thereto, To Adopt Generic Listing

Additionally, with respect to a Commodity-Based Trust that meets the requirements of Exchange Rule 402(i)(6), the following requirements are satisfied: (A) the total global supply of the underlying crypto asset held by the Commodity-Based Trust has an average daily market value of at least \$700 million over the last 12 months; and (B) the crypto asset held by the Commodity-Based Trust underlies a derivatives contract that trades on a market with which the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in the Intermarket Surveillance Group. For purposes of this rule the term “crypto asset” means an asset that is generated, issued and/or transferred using a blockchain or similar distributive ledger technology network, including but not limited to, assets known as “tokens,” “digital assets,” “virtual currencies,” and “coins” and that relies on cryptographic protocols.

The proposed additional criteria would require a Commodity-Based Trust to: (1) meet the generic criteria for Commodity-Based Trust Shares of the applicable primary listing market and hold only a single crypto asset; (2) meet the criteria and guidelines set forth in Exchange Rule 402(a)¹⁴ and (b),¹⁵ or Exchange Rule 402(i)(6)(i)(B);¹⁶ and meet the requirements in 402(i)(6)(iii) prior to listing options on the Commodity-Based Trust.

As proposed, Exchange Rule 402(i)(6)(iii) requires Commodity-Based Trust that meets the requirements of 402(i)(6) to also satisfy the following requirements: (A) the total global supply of the underlying crypto asset held by the Commodity-Based Trust has an average daily market value of at least \$700 million over the last 12 months;

of reference, clarity, and consistency of the Rulebook.

¹⁴ Exchange Rule 402(a) provides that a security (which includes an ETF) on which options may be listed and traded on the Exchange must be a security registered (with the Commission) and be an NMS stock (as defined in Rule 600 of Regulation NMS under the Act), and the security shall be characterized by a substantial number of outstanding shares that are widely held and actively traded.

¹⁵ Exchange Rule 402(b) provides criteria and guidelines when evaluating potential underlying securities for the listing of options.

¹⁶ Exchange Rule 402(i)(6)(i)(B) provides that the Exchange-Traded Fund Shares are available for creation or redemption each business day from or through the issuing trust, investment company, commodity pool or other entity in cash or in kind at a price related to net asset value, and the issuer is obligated to issue Exchange-Traded Fund Shares in a specified aggregate number even if some or all of the investment assets and/or cash required to be deposited have not been received by the issuer, subject to the condition that the person obligated to deposit the investment assets has undertaken to deliver them 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 of the Exchange-Traded Fund Shares, all as described in the Exchange-Traded Fund Shares’ prospectus.

and (B) the crypto asset held by the Commodity-Based Trust underlies a derivatives contract that trades on a market with which the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in the Intermarket Surveillance Group (“ISG”).

The Exchange defines a “crypto asset” at Exchange Rule 402(i)(6)(iii) to mean, for purposes of this rule, an asset that is generated, issued and/or transferred using a blockchain or similar distributive ledger technology network, including but not limited to, assets known as “tokens,” “digital assets,” “virtual currencies,” and “coins” and that relies on cryptographic protocols.

The market value of the underlying crypto asset will be calculated by taking the total global supply of the particular crypto asset multiplied by the token price.¹⁷ Total supply of crypto assets includes all crypto assets currently issued and does not include unissued crypto assets.¹⁸

Further, the Exchange has specified in proposed Exchange Rule 402(i)(6)(iii) that the crypto asset held by the Commodity-Based Trust must underlie a derivatives contract that trades on a market with which the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in ISG.¹⁹ The Exchange will be required to ensure that this requirement is met prior to listing options on a Commodity-Based Trust pursuant to proposed Exchange Rule 402(i)(6).

As a result of this filing, the proposed listing criteria would permit a Commodity Based Trust that is generically listed on the applicable primary listing market and holds a single crypto asset to qualify for the listing of options on that ETF, provided Exchange Rule 402(i)(6)(iii) has also been met, as well as the listing criteria in Exchange Rule 402(a) and (b), or Exchange Rule 402(i)(6)(i)(B).

Similar to options on any ETF, an option on a Commodity-Based Trust that meets the requirements of Exchange

Rule 402(i)(6) would also be subject to the Exchange’s continued listing standards for options on ETFs set forth in Exchange Rule 403(g). Pursuant to Exchange Rule 403(g), ETFs approved for options trading pursuant to Exchange Rule 402(i) will not be deemed 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 ETFs, if the ETFs are delisted from trading pursuant to Exchange Rule 403(b)(4),²⁰ are halted or suspended from trading in their primary market.²¹ Additionally, options on ETFs may be subject to the suspension of opening transactions in any of the following circumstances:²²

(1) in the case of options covering ETFs approved for trading under Exchange Rule 402(i)(6)(i)(A), in accordance with the terms of paragraphs (b)(1), (2), and (3) of Exchange Rule 403;²³

(2) in the case of options covering ETFs approved for trading under Exchange Rule 402(i)(6)(i)(B), following the initial twelve-month period beginning upon the commencement of trading in the ETFs on a national securities exchange and are defined as an NMS stock, there are fewer than 50 record and/or beneficial holders of such ETFs 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 ETFs 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.

Consistent with current Exchange Rule 404, which governs the opening of options series on a specific underlying

²⁰ Exchange Rule 403(b)(5) provides, if an underlying security is approved for options listing and trading under the provisions of Rule 402(c), the trading volume of the Original Equity Security (as therein defined) prior to but not after the commencement of trading in the Restructure Security (as therein defined), including “when-issued” trading, may be taken into account in determining whether the trading volume requirement of subparagraph (3) is satisfied.

²¹ See Exchange Rule 403(g). With this filing the Exchange is also proposing to amend Exchange Rule 403(g) to reflect the changes in numbering proposed herein for Exchange Rule 402(i).

²² See *id.*

²³ Exchange Rule 403(b)(1) through (3) provides, if: (1) there are fewer than 6,300,000 shares of the underlying security held by persons other than those who are required to report their security holdings under Section 16(a) of the Act, (2) there are fewer than 1,600 holders of the underlying security, (3) the trading volume (in all markets in which the underlying security is traded) has been less than 1,800,000 shares in the preceding twelve (12) months.

¹⁷ The market supply information can be obtained from publicly available sources such as [coingecko.com](https://www.coingecko.com) or [coinmarketcap.com](https://www.coinmarketcap.com).

¹⁸ For example, if Bitcoin were the underlying crypto asset, the Exchange would consider the total supply of all Bitcoin currently issued instead of the maximum supply, which would be currently issued as well as unminted Bitcoin. As of September 12, 2025, Bitcoin’s total supply was 19,919,915 (the maximum supply was 21,000,000). See <https://www.coingecko.com/en/coins/bitcoin>. The Exchange would calculate market value by utilizing the total supply number multiplied by the Bitcoin price on that day.

¹⁹ For a list of the current members and affiliate members [sic] of ISG, see <https://isgportal.org/publicmembers>.

security (including ETFs), the Exchange will open at least one expiration month²⁴ for options on a Commodity-Based Trust that are approved subject to Exchange Rule 402(i)(6) and may also list series of options on Commodity-Based Trust Share for trading on a weekly,²⁵ monthly,²⁶ or quarterly²⁷ basis. The Exchange may also list long-term equity option series (“LEAPS”) that expire from 12 to 39 months from the time they are listed.²⁸

Pursuant to Exchange Rule 404, Interpretation and Policy .06, which governs strike prices of series of options on ETFs, the interval between strike prices of series of options on ETFs approved for options trading pursuant to Exchange Rule 402(i) shall be fixed at a price per share which is reasonably close to the price per share at which the underlying security is traded in the primary market at or about the same time such series of options is first open for trading on the Exchange, or at such intervals as may have been established on another options exchange prior to the initiation of trading on the Exchange. With respect to the Short Term Options Series or Weekly Program, during the month prior to expiration of an option class that is selected for the Short Term Option Series Program, the strike price intervals for the related non-Short Term Option (“Related non-Short Term Option”) shall be the same as the strike price intervals for the Short Term

Option.²⁹ Specifically, the Exchange may open for trading Short Term Option Series at strike price intervals of (i) \$0.50 or greater where the strike price is less than \$100, and \$1 or greater where the strike price is between \$100 and \$150 for all option classes that participate in the Short Term Options Series Program; (ii) \$0.50 for option classes that trade in one dollar increments and are in the Short Term Option Series Program; or (iii) \$2.50 or greater where the strike price is above \$150.³⁰ Additionally, the Exchange may list series of options pursuant to the \$1 Strike Price Interval Program,³¹ the \$0.50 Strike Program,³² and the \$2.50 Strike Price Program.³³ Pursuant to Exchange Rule 510, where the price of a series of options on a Commodity-Based Trust 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 \$0.10³⁴ consistent with the minimum increments for options on other ETFs listed on the Exchange. Any and all new series of a [sic] Commodity-Based Trust options that the Exchange lists will be consistent and comply with the expirations, strike prices, and minimum increments set forth in Rules 404 and 510, as applicable.

Further, options on a [sic] Commodity-Based Trusts that are approved subject to Exchange Rule 402(i)(6) would trade in the same manner as options on other ETFs on the Exchange. The Exchange Rules that currently apply to the listing and trading of all options on ETFs on the Exchange, including, for example, Rules that govern listing criteria, expirations, exercise prices, minimum increments, position and exercise limits, margin requirements, customer accounts and trading halt procedures would apply to the listing and trading of options on Commodity-Based Trusts that are approved subject to Exchange Rule 402(i)(6) in the same manner.

Position and exercise limits for options on Commodity-Based Trusts that are approved pursuant to Exchange Rule 402(i)(6) would be determined pursuant to Exchange Rules 307 and 309, respectively, as is the case for other options on other ETFs. Position and exercise limits for options on ETF vary according to the number of outstanding

shares and the trading volumes of the underlying ETF over the past six months, where the largest in capitalization and the most frequently traded ETFs have an option position and exercise limits of 250,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market; and smaller capitalization ETFs have position and exercise limits of 200,000, 75,000, 50,000 or 25,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market. Further, Exchange Rule 1502, which governs margin requirements applicable to trading on the Exchange, including options on ETFs, will also apply to the trading of options on a Commodity-Based Trusts listed pursuant to Exchange Rule 402(i)(6).

The Exchange represents that the same surveillance procedures applicable to all other options on other ETFs currently listed and traded on the Exchange will apply to the trading of options on Commodity-Based Trusts that are approved subject to Exchange Rule 402(i)(6).³⁵ The Exchange represents that it has the necessary systems capacity to support the new option series. The Exchange believes that its existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior which might potentially arise from listing and trading options on ETFs, including the listing of options on Commodity-Based Trusts that are approved subject to Exchange Rule 402(i)(6). Also, the Exchange may obtain information from designated contract markets that are members of the ISG related to a financial instrument that is based, in whole or in part, upon an interest in or performance of a crypto asset, as applicable. The Exchange has specified in proposed Exchange Rule 402(i)(6) that the crypto asset held by the Commodity-Based Trust must underlie a derivatives contract that trades on a market with which the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in ISG.³⁶ The Exchange will be required to ensure that this requirement is met prior to listing options on a Commodity-Based Trust

²⁴ See Exchange Rule 404(b). The monthly expirations are subject to certain listing criteria for underlying securities described within Exchange Rule 404 and its Interpretations and Policies. 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 Exchange Rule 404(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. Pursuant to Exchange Rule 404(e), 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.

²⁵ See Exchange Rule 404, Interpretation and Policy .02.

²⁶ See Exchange Rule 404, Interpretation and Policy .13.

²⁷ See Exchange Rule 404, Interpretation and Policy .03.

²⁸ See Exchange Rule 406.

²⁹ See Exchange Rule 404, Interpretation and Policy .02(e).

³⁰ *Id.*

³¹ See Exchange Rule 404, Interpretation and Policy .01.

³² See Exchange Rule 404, Interpretation and Policy .04.

³³ See Exchange Rule 404(f).

³⁴ See Exchange Rule 510.

³⁵ The surveillance program includes real-time patterns for price and volume movements and post-trade surveillance patterns (e.g., spoofing, marking the close, ping, phishing).

³⁶ There are a number of futures contracts on digital asset commodities that are listed and trading on the CME and Coinbase Derivatives, both of which are ISG members. See <https://www.cmegroup.com/markets/cryptocurrencies.html#products>. See also <https://www.coinbase.com/derivatives>.

listed pursuant to proposed Exchange Rule 402(i)(6).

Additionally, the Exchange has also analyzed its capacity and represents that it believes the Exchange and the Options Price Reporting Authority or "OPRA" have the necessary systems capacity to handle the additional traffic associated with the listing of new series of ETFs, including options on a [sic] Commodity-Based Trusts, that are approved subject to Exchange Rule 402(i)(6), up to the number of expirations currently permissible under the Exchange Rules.

Finally, today, the Exchange lists and trades options on ETFs that would qualify for listing as an option on a Commodity-Based Trust under proposed Exchange Rule 402(i)(6),³⁷ and it has not identified any issues with the listing and trading of options on those ETFs.

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.³⁸ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)³⁹ 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)⁴⁰ 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 its proposal to establish new listing criteria at Exchange Rule 402(i)(6) with respect to options on Commodity-Based

Trusts, without the need for additional approvals, 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 it would allow the Exchange to immediately list and trade qualifying options on Commodity-Based Trusts, provided the initial listing criteria has been met, without any additional approvals from the Commission.

Specifically, the Exchange's proposal to adopt Exchange Rule 402(i)(6) to allow the listing and trading of options on units that represent interests in Commodity-Based Trusts that meet the generic listing standards for Commodity-Based Trust Shares of the applicable primary listing market,⁴¹ and hold a single crypto asset, is consistent with the Act because it will permit the Exchange to offer options on Commodity-Based Trusts soon after the listing of the ETF on the primary listing market, provided that all the generic listing standards for that Commodity-Based Trust on that primary listing market have been met. Listing these options will avail market participants of the opportunity to hedge their positions in the Commodity-Based Trusts in a timely manner, thereby providing investors with the ability to hedge their exposure to the underlying Commodity-Based Trust. Options on Commodity-Based Trusts benefits investors, similar to the listing of any other option on an ETF, by providing investors with a relatively lower-cost risk management tool to manage their positions and associated risk in their portfolios more easily in connection with exposure to the price of a crypto asset. Additionally, listing options on Commodity-Based Trusts provides investors with the ability to transact in such options on a listed market as opposed to the OTC options market, which increases market transparency and enhances the process of price discovery to the benefit of all investors.

Also, this proposal would permit options on Commodity-Based Trusts to be listed on the Exchange in the same manner as all other securities that are subject to the current listing criteria in Exchange Rule 402. The Exchange notes that the majority of ETFs are able to list and trade options once the initial listing criteria have been met without the need for additional approvals. The proposed rule change would allow options on certain Commodity-Based Trusts to likewise list and trade options once the initial listing criteria on the primary listing market have been met without the need for additional approvals.

As proposed, the Exchange would list options in a Commodity-Based Trust that met the generic criteria of the applicable primary listing market, provided the Commodity-Based Trust held only a single crypto asset. Further, these options on Commodity-Based Trusts would also be required to satisfy the conditions in proposed Exchange Rule 402(i)(6)(iii). Specifically, a Commodity-Based Trust that met the requirements of proposed Exchange Rule 402(i)(6) would also have to satisfy the following requirements in proposed Exchange Rule 402(i)(6)(iii): (A) the total global supply of the underlying crypto asset held by the Commodity-Based Trust has an average daily market value of at least \$700 million over the last 12 months; and (B) the crypto asset held by the Commodity-Based Trust underlies a derivatives contract that trades on a market with which the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in the ISG.

These requirements are consistent with the Act and the protection of investors as they should ensure that the underlying ETF has sufficient liquidity prior to listing options, which will serve to prevent disruption to the underlying market. The Exchange believes that market supply serves as a good measure of liquidity to prevent the addition of options trading on the Commodity-Based Trust from disrupting the market for the underlying security. Requiring the underlying crypto asset to have a requisite amount of deliverable supply, in addition to all the other criteria the ETF is required to have under the applicable primary listing market rules, should ensure adequate liquidity prior to listing. Further, ensuring the crypto asset held by the Commodity-Based Trust underlies a derivatives contract that trades on a market with which the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in the ISG, will provide the Exchange with information to adequately surveil options on qualifying Commodity-Based Trusts. Today, the Exchange has a comprehensive surveillance sharing agreement in place with both the CME and Coinbase Derivatives through its common membership in ISG. This facilitates the sharing of information that is available to the CME and Coinbase Derivatives through their surveillance of their respective markets, including their surveillance of their respective digital asset futures markets.

The Exchange also believes the proposed rule change will remove impediments to and perfect the

³⁷ The following ETFs currently have options listed on them on the Exchange: iShares Bitcoin Trust, the Fidelity Wise Origin Bitcoin Fund, the ARK21Shares Bitcoin ETF, the Grayscale Bitcoin Trust (BTC), the Grayscale Bitcoin Mini Trust BTC, and the Bitwise Bitcoin ETF. See Exchange Rule 402(i)(4). The Exchange filed rule proposals and received the appropriate regulatory notice or approval to list the aforementioned options on the ETFs.

³⁸ 15 U.S.C. 78f(b).

³⁹ 15 U.S.C. 78f(b)(5).

⁴⁰ *Id.*

⁴¹ See *supra* note 11.

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. Options on qualifying Commodity-Based Trusts must satisfy the initial listing standards and continued listing standards currently in the Exchange Rules applicable to options on all ETFs, including ETFs that hold other crypto assets already deemed appropriate for options trading on the Exchange in addition to the proposed criteria. Options on qualifying Commodity-Based Trusts would trade in the same manner as any other ETF options—the same Exchange Rules that currently govern the listing and trading of all ETF options, including permissible expirations, strike prices and minimum increments, and applicable position and exercise limits and margin requirements, will govern the listing and trading of options on qualifying Commodity-Based Trusts.

The Exchange represents that it has the necessary systems capacity to support the listing and trading of options on qualifying Commodity-Based Trusts. 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 of these options on Commodity-Based Trust, particularly in light of the additional requirement that the crypto asset held by the Commodity-Based Trust underlies a derivatives contract that trades on a market with which the Exchange has a comprehensive surveillance sharing agreement, whether directly or through common membership in ISG.

Finally, today, the Exchange lists and trades options on ETFs that would qualify for listing as an option on a Commodity-Based Trust under proposed Exchange Rule 402(i)(6),⁴² and it has not identified any issues with the listing and trading of options on those ETFs.

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. In this regard

⁴² The following ETFs currently have options listed on them on the Exchange: iShares Bitcoin Trust, the Fidelity Wise Origin Bitcoin Fund, the ARK21Shares Bitcoin ETF, the Grayscale Bitcoin Trust (BTC), the Grayscale Bitcoin Mini Trust BTC, and the Bitwise Bitcoin ETF. See Exchange Rule 402(i)(4). The Exchange filed rule proposals and received the appropriate regulatory notice or approval to list the aforementioned options on the ETFs.

and as indicated above, the Exchange notes that the rule change is being proposed as a competitive response to the filing submitted by ISE.⁴³

The Exchange does not believe that the proposal to amend the listing criteria at Exchange Rule 402(i)(6), with respect to ETFs, to adopt new criteria to permit the listing and trading of options on certain Commodity-Based Trusts that hold a single crypto asset and that were listed pursuant to the generic listing standards for Commodity-Based Trust Shares of the applicable primary listing market, without the need for additional approvals, will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Options on qualifying Commodity-Based Trusts would need to satisfy the initial listing standards set forth in the Exchange Rules in the same manner as any other ETF before the Exchange could list options on them. Additionally, options on qualifying Commodity-Based Trusts will be equally available to all market participants who wish to trade such options. The Exchange Rules currently applicable to the listing and trading of options on ETFs on the Exchange will apply in the same manner to the listing and trading of all options on qualifying Commodity-Based Trusts.

Additionally, the Exchange notes that listing and trading options on qualifying Commodity-Based Trusts 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 in a timely manner.

The Exchange does not believe that the proposal to adopt new listing criteria at Exchange Rule 402(i)(6) to permit the listing and trading of certain options on a Commodity-Based Trust, without the need for additional approvals, will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Other options exchanges are free to amend their applicable rules to permit them to list and trade options on Commodity-Based Trusts.

⁴³ See *supra* note 4.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act⁴⁴ and subparagraph (f)(6) of Rule 19b-4 thereunder.⁴⁵

A proposed rule change filed under Rule 19b-4(f)(6)⁴⁶ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),⁴⁷ the Commission may designate a shorter time if such action is consistent with protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. The Commission believes that waiving 30-day operative delay is consistent with the protection of investors and the public interest because the proposal seeks to amend the Exchange's rules to be consistent with an amendment filed by the Exchange during a government shutdown, and which would have replaced the proposed rule change that did become effective if the Commission could have received amendments during the pendency of the government shutdown.⁴⁸ The proposal also aligns the rule text relating to Commodity-Based Trust Shares with the rule text of other exchanges and does not introduce any novel regulatory issues.⁴⁹ Accordingly, the Commission

⁴⁴ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴⁵ 17 CFR 240.19b-4(f)(6). 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 Commission is waiving this requirement.

⁴⁶ 17 CFR 240.19b-4(f)(6).

⁴⁷ 17 CFR 240.19b-4(f)(6)(iii).

⁴⁸ See *supra* Section II.A.1.

⁴⁹ See e.g., Nasdaq ISE, LLC, Options Rules, Options 4, Section 3(h); Cboe Exchange, Inc. Rule 4.3(a).

designates the proposed rule change to be operative upon filing.⁵⁰

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule 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-MIAX-2025-49 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-MIAX-2025-49. 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 filing 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-MIAX-2025-49 and should be submitted on or before January 13, 2026.

⁵⁰ For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁵¹

Sherry R. Haywood,
Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104456; File No. SR-NASDAQ-2025-069]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 1, To Adopt Additional Initial Listing Criteria for Companies Primarily Operating in China

December 18, 2025.

I. Introduction

On September 4, 2025, the Nasdaq Stock Market LLC ("Exchange" or "Nasdaq") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to adopt additional initial listing criteria for companies primarily operating in the People's Republic of China ("China"), including the Hong Kong Special Administrative Region ("Hong Kong") and the Macau Special Administrative Region ("Macau"). On September 12, 2025, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced and superseded the original filing in its entirety. The proposed rule change, as modified by Amendment No. 1, was published for comment in the **Federal Register** on September 19, 2025.³ On September 25, 2025, the Commission designated a longer period within which to take action on the proposed rule change.⁴ The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act⁵ to determine

whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.

II. Description of the Proposed Rule Change, as Modified by Amendment No. 1

As described in more detail in the Notice,⁶ the Exchange states that, since 2020, there has been a sharp increase in the number of companies from China seeking to list on U.S. national securities exchanges, such as Nasdaq, with a record number of Chinese companies having sought a U.S. listing in 2024 and a continuation of that pace in 2025.⁷ The Exchange states that along with increasing U.S. investor interest in Chinese companies, U.S. policymakers and regulatory agencies have voiced concerns regarding the listing of Chinese companies on U.S. national securities exchanges, citing risks to investors and national security.⁸ In response, efforts have been made by Congress,⁹ as well as by Nasdaq,¹⁰ to address these concerns on a broader level.¹¹

The Exchange states that it has also identified concerns with the trading of companies headquartered, incorporated, or whose business is principally administered in China.¹² Specifically, the Exchange states that "nearly 70% of the matters that Nasdaq has referred to the SEC or FINRA since August 2022 have been related to trading in Chinese companies, while Chinese companies represent less than 10% of all Nasdaq listings."¹³ The Exchange also states that Chinese companies that list on Nasdaq through an initial public offering ("IPO") or business combination with certain characteristics, such as a small offering size or a low public float percentage, may not develop sufficient public float,

⁶ See Notice, *supra* note 3.

⁷ See *id.* at 45299.

⁸ See *id.* In particular, the Exchange states that Chinese companies present unique risks to U.S. investors "due to barriers on access to information and limitations on the ability of U.S. regulators to conduct investigations or enforce actions against the company and non-U.S. persons, which create concerns about the accuracy of disclosures, accountability and access to information." *Id.* at 45300.

⁹ See *id.* at 45299 (citing as an example Congress's passage of the Holding Foreign Companies Accountable Act in December 2020).

¹⁰ See, e.g., Securities Exchange Act Release No. 93256 (Oct. 4, 2021), 86 FR 56338 (Oct. 8, 2021) (NASDAQ-2021-007) (Order Granting Approval of a Proposed Rule Change To Adopt Additional Initial Listing Criteria for Companies Primarily Operating in Jurisdictions That Do Not Provide the PCAOB With the Ability To Inspect Public Accounting Firms).

¹¹ See Notice, *supra* note 3, at 45299.

¹² See *id.*

¹³ *Id.*

⁵¹ 17 CFR 200.30-3(a)(12), (59).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 103979 (Sept. 16, 2025), 90 FR 45298 ("Notice"). Comments received on the proposed rule change are available at: <https://www.sec.gov/comments/sr-nasdaq-2025-069/srnasdaq2025069.htm>.

⁴ See Securities Exchange Act Release No. 104058, 90 FR 46973 (Sept. 30, 2025). The Commission designated December 18, 2025, as the date by which the Commission should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change. See *id.*

⁵ 15 U.S.C. 78s(b)(2)(B).

investor base, and trading interest to provide the liquidity necessary to promote fair and orderly trading, and that as a result their securities may be more susceptible to manipulation by bad actors.¹⁴ Moreover, the Exchange states that challenges related to the ability of “U.S. authorities in bringing or enforcing actions against entities and individuals involved in potentially manipulative trading activities” in such cases further compounds the risk to investors.¹⁵ Accordingly, the Exchange proposes to enhance its initial listing standards by adopting stricter requirements for companies based in China (including Hong Kong and Macau).¹⁶

A. Identification of Companies Based in China, Hong Kong, and Macau

The Exchange proposes to adopt listing requirements in Nasdaq Rule 5210(l)¹⁷ that would apply to a company that is headquartered or incorporated in China (including Hong Kong and Macau) or whose business is principally administered in one of those jurisdictions (“China-based company”). The Exchange would determine where a company is principally administered based on an analysis of the facts and circumstances,¹⁸ including if: (1) the company’s books and records are located in that jurisdiction; (2) at least 50% of the company’s assets are located in such jurisdiction; (3) at least 50% of the company’s revenues are derived from such jurisdiction; (4) at least 50% of the company’s directors are citizens of, or reside in, such jurisdiction; (5) at least 50% of the company’s officers are citizens of, or reside in, such jurisdiction; (6) at least 50% of the company’s employees are based in such jurisdiction; or (7) the company is controlled by, or under common control with, one or more persons or entities that are citizens of, reside in, or whose business is headquartered, incorporated, or principally administered in such jurisdiction.¹⁹

¹⁴ See *id.*

¹⁵ *Id.*

¹⁶ See *id.* The Exchange states that a company that falls under proposed Nasdaq Rule 5210(l) would also need to comply with all other applicable listing requirements. See *id.* at 45300.

¹⁷ The Exchange also proposes to renumber the remainder of Nasdaq Rule 5210 as subsections (m) and (n).

¹⁸ The Exchange states that it would consider the proposed “elements holistically, recognizing that there are various factors to consider when determining where a company conducts its principal business activities.” *Id.*

¹⁹ See proposed Nasdaq Rule 5210(l). The Exchange states that several of the factors in proposed Nasdaq Rule 5210(l) are used in its rules to determine whether a company’s business is principally administered in a “Restrictive Market.”

B. Minimum \$25 Million Offering Size for an IPO

The Exchange proposes to require that, in the case of an IPO, a China-based company must offer a minimum amount of securities in a Firm Commitment Offering²⁰ in the U.S. to Public Holders²¹ that would result in gross proceeds to the company of at least \$25 million.²² The Exchange states that it has observed that China-based companies listing on Nasdaq in connection with an IPO with an offering size below \$25 million have a higher rate of compliance concerns.²³

C. Minimum \$25 Million Market Value of Publicly Held Shares for a Business Combination

The Exchange proposes to require that in the case of a business combination, as described in Nasdaq Rule 5110(a) (Business Combinations with non-Nasdaq Entities Resulting in a Change of Control) or IM-5101-2 (Listing of Companies Whose Business Plan is to Complete One or More Acquisitions) (“Business Combination”), a China-based company must have a minimum Market Value of Unrestricted Publicly Held Shares²⁴ following the business combination equal to at least \$25

See Notice, *supra* note 3, at 45300, n.11; Nasdaq Rule 5005(a)(37) (defining “Restrictive Market” to mean “a jurisdiction that does not provide the Public Company Accounting Oversight Board with access to conduct inspections of public accounting firms that audit Nasdaq-listed companies. A Company’s business will be considered to be principally administered in a Restrictive Market if: (i) the Company’s books and records are located in that jurisdiction; (ii) at least 50% of the Company’s assets are located in such jurisdiction; or (iii) at least 50% of the Company’s revenues are derived from such jurisdiction.”).

²⁰ Nasdaq Rule 5005(a)(17) defines “Firm Commitment Offering” as “an offering of securities by participants in a selling syndicate under an agreement that imposes a financial commitment on participants in such syndicate to purchase such securities.”

²¹ Nasdaq Rule 5005(a)(36) defines “Public Holders” as “holders of a security that includes both beneficial holders and holders of record, but does not include any holder who is, either directly or indirectly, an Executive Officer, director, or the beneficial holder of more than 10% of the total shares outstanding.”

²² See proposed Nasdaq Rule 5210(l)(i).

²³ See Notice, *supra* note 3, at 45300.

²⁴ See Nasdaq Rule 5005(a)(23), (46) for the definitions of “Market Value” and “Unrestricted Publicly Held Shares.” See also Nasdaq Rule 5005(a)(35), (38), (47) for the definitions of “Publicly Held Shares,” “Restricted Securities,” and “Unrestricted Securities.” The Exchange states that “Market Value of Unrestricted Publicly Held Shares excludes securities subject to resale restrictions from the calculation of Publicly Held Shares because securities subject to resale restrictions are not freely transferrable or available for outside investors to purchase and therefore do not truly contribute to a security’s liquidity upon listing.” Notice, *supra* note 3, at 45300.

million.²⁵ The Exchange states that Business Combinations involving China-based companies present similar risk to U.S. investors as do IPOs that involve China based-companies.²⁶

D. Direct Listings of China-Based Companies

The Exchange proposes to provide that, in the case of a Direct Listing (as defined in Nasdaq Rule IM-5315-1 (Determination of Price-Based Requirements for Direct Listings on the Nasdaq Global Select Market)), a China-based company must meet: (i) all applicable listing requirements for the Nasdaq Global Select Market and the additional requirements of IM-5315-1; or (ii) the applicable listing requirements for the Nasdaq Global Market and the additional requirements of IM-5405-1 (Determination of Price-Based Requirements for Direct Listings on the Nasdaq Global Market).²⁷ Further, a China-based company would not be permitted to list on the Nasdaq Capital Market in connection with a Direct Listing.²⁸

E. Transfer of a China-Based Company Listing

The Exchange proposes to provide that in the case of a China-based company transferring its listing from the over-the-counter (“OTC”) market or from another national securities exchange, the company must have a minimum Market Value of Unrestricted Publicly Held Shares²⁹ of at least \$25 million and have traded on the other market for at least one year.³⁰ The Exchange states that a China-based company that initially lists on another market and “quickly transfer[s] its listing to Nasdaq” may present similar risks to U.S. investors as an IPO and that the minimum one-year requirement would provide sufficient time for a China-based company “to establish a trading history of operations upon which investors can rely, and which Nasdaq could consider in determining whether the company is ready for the rigors of being public company and

²⁵ See proposed Nasdaq Rule 5210(l)(ii). The Exchange states that adopting this additional requirement would help prevent China-based companies from using a business combination to avoid the requirement being imposed on IPOs in proposed Nasdaq Rule 5210(l)(i).

²⁶ See Notice, *supra* note 3, at 45300.

²⁷ See proposed Nasdaq Rule 5210(l)(iii).

²⁸ See *id.* The Exchange states that adopting this additional requirement would help prevent companies from using a direct listing to avoid the requirement being imposed on IPOs in proposed Nasdaq Rule 5210(l)(i). See Notice, *supra* note 3, at 45301.

²⁹ See *supra* note 24 (defining “Market Value of Unrestricted Publicly Held Shares”).

³⁰ See proposed Nasdaq Rule 5210(l)(iv).

adhering to the regulatory requirements.”³¹

F. Implementation

Finally, the Exchange proposes that the effective date of the proposal would be 30 days after Commission approval and thus apply to companies listing on or after 30 days from the date of the Commission’s approval order.³²

III. Proceedings To Determine Whether To Approve or Disapprove SR–NASDAQ–2025–069, as Modified by Amendment No. 1, and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act³³ to determine whether the proposed rule change, as modified by Amendment No. 1, should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide additional comment on the proposed rule change to inform the Commission’s analysis of whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.

Pursuant to Section 19(b)(2)(B) of the Act,³⁴ the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of, and input from commenters with respect to, the proposed rule change’s consistency with the Act, and in particular, Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.³⁵

The development and enforcement of meaningful listing standards³⁶ by an exchange is of critical importance to financial markets and the investing public. Among other things, such listing standards help ensure that exchange-listed companies will have sufficient public float, investor base, and trading interest to provide the depth and liquidity to promote fair and orderly markets. Meaningful listing standards are also important given investor expectations regarding the nature of securities that have achieved an exchange listing, and the role of an exchange in overseeing its market and assuring compliance with its listing standards.³⁷

As discussed above, the Exchange proposes to adopt heightened initial listing requirements for China-based companies. The Exchange states that China-based companies that have certain characteristics, such as a small offering size or a low public float percentage, may not develop sufficient public float, investor base, and trading interest to provide the liquidity necessary to promote fair and orderly trading, and that as a result their securities may be more susceptible to manipulation by bad actors.³⁸ The Exchange also states that U.S. authorities face challenges in such cases in bringing or enforcing actions against entities and individuals involved in potentially manipulative trading

activities, and that these challenges compound the risk to investors.³⁹

One commenter expressed general support for the proposal.⁴⁰ This commenter stated that it supports “Nasdaq for taking action to preserve market integrity from the high volatility and potential market manipulation of the smallest microcap Chinese companies.”⁴¹ Another commenter supported the proposal, but recommended that “the increased standards should apply to companies based in additional foreign jurisdictions where it is determined there are elevated levels of fraud.”⁴² This commenter stated that, “[o]therwise, fraudsters will simply move to other jurisdictions where it’s even easier to commit fraud” and that “other jurisdictions also see many instances of fraudulent activities.”⁴³

Another commenter proposed certain modifications to the proposal, while also expressing general support for Nasdaq’s ongoing efforts to enhance its listing standards.⁴⁴ In particular, this commenter expressed concern that the proposed scope of issuers that would be considered to be China-based companies “could capture issuers that are incorporated, headquartered, and operating entirely in the United States, or in other transparent jurisdictions, merely because (i) they were founded or controlled by entrepreneurs who are Chinese citizens or (ii) 50% of their officers or directors are Chinese citizens, even if such individuals have long resided in the United States.”⁴⁵ This commenter stated that it believes that the current proposal “risks unintentionally capturing issuers that do not present the same regulatory concerns” for which the proposal was designed to address and suggested that the requirements in the proposal only apply to issuers “principally operating in China, rather than issuers that are based in the U.S. simply because their founders, controlling persons, directors, or officers are Chinese citizens.”⁴⁶ This

³⁶ The Commission notes that this reference to “listing standards” is referring to both initial and continued listing standards.

³⁷ See, e.g., Securities Exchange Act Release Nos. 88716 (Apr. 21, 2020), 85 FR 23393 (Apr. 27, 2020) (SR–NASDAQ–2020–001) (Order Approving a Proposed Rule Change To Modify the Delisting Process for Securities With a Bid Price at or Below \$0.10 and for Securities That Have Had One or More Reverse Stock Splits With a Cumulative Ratio of 250 Shares or More to One Over the Prior Two-Year Period); 88389 (Mar. 16, 2020), 85 FR 16163 (Mar. 20, 2020) (SR–NASDAQ–2019–089) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Amend Rule 5815 To Preclude Stay During Hearing Panel Review of Staff Delisting Determinations in Certain Circumstances). See also Securities Exchange Act Release No. 81856 (Oct. 11, 2017), 82 FR 48296, 48298 (Oct. 17, 2017) (SR–NYSE–2017–31) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Amend the Listed Company Manual To Adopt Initial and Continued Listing Standards for Subscription Receipts) (stating that “[a]dequate standards are especially important given the expectations of investors regarding exchange trading and the imprimatur of listing on a particular market” and that “[o]nce a security has been approved for initial listing, maintenance criteria allow an exchange to monitor the status and trading characteristics of that issue . . . so that fair and orderly markets can be maintained”).

³⁸ See *supra* note 14 and accompanying text.

³⁹ See *supra* note 15 and accompanying text.

⁴⁰ See Letter from Emmanuel Tamrat, Senior Research Analyst, Council of Institutional Investors, dated Oct. 10, 2025 (“CII Letter”).

⁴¹ CII Letter at 2.

⁴² Letter from Jeffrey Starr, Managing Director, Head of Operations, Charles Schwab & Co., dated Dec. 16, 2025 (“Schwab Letter”).

⁴³ Schwab Letter at 4.

⁴⁴ See Letter from Louis E. Taubman, Esq., Managing Partner, Hunter Taubman Fischer & Li LLC, dated Sept. 16, 2025 (“HTFL Letter”).

⁴⁵ HTFL Letter at 2.

⁴⁶ *Id.* at 2. This commenter also stated that the proposed listing standard should be based on “operational jurisdiction and regulatory overnight, not citizenship *per se*” so as not to create “unintended barriers for legitimate issuers

³¹ Notice, *supra* note 3, at 45301. The Exchange states that companies trading in the OTC market at the time of application must also satisfy a minimum average daily trading volume before initial listing. See *id.* at 45301, n.19; Nasdaq Rules 5405(a)(4) and 5505(a)(5).

³² See Notice, *supra* note 3, at 45301.

³³ 15 U.S.C. 78s(b)(2)(B).

³⁴ *Id.*

³⁵ 15 U.S.C. 78f(b)(5).

commenter also suggested extending the transition period for compliance with the proposal from 30 days to 60 days for issuers with pending initial listing applications.⁴⁷

Finally, one commenter opposed the proposal, stating it “would be unlawful and make for bad policy.”⁴⁸ This commenter stated that the proposal is “not necessary or appropriate to protect national security” and is “anti-competitive as it discriminates against certain Chinese issuers imposing additional, more onerous listing criteria on them than are imposed on other foreign issuers.”⁴⁹ Additionally, the commenter stated that the proposal does not provide adequate justification for being “writ[ten] . . . in terms of national origin.”⁵⁰

The Commission asks that commenters address the sufficiency of the Exchange’s statements in support of the proposal, which are set forth in the Notice, in addition to any other comments they may wish to submit about the proposed rule change, as modified by Amendment No. 1. In particular, the Commission seeks comment on whether the proposal to impose heightened initial listing requirements on China-based issuers is designed to be consistent with the requirements of Section 6(b)(5) of the Act⁵¹ or raises any new or novel concerns not previously contemplated by the Commission.

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their data, views, and arguments with respect to the issues identified above, including the issues raised by commenters and the Exchange’s response, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposed rule change, as modified by Amendment No. 1, is consistent with Sections 6(b)(5) or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be

facilitated by an oral presentation of data, views, and arguments, the Commission will consider, pursuant to Rule 19b–4 under the Act,⁵² any request for an opportunity to make an oral presentation.⁵³

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change, as modified by Amendment No. 1, should be approved or disapproved by January 13, 2026. Any person who wishes to file a rebuttal to any other person’s submission must file that rebuttal by January 27, 2026. The Commission asks that commenters address the sufficiency of the Exchange’s statements in support of the proposal, in addition to any other comments they may wish to submit about the proposed rule change.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR–NASDAQ–2025–069 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–2025–069. 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 filing 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–2025–069

and should be submitted by January 13, 2026. Rebuttal comments should be submitted by January 27, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁵⁴

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025–23660 Filed 12–22–25; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review; Correction

AGENCY: U.S. Small Business Administration.

ACTION: 30-Day notice; correction.

SUMMARY: The Small Business Administration (SBA) published a document in the **Federal Register** of December 8, 2025, concerning request for comments on a collection of information under OMB review for SBA Form 1993 (OMB Control No. 3245–0313).

FOR FURTHER INFORMATION CONTACT:

Interim Agency Clearance Officer Shauniece Carter; Shauniece.Carter@sba.gov; (202) 921–2198.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of December 8, 2025, in FR Doc. 2025–22266, on page 56824, in the third column, correct the **DATES** caption to read:

DATES: Submit comments on or before January 7, 2026.

Shauniece Carter,

Interim Agency Clearance Officer.

[FR Doc. 2025–23646 Filed 12–22–25; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF STATE

[Public Notice 12891]

30-Day Notice of Proposed Information Collection: Electronic Medical Examination for Visa or Immigration Benefit (eMedical)

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for

operating under robust local regulations.” *Id.* (emphasis omitted).

⁴⁷ See *id.* at 3.

⁴⁸ Letter from Joseph D. Wilson, Esq., Bevilacqua PLLC, dated Oct. 10, 2025 (“Bevilacqua Letter”). The commenter stated that the proposal is inconsistent with Section 3(f) and Section 6(b)(5) of the Act. See *id.* at 2–3.

⁴⁹ Bevilacqua Letter at 2.

⁵⁰ *Id.*

⁵¹ 15 U.S.C. 78f(b)(5).

⁵² 17 CFR 240.19b–4.

⁵³ Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Public Law 94–29 (June 4, 1975), grants to the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. See Securities Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

⁵⁴ 17 CFR 200.30–3(a)(57).

approval. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments up to January 22, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Electronic Medical Examination for Visa or Immigration Benefit (eMedical).

- *OMB Control Number:* 1405–0230.

- *Type of Request:* Extension with change.

- *Originating Office:* Bureau of Consular Affairs, Visa Office.

- *Form Number(s):* DS–7794.

- *Respondents:* Panel Physicians.

- *Estimated Number of Respondents:* 800.

- *Estimated Number of Responses:* 550,000.

- *Average Time per Response:* 1 hour.

- *Total Estimated Burden Time:* 550,000 hours.

- *Frequency:* Once per each medical examination performed for a U.S. visa or immigration benefit.

- *Obligation to Respond:* Mandatory.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.

- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.

- Enhance the quality, utility, and clarity of the information to be collected.

- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The DS–7794 is completed by panel physicians to report the medical status of visa applicants; refugees; follow-to-join refugees and asylees; and certain parolees. The form records the medical information necessary to determine whether an alien has a medical condition affecting his or her eligibility for a visa or immigration benefit. The information requested is limited to the result of any diagnostic tests required for the diagnosis of diseases identified as communicable diseases of public health significance, as well as other evaluations identified as necessary to confirm a medical ineligibility under INA § 212(a)(1), 8 U.S.C. 1182(a)(1) or to comply with other requirements. Collecting this information is essential to protecting public health in the United States.

Methodology

A panel physician, designated by the consular post, performs a medical examination of the applicant and completes the electronic form in the eMedical portal in accordance with instructions issued by the Centers for Disease Control (CDC). The information collected is retained by the Bureau of Consular Affairs and available to the CDC and DHS.

John L. Armstrong,

Senior Bureau Official, Bureau of Consular Affairs, Department of State.

[FR Doc. 2025–23697 Filed 12–22–25; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF STATE

[Public Notice: 12893]

Notice of Determinations; Culturally Significant Object Being Imported for Exhibition—Determinations: “A Visiting Masterpiece: Giovanni Bellini’s ‘Dead Christ Supported by Angels’” Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that a certain object being imported from abroad pursuant to an agreement with its foreign owner or custodian for temporary display in the exhibition “A Visiting Masterpiece: Giovanni Bellini’s ‘Dead Christ Supported by Angels’” at The Morgan Library & Museum, New York, New York, and at possible additional exhibitions or venues yet to be determined, is of cultural significance, and, further, that its temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that

Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT:

Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: section2459@state.gov). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Stefanie E. Williams,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2025–23644 Filed 12–22–25; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 12881]

30-Day Notice of Proposed Information Collection: Request for Department of State Personal Identification Card

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments up to January 22, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to John Ferguson, who may be reached on (202) 247-0511 or at Fergusonjm3@state.gov.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:*

Request for Department of State Personal Identification Card.

- *OMB Control Number:* 1405-0232.

• *Type of Request:* Renewal of a currently approved collection.

- *Originating Office:* Diplomatic Security, Domestic Operations, Security Support Division (DS/DO/DFP/SSD Security Support).

- *Form Number:* DS-1838 and DS-7783.

- *Respondents:* Department employees and contractors.

- *Estimated Number of Respondents:* 13,500.

- *Estimated Number of Responses:* 13,500.

- *Average Time per Response:* 5 minutes.

- *Total Estimated Burden Time:* 1, 125 hours per year.

- *Frequency:* On occasion (when new badge is required, or badge expires).

- *Obligation to Respond:* Mandatory.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.

- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.

- Enhance the quality, utility, and clarity of the information to be collected.

- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The collection of information requested on the DS-1838 and DS-7783 is necessary to comply with:

Homeland Security Presidential Directive 12 (HSPD-12) was issued August 27, 2004, to set policy for a common, reliable, and secure

identification standard for federal employees and contractors for accessing federally controlled facilities and federal information systems. In order to keep Federal and other facilities where there is potential for terrorist attacks secure, wide variations in the quality and security of forms of identification need to be eliminated.

Federal Information Processing Standard Publication 201 (FIPS 201) is a United States Federal government standard that specifies Personal Identity Verification (PIV) requirements for Federal employees and contractors. The NIST (National Institute of Standards and Technology) Computer Security Division initiated a new program for improving the identification and authentication of Federal employees and contractors for access to Federal facilities and information systems.

All Department employees and contractors are required to submit application for a Personal Identification Card (DS-1838 domestically or DS-7783 overseas) at the time of hire.

Methodology

Information is collected by a form (obtained from MyData forms) or automated badge request (ABR) online.

George Semertsidis,

(Acting) Deputy Assistant Secretary Diplomatic Security Department of State.

[FR Doc. 2025-23637 Filed 12-22-25; 8:45 am]

BILLING CODE 4710-43-P

DEPARTMENT OF STATE

[Public Notice 12890]

30-Day Notice of Proposed Information Collection: Medical Examination for Visa or Immigration Benefit

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 (PRA), we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments up to January 22, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/

PRAMain. Find this information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:*

Medical Examination for Visa or Immigration Benefit.

- *OMB Control Number:* 1405-0113.

- *Type of Request:* Extension without change.

- *Originating Office:* Bureau of Consular Affairs, Visa Office.

- *From Number(s):* DS-2054, DS-3025, DS-3026, and DS-3030.

- *Respondents:* Panel Physicians on behalf of Visa Applicants; Refugee/Asylum Applicants (including “following-to-join”); Parole Applicants with Boarding Foils.

- *Estimated Number of Respondents:* 800.

- *Estimated Number of Responses:* 146,000.

- *Average Time per Response:* 1 hour.

- *Total Estimated Burden Time:*

146,000 hours.

- *Frequency:* Once for each medical examination performed for a U.S. visa or immigration benefit.

- *Obligation to Respond:* Mandatory.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.

- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.

- Enhance the quality, utility, and clarity of the information to be collected.

- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

Forms for this collection are completed by panel physicians on behalf of aliens seeking a visa; refugees; refugees and asylees (including following-to-join); and certain parolees. The forms record the medical information necessary to determine whether an alien has a medical or other condition affecting his or her eligibility

for a visa or immigration benefit. The information requested includes the result of any diagnostic tests required for the diagnosis of diseases identified as communicable diseases of public health significance, as well as other evaluations identified as necessary to confirm a medical ineligibility under INA § 212(a)(1), 8 U.S.C. 1182(a)(1) or to comply with other requirements. Collecting this information is essential to protecting public health in the United States.

Methodology

A panel physician designated by the consular post performs a medical examination of the applicant and completes the forms according to instructions issued by the Centers for Disease Control (CDC). Respondents submit the forms to the appropriate embassy or consulate, either by providing the completed forms with the applicant in a sealed envelope or by sending them directly via courier. The information collected is retained by the Bureau of Consular Affairs. It is also provided to CDC and the Department of Homeland Security upon arrival at the port of entry.

Agency Response to 60-Day Notice Public Comments

The Department solicited public comments for a period of 60 days with the publication of 90 FR 16420 (April 17, 2025). During this initial 60-day notice-and-comment period, the Public submitted three responsive comments and raised several concerns for the Department's consideration.

Issue #1—Applicant Medical Information Access Rights: *“Reclassifying the respondent as the panel physician must not inadvertently curtail an individual's ability to obtain and review his or her own medical examination records.”*

Reclassification of the respondent does not change the designation of those completed DS medical forms upon which the results of the exam are recorded as visa records, which are confidential under INA 222(f) and generally may not be shared with the applicant. Panel physicians remain permitted to share their own records in the form of lab reports and similar documentation with the applicant upon request.

Issue #2—Accessibility and Appeals: *“Applicants must have access to their exam results and an accessible, standardized appeals process if they believe findings are inaccurate or discriminatory.”*

Applicants may request the underlying test results and medical

information from the panel physician. If an applicant wishes to present additional information to attempt to overcome a refusal of an immigrant visa application, he or she may do so consistent with 22 CFR 42.81(e).

Applicants who wish to overcome medical ineligibility must file Form I–601 or I–602. These waiver forms are submitted to DHS on an individual basis. After submission and upon DHS request, CDC may review the waiver requests and supporting medical examination to provide an opinion regarding the case.

Issue #3—HIV Status Information: *“The DS–2054 series must be updated to reflect that HIV is no longer a ground of inadmissibility and cannot be used as a basis for denial, delay, or stigma.”*

While the proposed DS–2054 does not contain an HIV status field, the Department acknowledges the proposed DS–3026 does contain an HIV blood test field and the DS–3030 contains a field to mark a known HIV infection. All panel physicians are required to abide by CDC Technical Instructions, which provide that HIV testing is recommended for individuals with signs or symptoms of HIV infection but NOT required.

The Department defers to CDC expertise in matters related to protecting American public health, and CDC has requested the HIV fields remain on the Department's visa medical forms, noting that HIV is an important risk factor for tuberculosis (the largest cause of death among individuals with HIV infection is tuberculosis). The CDC Technical Instructions, therefore, require additional tuberculosis testing for aliens who disclose that they have HIV. The Technical Instructions make clear that HIV is not an inadmissible condition (https://www.cdc.gov/immigrant-refugee-health/hcp/panel-physicians/index.html#cdc_generic_section_3-technical-instructions), and panel physicians are not screening applicants for HIV.

Issue #4—Privacy Protection: *“The Department must explicitly define how medical data is protected, limit disclosure to DHS and CDC only as necessary, and prohibit long-term storage or secondary use without applicant consent.”*

An alien's decision to apply for the privilege of entry to the United States is voluntary, and furnishing medical information as part of that application process is also voluntary. Visa records, including Personal Health Information (PHI), are protected in accordance with INA Section 222(f). Consistent with Section 222(f), information may be provided to other federal agencies who

need the information to administer or enforce U.S. laws and protect homeland security. An applicant for a U.S. visa or immigration benefit who subjects him- or herself to medical examination agrees to the disclosure of this PHI in accordance with federal law.

Individuals who fail to disclose requested medical information may experience processing delays and be denied a U.S. visa or immigration benefit. The Department of State's record disposition schedule notes that visa records are retained by the Department temporarily, and longer retention is authorized only if required for business use. The applicant consents to record retention when he or she chooses to apply for a U.S. visa or immigration benefit.

Issue #5: Panel Physician Bias and Medical Requirements: *“The Department must ensure panel physicians are trained in trauma-informed, culturally competent care and prohibit discriminatory screening practices based on socioeconomic status, English language competency, race, gender identity, HIV status, or disability.”*

The Department defers to CDC with respect to panel physician qualifications and medical examination requirements. Though designated by local U.S. embassies or consulates, panel physicians are medically trained and licensed doctors who must abide by standards and technical instructions issued by the CDC. Consular sections, in collaboration with the Visa Office and CDC, may decide to terminate an agreement with a panel physician if the physician fails to abide by these standards and instructions.

Issue #6: Financial Burden to Alien Applicants: *“The Department should cap the costs of medical examinations, publish fee ranges, and ensure medical examinations remain affordable, especially for refugee and asylum applicants.”*

Respondents to this information collection are panel physicians. The Paperwork Reduction Act requires agencies to estimate burden figures for the respondents to an information collection. Although subjected to the medical examination, alien applicants are not respondents as they do not complete these forms. As such, burden figures associated with out-of-pocket costs to alien applicants fall outside the scope of this Notice. The Department further notes that refugees are not responsible for medical examination

fees, which are covered as part of the refugee admittance process.

John L. Armstrong,
Senior Bureau Official, Bureau of Consular
Affairs, Department of State.

[FR Doc. 2025–23695 Filed 12–22–25; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF STATE

[Public Notice: 12894]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: “Raphael: Sublime Poetry” Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition “Raphael: Sublime Poetry” at The Metropolitan Museum of Art, New York, New York, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: section2459@state.gov). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Stefanie E. Williams,
Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2025–23645 Filed 12–22–25; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 12895]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: “A Bestiary of Ancient Nubia” Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to an agreement with their foreign owner or custodian for temporary display in the exhibition “A Bestiary of Ancient Nubia” at the Institute for the Study of Ancient Cultures Museum of the University of Chicago, in Chicago, Illinois, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: section2459@state.gov). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Stefanie E. Williams,
Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2025–23745 Filed 12–22–25; 8:45 am]

BILLING CODE 4710–05–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 290 (Sub-No. 420X)]

Norfolk Southern Railway Company—Abandonment Exemption—in the City of Baltimore, Md.

Norfolk Southern Railway Company (NSR) has filed a verified notice of

exemption (NOE) under 49 CFR part 1152 subpart F—*Exempt Abandonments* to abandon its freight rail easement over an approximately one-mile rail line extending from milepost UU 0.00 +/- to milepost UU 1.00 +/- in the City of Baltimore, Md. (the Line). The Line traverses U.S. Postal Service Zip Codes 21201 and 21211.

According to the verified notice, the Maryland Transit Administration (MTA) owns the portion of the Line from milepost UU 0.50 +/- to milepost UU 1.00 +/-,¹ and the National Railroad Passenger Corporation (Amtrak) owns the portion of the Line from milepost UU 0.00 +/- to milepost UU 0.50 +/- but NSR retained the “freight operating easement, rights and operations” for the Line. NSR states that because neither MTA nor Amtrak have a residual common carrier obligation to provide rail freight service over the Line, the entire common carrier obligation of any rail carrier or party to provide freight service over the Line will be extinguished with the abandonment of the freight operating rights. NSR further states that MTA’s passenger services will continue after NSR abandons its easement and, therefore, the corridor is not available for alternative public use(s) and that it does not intend to negotiate for trail use/railbanking.

NSR has certified that: (1) no local freight traffic has moved over the Line for at least two years; (2) any overhead traffic on the Line can be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government on behalf of such user) regarding cessation of service over the Line is pending with either the Surface Transportation Board (Board) or any U.S. District Court or has been decided in favor of a complainant within the two-year period; and (4) the requirements at 49 CFR 1105.7(b) and 1105.8(c) (notice of environmental and historic reports), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to government agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho*, 360 I.C.C. 91 (1979). To address whether this

¹ MTA currently operates light rail transit service over the Line. The Board previously determined that MTA did not require authorization from the Board’s predecessor when MTA acquired the Line in 1990 and that MTA had not become a common carrier on the Line. *See Md. Transit Admin.—Pet. for Declaratory Ord.*, FD 34975, slip op. at 7–8 (STB served Oct. 9, 2007).

condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received,² this exemption will be effective on January 22, 2026, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,³ formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2), and interim trail use/railbanking requests under 49 CFR 1152.29 must be filed by January 2, 2026.⁴ Petitions to reopen and requests for public use conditions under 49 CFR 1152.28 must be filed by January 12, 2026.⁵

All pleadings, referring to Docket No. AB 290 (Sub-No. 420X), must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423-0001. In addition, a copy of each pleading must be served on NSR's representative, William A. Mullins, Mullins Law Group PLLC, 2001 L St. NW, Suite 720, Washington, DC 20036.

² Persons interested in submitting an OFA must first file a formal expression of intent to file an offer, indicating the type of financial assistance they wish to provide (*i.e.*, subsidy or purchase) and demonstrating that they are preliminarily financially responsible. See 49 CFR 1152.27(c)(2)(i).

³ The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. See *Exemption of Out-of-Serv. Rail Lines*, 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

⁴ Filing fees for OFAs and trail use requests can be found at 49 CFR 1002.2(f)(25) and (27), respectively.

⁵ NSR previously filed a verified NOE to abandon the Line on October 31, 2024, in Docket No. AB 290 (Sub-No. 412X). Notice of the exemption was served and published in the **Federal Register** on November 20, 2024 (89 FR 91869). On December 6, 2024, NSR requested permission to withdraw its NOE to resolve certain real estate and other issues. Prior to NSR's request to withdraw its NOE, James Riffin filed a notice of intent to file an OFA to purchase the Line. The Acting Director of the Office of Proceedings (now, the Office of Chief Counsel) granted NSR's request to withdraw its NOE and dismissed the proceeding without prejudice to NSR seeking authority to abandon the Line in the future. *Norfolk S. Ry.—Aban. Exemption—in Balt. City, Md.*, AB 290 (Sub-No. 412X) (STB served Dec. 9, 2024). By decision served April 14, 2025, the Board construed a submission by Riffin as a request to reopen the Acting Director's decision and denied that request. *Norfolk S. Ry.—Aban. Exemption—in Balt. City, Md.*, AB 290 (Sub-No. 412X) (STB served Apr. 14, 2025). Riffin's challenge to the decisions before the U.S. Court of Appeals for the District of Columbia Circuit remains pending. *Riffin v. STB*, Nos. 24-1385 & 25-1141 (consol.) (D.C. Cir.). Given the pending litigation, if necessary, the Board will address further the effective date of this notice in a subsequent decision.

If the verified notice contains false or misleading information, the exemption is void ab initio.

NSR has filed a combined environmental and historic report that addresses the potential effects, if any, of the abandonment on the environment and historic resources. OEA will issue a Draft Environmental Assessment (Draft EA) by December 26, 2025. The Draft EA will be available to interested persons on the Board's website, by writing to OEA, or by calling OEA at (202) 245-0294. If you require an accommodation under the Americans with Disabilities Act, please call (202) 245-0245.

Comments on environmental or historic preservation matters must be filed within 15 days after the Draft EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), NSR shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the Line. If consummation has not been effected by NSR's filing of a notice of consummation by December 23, 2026, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available at www.stb.gov.

Decided: December 18, 2025.

By the Board, Anika S. Cooper, Chief Counsel, Office of Chief Counsel.

Tammy Lowery,
Clearance Clerk.

[FR Doc. 2025-23648 Filed 12-22-25; 8:45 am]

BILLING CODE 4915-01-P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 290 (Sub-No. 419X)]

Norfolk Southern Railway Company— Abandonment Exemption—in Summit County, Ohio

Norfolk Southern Railway Company (NSR) has filed a verified notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments* to abandon approximately 1.16-miles of rail line extending from milepost AI 0.29 +/- to milepost AI 1.45 +/- in Summit County, Ohio (the Line). The Line traverses U.S. Postal Service Zip Code 44236.

NSR has certified that: (1) no local traffic has moved over the Line for at least two years; (2) any overhead traffic on the Line can be rerouted over other lines; (3) no formal complaint filed by

a user of rail service on the Line (or a state or local government entity acting on behalf of such user) regarding cessation of service over the Line is pending with either the Surface Transportation Board (Board) or any U.S. District Court or has been decided in favor of a complainant within the two-year period; and (4) the requirements at 49 CFR 1105.7(b) and 1105.8(c) (notice of environmental and historic reports), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to government agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received,¹ this exemption will be effective on January 22, 2026, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,² formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2), and interim trail use/railbanking requests under 49 CFR 1152.29 must be filed by January 2, 2026.³ Petitions to reopen and requests for public use conditions under 49 CFR 1152.28 must be filed January 12, 2026.

All pleadings, referring to Docket No. AB 290 (Sub-No. 419X), must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423-0001. In addition, a copy of each pleading must be served on NSR's representative, Crystal M. Zorbaugh, Mullins Law

¹ Persons interested in submitting an OFA must first file a formal expression of intent to file an offer, indicating the type of financial assistance they wish to provide (*i.e.*, subsidy or purchase) and demonstrating that they are preliminarily financially responsible. See 49 CFR 1152.27(c)(2)(i).

² The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. See *Exemption of Out-of-Serv. Rail Lines*, 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

³ Filing fees for OFAs and trail use requests can be found at 49 CFR 1002.2(f)(25) and (27), respectively.

Group PLLC, 2001 L Street NW, Suite 720, Washington, DC 20036.

If the verified notice contains false or misleading information, the exemption is void ab initio.

NSR has filed a combined environmental and historic report that addresses the potential effects, if any, of the abandonment on the environment and historic resources. OEA will issue a Draft Environmental Assessment (Draft EA) by December 29, 2025. The Draft EA will be available to interested persons on the Board's website, by writing to OEA, or by calling OEA at (202) 245-0294. If you require an accommodation under the Americans with Disabilities Act, please call (202) 245-0245. Comments on environmental or historic preservation matters must be filed within 15 days after the Draft EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/railbanking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), NSR shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the Line. If consummation has not been effected by NSR's filing of a notice of consummation by December 23, 2026, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available at www.stb.gov.

Decided: December 18, 2025.

By the Board, Anika S. Cooper, Chief Counsel, Office of Chief Counsel.

Zantori Dickerson,
Clearance Clerk.

[FR Doc. 2025-23649 Filed 12-22-25; 8:45 am]

BILLING CODE 4915-01-P

SURFACE TRANSPORTATION BOARD

[Docket No. MCF 21141]

Van Pool Transportation LLC and Ag Van Pool Holdings, LP—Continuance in Control—Rolling V Bus Corp. and STS of New Mexico, LLC

AGENCY: Surface Transportation Board.

ACTION: Notice Tentatively Approving and Authorizing Continuance in Control.

SUMMARY: On November 26, 2025, Van Pool Transportation LLC (Van Pool) and AG Van Pool Holdings, LP (AG Holdings) (collectively, Applicants), both noncarriers, seek Board approval to continue in control of two of Applicants' subsidiaries—Rolling V Bus

Corp. (Rolling V) and STS of New Mexico, LLC (STS)—upon Rolling V and STS becoming federally regulated passenger motor carriers. The Board is tentatively approving and authorizing the proposed continuance in control. If no opposing comments are timely filed, this notice will be the final Board action.

DATES: Comments must be filed by February 6, 2026. If any comments are filed, Applicants may file a reply by February 23, 2026. If no opposing comments are filed by February 6, 2026, this notice shall be effective on February 7, 2026.

ADDRESSES: Comments, referring to Docket No. MCF 21141, may be filed with the Board either via e-filing on the Board's website or in writing addressed to: Surface Transportation Board, 395 E Street SW, Washington, DC 20423-0001. In addition, send one copy of comments to Applicants' representative: Kiefer A. Light, Beacon Mobility Corp., 3700 Embassy Parkway, Suite 500, Akron, OH 44333.

FOR FURTHER INFORMATION CONTACT: Amy Ziehm at (202) 918-5462. If you require an accommodation under the Americans with Disabilities Act, please call (202) 245-0245.

SUPPLEMENTARY INFORMATION: According to the application, Van Pool is a Delaware limited liability company indirectly controlled by AG Holdings through intermediary holding companies.¹ (Appl. 2-3.) Neither Van Pool nor AG Holdings is a federally regulated carrier. (*Id.*) However, Van Pool directly owns and controls all equity and voting interest in the

¹ Specifically, Applicants state that Van Pool is wholly owned by VP Intermediate Company (VP Intermediate), a Delaware corporation and noncarrier holding company, and that VP Intermediate is wholly owned by Beacon Mobility Corp. (Beacon Mobility), a Delaware corporation and noncarrier holding company. (Appl. 14.) Beacon Mobility is wholly owned by Beacon Mobility Intermediate Corp. (Beacon Intermediate), a Delaware corporation and noncarrier holding company. (*Id.*) Beacon Intermediate is wholly owned by Beacon Mobility Preferred Issuer, LLC (Beacon Preferred), a Delaware limited liability company and noncarrier holding company, and Beacon Preferred is wholly owned by Van Pool Group Holdings, L.P. (Group Holdings), a Delaware limited partnership and noncarrier holding company. (*Id.*) Group Holdings is majority-owned and controlled by AG Holdings, a Delaware limited partnership and noncarrier holding company. (*Id.*) AG Holdings is owned by investment funds affiliated with Audax Management Company, LLC (the Audax Funds), a Delaware limited liability company. (*Id.* at 14.) According to Applicants, none of these entities has interstate passenger motor carrier authority, a U.S. Department of Transportation (USDOT) Number, or a USDOT Safety Rating, and none of the entities control any regulated interstate passenger carriers other than as set forth in the application. (*Id.*)

following 22 interstate passenger motor carriers (the Affiliated Carriers):²

- NRT Bus, Inc., which primarily provides non-regulated student transportation services for schools in Massachusetts (Essex, Middlesex, Norfolk, Suffolk, and Worcester Counties), and occasional charter services, (*Id.* at 4);
- Trombly Motor Coach Service, Inc., which primarily provides non-regulated student transportation services for schools in Massachusetts (Essex and Middlesex Counties), and occasional charter services, (*id.*);
- Salter Transportation, Inc., which primarily provides non-regulated student transportation services for schools in Massachusetts (Essex County) and New Hampshire, and occasional charter services, (*id.* at 4-5);
- Easton Coach Company, LLC, which provides (i) intrastate paratransit, shuttle, and line-run services under contracts with regional transportation authorities and other organizations, primarily in New Jersey and eastern Pennsylvania, and (ii) private intrastate and interstate charter motor coach and shuttle services, primarily in eastern Pennsylvania, (*id.* at 5);
- F. M. Kuzmeskus, Inc., dba Travel Kuz, which provides (i) non-regulated school bus transportation services, (ii) intrastate and interstate motor coach and limousine charter services, and (iii) limited intrastate and interstate charter services using school buses, all in western Massachusetts and southern Vermont, (*id.* at 5-6);
- Alltown Bus Service Inc. (Alltown), which primarily provides non-regulated student transportation services for schools in the metropolitan area of Chicago, Ill., and its northern suburbs. Alltown also provides occasional charter services, (*id.* at 6);
- DS Bus Lines, Inc., which primarily provides (i) non-regulated student transportation services for schools in Kansas (Beloit, Kansas City, Lincoln, Olathe, and Shawnee), Missouri (Belton and Smithville), Colorado (the metropolitan area of Denver), and Oklahoma (the metropolitan area of Tulsa), (ii) intrastate employee shuttle services in Colorado and Texas, and (iii) occasional charter services, (*id.*);
- Royal Coach Lines, Inc., which primarily provides (i) non-regulated student transportation services for schools in the metropolitan area of Westchester County, NY, and southern

² Additional information about these motor carriers, including principal place of business, USDOT numbers, motor carrier numbers, USDOT safety fitness ratings, fleet composition, and driver count, can be found in the application. (*See* Appl., Ex. A.)

Connecticut and (ii) contract and charter transportation services in the same areas for activities such as summer camps, events, and group trips, (*id.* at 6–7);

- Local Motion, LLC, which provides non-regulated school bus, charter, and shuttle services in the metropolitan area of Boston, Mass., (*id.* at 7);

- Butler's Bus Service, Inc. (BBS), which primarily provides non-regulated student transportation services for schools in the New Hampshire cities of Manchester, North Haverhill, Milford, and Center Barnstead, and the Vermont cities of Orleans, Lyndonville, and White River Junction. BBS also provides occasional charter services, (*id.*);

- TransAction Corporate Shuttles, Inc., which provides shuttle, on-demand transportation, and charter services in Massachusetts, (*id.* at 7–8);

- Dell Transportation Corp. (Dell), which primarily provides non-regulated student transportation for schools, and occasional charter services. The geographic service area of Dell is primarily the towns of Hempstead, NY, Port Washington, NY, and Great Neck, NY, (*id.* at 8);

- Hendrickson Bus Corporation (Hendrickson), which primarily provides non-regulated student transportation for schools, and charter transportation for school-related extracurricular activities such as athletic events, field trips, and other school-sponsored functions. The geographic service area of Hendrickson is primarily Bayville, NY, and Port Washington, NY, (*id.*);

- Huntington Coach Corporation (Huntington Corp.), which provides primarily non-regulated student transportation for schools, and charter transportation for school-related extracurricular activities such as athletic events, field trips, and other school-sponsored functions. The geographic service area that Huntington Corp. serves is primarily Northport, NY, and Huntington Station, NY, (*id.* at 8–9);

- Huntington Coach, LLC (Huntington LLC), which primarily provides non-regulated student transportation for schools, and charter transportation for school-related extracurricular activities such as athletic events, field trips, and other school-sponsored functions. The geographic service area of Huntington LLC is primarily Huntington Station, NY, (*id.* at 9);

- Towne Bus Corp. (Towne Corp.), which primarily provides non-regulated student transportation for schools, and charter transportation for school-related extracurricular activities such as athletic events, field trips, and other school-sponsored functions. The geographic

service area of Towne Corp. is primarily Long Island, NY, (*id.*);

- Towne Bus LLC (Towne LLC), which primarily provides non-regulated student transportation for schools, and transportation for school-related extracurricular activities such as athletic events, field trips, and other school-sponsored functions. The geographic service area of Towne LLC is primarily Long Island, NY, (*id.* at 9–10);

- Van Trans LLC (Van Trans), which primarily provides non-regulated student transportation for schools, and transportation for school-related extracurricular activities such as athletic events, field trips, and other school-sponsored functions. The geographic service area of Van Trans is primarily Bronx, NY, (*id.* at 10);

- WE Transport (NY) LLC (WE NY), which primarily provides non-regulated student transportation for schools, and transportation for school-related extracurricular activities such as athletic events, field trips, and other school-sponsored functions. The geographic service area of WE NY is primarily Long Island, NY, (*id.*);

- WE Transport LLC (Connecticut) (WE CT), which primarily provides non-regulated student transportation for schools, and transportation for school-related extracurricular activities such as athletic events, field trips, and other school-sponsored functions. The geographic service area of WE CT is primarily Bridgeport, Conn., (*id.* at 10–11);

- WE Transport, Inc. (WE Transport), which primarily provides non-regulated student transportation for schools, and transportation for school-related extracurricular activities such as athletic events, field trips, and other school-sponsored functions. The geographic service area of WE Transport is primarily Long Island, NY, (*id.* at 11); and

- George M. Carroll Transportation, Inc., dba George M. Carroll Inc. (GMCT), which primarily provides (i) regular home-to-school transportation services, with a focus on special needs students and (ii) charter services that primarily involve transportation to and from school-related extracurricular activities such as athletic events, field trips, and other school-sponsored functions, with a focus on special needs students. GMCT also provides occasional non-school-related charter services for special occasions such as weddings, wine tours, proms, sporting events, and airport trips. The geographic service area of GMCT is primarily within Orange County, NY, (*id.* at 11–12).

Additionally, on December 12, 2025, the Board published notice tentatively

approving Applicants' acquisition of control of Lavdas Enterprises, Inc., dba Lavdas Limousines, Inc. (Lavdas) (90 FR 57803). *See Van Pool Transp. LLC—Acquis. of Control—Lavdas Enters., Inc. (Lavdas Transaction)*, MCF 21140 (STB served Dec. 12, 2025); (*see also* Appl. 11 n.2). Lavdas primarily provides luxury charter transportation service in southeast Michigan. *Lavdas Transaction*, MCF 21140, slip op. at 5. On rare occasions, Lavdas's charter operations include interstate service into surrounding states, including Illinois. (*Id.*) If no opposing comments are timely filed in Docket No. MCF 21140 with respect to Applicants' acquisition of control of Lavdas, Applicants will control 23 interstate passenger motor carriers as of January 27, 2026.

In the present application, Applicants seek Board approval to continue in control of Rolling V and STS upon those entities obtaining approval from the Federal Motor Carrier Safety Administration (FMCSA) to operate as regulated passenger motor carriers. Rolling V is a New York corporation that currently operates as a motor carrier primarily providing non-regulated home-to-school transportation services in addition to intrastate charter, shuttle, and transit services within the State of New York, particularly the cities of Walton, Livingston Manor, Neversink, Liberty, South Fallsburg, and Ellenville. (Appl. 12.) STS is a New Mexico limited liability company that currently operates as a motor carrier primarily providing home-to-school and charter student transportation services within Dona Ana County, NM, particularly the City of Las Cruces and its surrounding areas. (*Id.* at 12–13.) According to Applicants, both Rolling V and STS currently operate exclusively in intrastate commerce but are seeking FMCSA's approval to expand their existing charter operations to include interstate service. (*Id.* at 12.) The application indicates that the interstate service provided by Rolling V and STS, if authorized, is expected to be, in both the near-term and the long-term, an insignificant proportion of overall service by those entities. (*Id.*)

Under 49 U.S.C. 14303(b), the Board must approve and authorize a transaction that it finds is consistent with the public interest, taking into consideration at least (1) the effect of the proposed transaction on the adequacy of transportation to the public, (2) the total fixed charges resulting from the proposed transaction, and (3) the interest of affected carrier employees. Here, Applicants have submitted the information required by 49 CFR 1182.2,

including (1) information to demonstrate that Applicants' continuance in control of Rolling V and STS, upon those entities becoming regulated passenger motor carriers, is consistent with the public interest under 49 U.S.C. 14303(b), *see* 49 CFR 1182.2(a)(7); and (2) a jurisdictional statement under 49 U.S.C. 14303(g) that the aggregate gross operating revenues of the involved carriers exceeded \$2 million during a consecutive 12-month period ending not more than six months before the date of the agreement of the parties, *see* 49 CFR 1182.2(a)(5). (*See* Appl. 15–18.)

Applicants do not expect the proposed continuance in control to have a material, detrimental impact on the adequacy of transportation services available to the public. (*Id.* at 15.) According to Applicants, services available to the public will be improved as operating efficiencies are realized and additional services and capacity are made available. (*Id.*) Applicants add that their continuance in control of Rolling V and STS is consistent with the practices within the passenger motor carrier industry of strong, well-managed transportation organizations adapting their corporate structure to operate several different passenger carriers within similar service markets, but in different geographic areas. (*Id.* at 15–16.) Applicants state that the interstate charter services to be provided by Rolling V and STS would supplement the home-to-school student transportation services that those entities currently provide; that each of these market segments have their own service characteristics; and that Applicants' continuance in control of Rolling V and STS is expected to result in improved operating efficiencies, increased equipment utilization rates, and cost savings derived from economies of scale, all of which will help to ensure the provision of adequate service to the public. (*Id.*)

Applicants assert that the impact of the transaction on the regulated motor carrier industry will be minimal at most. (*Id.* at 18.) According to Applicants, demand for school bus transportation and charter services in the areas served by Rolling V and STS is strong and is expected to increase in the foreseeable future. (*Id.* at 17.) Applicants assert that the markets that Rolling V and STS serve are very competitive due to the significant number of national, regional, and local providers operating in those markets. (*Id.* at 17–18.) Applicants state that, with respect to Rolling V, competing providers include Student Transportation of America, First Student, and Durham School Services.

(*Id.* at 18.) Applicants further state that, with respect to STS, competing providers include All Aboard America, Greyhound Lines, and El Paso Limousine. (*Id.*) Applicants also state that Rolling V's service area and STS' service area are geographically dispersed from service areas of the 22 regulated carriers that Applicants control at present and that there is very limited overlap in customer bases as between those 22 regulated carriers and Rolling V and STS. (*Id.* at 18.) The same appears to be true with respect to Lavdas; Rolling V operates primarily in New York, STS operates primarily in New Mexico, and Lavdas operates primarily in southeast Michigan.

Applicants assert that their continuance in control of Rolling V and STS will not result in an increase in fixed charges. (*Id.* at 16.)

According to Applicants, their continuance in control of Rolling V and STS is not expected to have a substantial impact on employees or labor conditions. (*Id.*) Applicants state that Rolling V and STS intend to provide the prospective interstate service using employee drivers that are already qualified to provide interstate charter bus service. (*Id.*) Applicants further state that they do not anticipate a measurable increase in force or changes in compensation levels and/or benefits associated with their continuance in control. (*Id.*)

Based on their representations, the Board finds that Applicants' continuance in control of Rolling V and STS is consistent with the public interest. The application will be tentatively approved and authorized. If any opposing comments are timely filed, these findings will be deemed vacated, and, unless a final decision can be made on the record as developed, a procedural schedule will be adopted to reconsider the application. *See* 49 CFR 1182.6. If no opposing comments are filed by expiration of the comment period, this notice will take effect automatically and will be the final Board action in this proceeding.

This action is categorically excluded from environmental review under 49 CFR 1105.6(c).

Board decisions and notices are available at www.stb.gov.

It is ordered:

1. Applicants' continuance in control of Rolling V and STS upon their becoming federally regulated passenger motor carriers is approved and authorized, subject to the filing of opposing comments.

2. If opposing comments are timely filed, the findings made in this notice will be deemed vacated.

3. This notice will be effective on February 7, 2026, unless opposing comments are filed by February 6, 2026. If any comments are filed, Applicants may file a reply by February 23, 2026.

4. A copy of this notice will be served on: (1) the U.S. Department of Transportation, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590; (2) the U.S. Department of Justice, Antitrust Division, 10th Street & Pennsylvania Avenue NW, Washington, DC 20530; and (3) the U.S. Department of Transportation, Office of the General Counsel, 1200 New Jersey Avenue SE, Washington, DC 20590.

Decided: December 18, 2025.

By the Board, Board Members Fuchs, Hedlund, and Schultz.

Aretha Laws-Byrum,
Clearance Clerk.

[FR Doc. 2025–23725 Filed 12–22–25; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Electric Vertical Takeoff and Landing and Advanced Air Mobility Integration Pilot Program-Announcement of Establishment of Program and Request for Proposals

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

ACTION: Notice of the establishment of the Electric Vertical Takeoff and Landing (eVTOL) and Advanced Air Mobility (AAM) Integration Pilot Program (eIPP) extension to submit proposals.

SUMMARY: This action extends the Electric Vertical Takeoff and Landing and Advanced Air Mobility Integration Pilot Program-Announcement of Establishment of Program and Request for Proposals which initially published on September 16, 2025.

DATES: The initial date for interested SLTT governments to submit a proposal to participate in the eIPP in accordance with the SIR posted to sam.gov was to be no later than 3 p.m. ET on December 11, 2025, the FAA proposes to change the information in the dates section to: Interested SLTT governments must submit a proposal to participate in the eIPP in accordance with dates listed in the SIR posted to sam.gov.

FOR FURTHER INFORMATION CONTACT: For general Program questions, Mr. Wade Terrell, Acting Director, Advanced Air Mobility Operations Division, 490 L'Enfant Plaza SW (Suite 500), Washington, DC 20024; telephone (405)

423-7936; email 9-AWA-eIPP@faa.gov; or, for solicitation questions, Mrs. Kristin Frantz, Contracting Officer, AAQ-590, UAS and Emerging Technologies Branch, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; telephone (404) 305-5779; email: Kristin.T.Frantz@faa.gov.

Issued in Washington, DC, on December 11, 2025.

Authority: Issued under authority provided by 49 U.S.C. 106(f), 44701(a), and 4470.

Wade E.K. Terrell,

Director, Advanced Air Mobility Operations.

[FR Doc. 2025-23732 Filed 12-22-25; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No.: FAA-2000-8527; Summary Notice No. 2025-71]

Petition for Exemption; Summary of Petition Received; SIMCOM Aviation Training.

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

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion nor omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before January 12, 2026.

ADDRESSES: Send comments identified by docket number FAA-2000-8527 using any of the following methods:

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

- **Mail:** Send comments to Docket Operations, M-30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

- **Hand Delivery or Courier:** Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey

Avenue SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- **Fax:** Fax comments to Docket Operations at (202) 493-2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

Docket: Background documents or comments received may be read at <http://www.regulations.gov> at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Kara White, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, at 202-267-9677.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

Dan A. Ngo,

Manager, Part 11 Petitions Branch, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA-2000-8527.

Petitioner: SIMCOM Aviation Training.

Section(s) of 14 CFR Affected: §§ 91.9(a), 91.531(a)(1), and 91.531(a)(2).

Description of Relief Sought: SIMCOM Aviation Training (SIMCOM) seeks an exemption to permit SIMCOM to train, test, and approve pilots, under its 14 CFR part 142 training center certificate, to operate certain Cessna CE-500 series aircraft without a pilot who is designated as second-in command.

[FR Doc. 2025-23652 Filed 12-22-25; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway Projects in Texas

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of limitation on claims for judicial review.

SUMMARY: The FHWA, on behalf of the Texas Department of Transportation (TxDOT), is issuing this notice to announce actions taken by TxDOT and other Federal agencies that are final agency actions. The actions relate to various proposed highway projects in the State of Texas. These actions grant licenses, permits, and approvals for the projects.

DATES: By this notice, the FHWA, on behalf of TxDOT, 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 projects listed below will be barred unless the claim is filed on or before May 22, 2026. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such a claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT:

Patrick Lee, Environmental Affairs Division, Texas Department of Transportation, 125 East 11th Street, Austin, Texas 78701; telephone: (512) 419-8604; email: Patrick.Lee@txdot.gov. TxDOT's normal business hours are 8 a.m. to 5 p.m. (Central Standard Time), Monday through Friday, except State holidays.

SUPPLEMENTARY INFORMATION: The environmental review, consultation, and other actions required by applicable Federal environmental laws for these projects are being, or have been, carried out by TxDOT pursuant to 23 U.S.C. 327 and a Memorandum of Understanding dated July 17, 2025, and executed by the FHWA and TxDOT.

Notice is hereby given that TxDOT and Federal agencies have taken final agency actions by issuing licenses, permits, and approvals for the highway projects in the State of Texas that are listed below.

The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion (CE), Environmental Assessment (EA), or Environmental Impact Statement (EIS) issued in connection with the projects and in other key project documents. The CE, EA, or EIS and other key documents for the listed projects are available by contacting the local TxDOT office at the address or telephone number provided for each project below.

This notice applies to all TxDOT and 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. *General*: National Environmental Policy Act (NEPA) [42 U.S.C. 4321 *et seq.*]; Federal-Aid Highway Act [23 U.S.C. 109 and 23 U.S.C. 128]; 23 CFR part 771.

2. *Air*: Clean Air Act [42 U.S.C. 7401–7671(q)].

3. *Noise*: Noise Control Act of 1972 [42 U.S.C. 4901–4918]; 23 CFR part 772.

4. *Land*: Section 4(f) of the Department of Transportation Act of 1966 [23 U.S.C. 138 and 49 U.S.C. 303]; 23 CFR part 774; Land and Water Conservation Fund (LWCF) [54 U.S.C. 200302–200310]; Landscaping and Scenic Enhancement (Wildflowers) [23 U.S.C. 319].

5. *Wildlife*: Endangered Species Act [16 U.S.C. 1531–1544 and 1536], Marine Mammal Protection Act [16 U.S.C. 1361–1423h]; Anadromous Fish Conservation Act [16 U.S.C. 757(a)–757(f)]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)]; Migratory Bird Treaty Act [16 U.S.C. 703–712]; Magnuson-Stevenson Fishery Conservation and Management Act of 1976, as amended [16 U.S.C. 1801–1891d], with Essential Fish Habitat requirements [16 U.S.C. 1855(b)(2)].

6. *Historic and Cultural Resources*: Section 106 of the National Historic Preservation Act of 1966, as amended [54 U.S.C. 300101 *et seq.*]; Archaeological Resources Protection Act of 1979 (ARPA) [16 U.S.C. 470(aa)–470(II)]; Preservation of Historical and Archaeological Data [54 U.S.C. 312501–312508]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013; 18 U.S.C. 1170].

7. *Social and Economic*: Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

8. *Wetlands and Water Resources*: Clean Water Act [33 U.S.C. 1251–1377] (Section 404, Section 401, Section 319); Coastal Barriers Resources Act (CBRA) [16 U.S.C. 3501–3510]; Coastal Zone Management Act (CZMA) [16 U.S.C. 1451–1466]; Safe Drinking Water Act (SDWA) [42 U.S.C. 300f–300j–26]; Rivers and Harbors Act of 1899 [33 U.S.C. 401–406]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287]; Emergency Wetlands Resources Act [16 U.S.C. 3921, 3931]; Wetlands Mitigation, [23 U.S.C. 119(g) and 133(b)(3)]; Flood Disaster Protection Act [42 U.S.C. 4001–4130].

9. *Hazardous Materials*: Comprehensive Environmental Response, Compensation, and Liability

Act (CERCLA) [42 U.S.C. 9601–9675]; Superfund Amendments and Reauthorization Act of 1986 (SARA); Resource Conservation and Recovery Act (RCRA) [42 U.S.C. 6901–6992(k)].

10. *Executive Orders*: E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 13112 Invasive Species.

The projects subject to this notice are:

1. Cordova Road from SH 46 to SH 123, Guadalupe County, Texas. The project will widen Cordova Road from two to four lanes with a shared use path on both sides of the roadway. The project will also include a raised median with intermittent breaks to accommodate a center left-turn lane. The project is 3.45 miles long. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on September 2, 2025, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting the TxDOT San Antonio District Office at 4615 NW Loop 410, San Antonio, TX 78229; telephone: (210) 615–5839.

2. Trenton Road from I–69C to FM 907, Hidalgo County, Texas. The project will widen and reconstruct the existing two-lane rural roadway to a four-lane urban roadway. The proposed 66-foot-wide road would consist of four 12-foot-wide travel lanes, a 14-foot-wide continuous left-turn lane, a 10-foot-wide shared use path on one side of the roadway, and a 5-foot-wide sidewalk on the opposite side of the road. The project is approximately 3.4 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on September 3, 2025, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting the TxDOT Pharr District Office at 600 West Interstate 2, Pharr, TX 78577; telephone: (956) 702–6101.

3. SH 185 from 7th Street to King Road, Victoria County, Texas. The project will construct a two-lane overpass on SH 185 over the existing railroad tracks in Bloomington from 7th Street to 0.1 mile south of King Road, a distance of approximately 0.92 mile.

Access roads will be constructed on each side of the overpass to provide access to existing city streets and commercial/residential properties. Additionally, FM 616 will be realigned as part of the project. The realignment of FM 616 will be from the intersection with King Road east of Bloomington, shifting to the south side of and parallel to King Rd, intersecting with SH 185 just south of the existing SH 185/King Rd intersection, and merging back into King Rd just west of the existing intersection of King Rd and SH 185. King Rd will terminate in cul-de-sacs on the east side of SH 185 as well as the east end of King Rd approximately 0.5 miles east of SH 185. Herbert Avenue will be extended approximately 100 ft to provide access to the realigned FM 616. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on September 5, 2025, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting the TxDOT Yoakum District Office at 403 Huck St., Yoakum, TX 77995; telephone: (361) 293–4300.

4. SH 75 from south of FM 3083 to League Line Road, Montgomery County, Texas. The project consists of widening SH 75 from a two-lane roadway to a four-lane divided roadway for 4.9 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on September 26, 2025, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting the TxDOT Houston District Office located at 7600 Washington Avenue, Houston, TX 77007; telephone: (713) 802–5000.

5. IH 20 from SH 19 to FM 17, Van Zandt County, Texas. The project will construct a westbound frontage road on IH 20. The project length is 1.362 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on September 29, 2025, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting the TxDOT Tyler District Office at 2709 W Front St., Tyler, TX 75702; telephone: (903) 510–9100.

6. Vallecillo Road New Location and Reconstruction from FM 1472 to IH 35, Webb County, Texas. The Vallecillo

Road project is a new location east-west roadway within the city limits of the City of Laredo. It is situated about a mile and a half north of IH 69 West and aligned with A.F. Muller Boulevard, directly connecting FM 1472 (Mines Road) with IH 35. The project will be approximately 2.85 miles in length and consist of four travel lanes, two in each direction, and will have a raised concrete median in the center. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on October 2, 2025, and other documents in the TxDOT project file. The Categorical Exclusion Documentation and other documents in the TxDOT project file are available by contacting the TxDOT Laredo District Office at 1817 Bob Bullock Loop, Laredo, TX 78043; telephone: (956) 712-7400.

7. FM 529 from Waller County Line to Katy Hockley Cutoff Road, Harris County, Texas. The project includes widening FM 529 from a two-lane roadway to a four-lane roadway between FM 362 and Katy Hockley Road and from two lanes to six lanes between Katy Hockley Cutoff Road and SH 99. The project is approximately 12 miles long. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on October 2, 2025, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting the TxDOT Houston District Office located at 7600 Washington Avenue, Houston, TX 77007; telephone: (713) 802-5000.

8. FM 755 Rehab Super 2 from Starr/Brooks County Line to FM 1017, Starr County, Texas. The project will consist of the reconstruction of the roadway by adding two feet of additional pavement on each side of the road, and the addition of passing lanes. The road footprint will be widened from 40 to 44 feet throughout the project limits. The project is 7.949 miles long. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on October 31, 2025, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting the TxDOT Pharr District Office at 600 West Interstate 2, Pharr, TX 78577; telephone: (956) 702-6101.

9. Barbarosa Road/Saur Lane from FM 1101 to Saengerhalle Road, Bexar County, Texas. The project will upgrade the existing roadway to have two travel lanes in each direction with a combination of center turn lane and medians. Turn lanes will be constructed at major intersections. A continuous sidewalk will be provided along the northern side of the roadway between FM 1101 and Westmeyer Road. A shared-use path will be provided between FM 1101 and Saengerhalle Road on the southside of the roadway. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on November 20, 2025, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting the TxDOT San Antonio District Office at 4615 NW Loop 410, San Antonio, TX 78229; telephone: (210) 615-1110.

10. 30 East Corridor From I-45 to Ferguson Road, Dallas County, Texas. The project will widen I-30 between I-45 and Ferguson Road from eight mainlanes (four in each direction) to ten mainlanes (five in each direction) and add two reversible managed lanes in the center median. The mainlanes will be depressed to a lower elevation than that of the proposed frontage roads. Access ramps throughout the project will be reconstructed. The project will construct new cross street bridges across the depressed mainlanes. The project length is approximately five miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final EA, the Finding of No Significant Impact (FONSI) issued on October 24, 2025, and other documents in the TxDOT project file. The EA, FONSI, and other documents in the TxDOT project file are available by contacting the TxDOT Dallas District Office at 4777 E Highway 80, Mesquite, TX 75150; telephone: (214) 320-4480.

(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)).

Issued on: December 18, 2025.

Ed Burgos-Gomez,

*Acting Director Program Development,
Federal Highway Administration.*

[FR Doc. 2025-23636 Filed 12-22-25; 8:45 am]

BILLING CODE 4910-RY-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2024-0255]

Agency Information Collection Activities; Approval of a New Information Collection Request: Study of Warning Devices for Stopped Commercial Motor Vehicles

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for review and approval. This notice invites comments on a proposed information collection titled "Study of Warning Devices for Stopped Commercial Motor Vehicles." It is an experimental study that requires data collection for evaluating whether warning devices meaningfully influence crash-relevant aspects of human performance in the presence of a parked or disabled commercial motor vehicle (PDCMV), and if so, how and to what extent. These data collection efforts are expected to require the participation of 256 drivers. A total of 9 comments were provided in response to the 60-day **Federal Register** notice (91 FR 1591). The total burden hours reported in the 60-day FR published on January 8, 2025, has now been decreased by 128 hours after FMCSA inadvertently included but has now removed the 128 hours from the burden estimate. The 128 hours is the time estimated for respondents to travel to and from the location where the collection of information will occur.

DATES: Comments on this notice must be received on or before January 22, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be submitted within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Samuel White, Research Division, DOT, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590; 202-366-3068; Samuel.White@dot.gov.

SUPPLEMENTARY INFORMATION:

Title: Study of Warning Devices for Stopped Commercial Motor Vehicles
OMB Control Number: 2126–00XX.

Type of Request: New ICR.

Respondents: Drivers.

Estimated Number of Respondents: 256.

Estimated Time per Response: 2.0 to 2.5 Hours.

Expiration Date: This is a new ICR.

Frequency of Response: Once.

Estimated Total Annual Burden: 504.92 hours.

Background

PDCMV on the road negatively impact traffic operations and safety.¹ To increase the conspicuity of PDCMVs and mitigate crash risk, FMCSA requires specific warning devices to be carried² on all commercial motor vehicles (CMVs) and, except in the case of necessary traffic stops, be deployed³ near the vehicle whenever it is stopped on the road or shoulder. The Federal Motor Carrier Safety Regulations prescribe specific rules⁴ concerning how and where the warning devices must be placed, based on road and traffic attributes (e.g., whether the road is straight or curved, whether the vehicle is stopped in a business or residential district, whether the road is divided or undivided, etc.) as well as the presence of conditions affecting visibility (e.g., time of day, physical obstructions, etc.). These requirements follow from the basic notion that increasing the conspicuity of a PDCMV makes it easier to see and recognize, thereby reducing the risk of a crash involving passing motorists.

In addition, the National Highway Traffic Safety Administration (NHTSA) prescribes performance and design specifications⁵ for warning devices under 49 CFR 571.125 of the Federal Motor Vehicle Safety Standards (FMVSS). For instance, this standard establishes minimum specifications for factors affecting the conspicuity (including reflectivity, color, luminance) of warning triangles, the

most commonly utilized type of warning device (due to their reusability, shelf life, and fire-risk safety concerns compared to flares or fuses). The purpose of this standard is “to assure that the warning devices can be readily observed during daytime and nighttime lighting conditions, have a standardized shape for quick message recognition, and perform properly when deployed.”⁶

Public interest in warning device requirements for PDCMVs has increased in recent years for several reasons. For example, advances in automated driving system (ADS) technology have raised critical questions regarding potential barriers to regulatory compliance with warning device safety standards⁷ and regulations⁸ which reference or require a “driver.” In addition, alternative types of warning devices developed by industry, including those intended to increase driver safety during device deployment, have resulted in multiple applications for exemption from the corresponding safety regulations.^{9 10} These recent issues related to warning device requirements also call attention to the historically unresolved questions of whether the use of such devices improves traffic safety and, if so, how and to what extent.

Past attempts by the Federal Highway Administration (FHWA)^{11 12} and other researchers¹³ to answer those questions

yielded generally inconclusive or inconsistent results, which possibly influenced NHTSA’s past decision not to pursue conducting its own research on the topic.¹⁴ FMCSA (previously under FHWA) itself has never conducted experimental research on the impact of using warning devices. As the only regulatory authority which still requires CMV operators to use warning devices, the responsibility to answer these questions finally and definitively is best charged to FMCSA.

Given the increasing focus on ADS, questions surrounding the safety of CMV drivers when deploying warning devices, and the availability of new technology and alternative devices since these questions were last explored in the 1980s, there is a need to thoroughly evaluate the effectiveness of warning devices under current regulations. In addition, advanced research instruments unavailable or not in use at the time of all past research on this topic are now in common use and would permit far more sophisticated analyses of the effects of warning devices on driver behavior. This includes sensors which can precisely measure and record the location of vehicles (e.g., differential Global Positioning System), eye-tracking devices which allow the researcher to determine the precise moment when a driver first glanced at a PDCMV, and instrumented vehicles which record accurate, high-frequency data related to drivers’ interactions with a vehicle’s controls.

FMCSA plans to implement these modern tools in a controlled experiment at a closed-course, state-of-the-art driving research facility that will allow the most comprehensive examination of the effects of warning devices to date. The results of the study may support future rulemaking related to warning devices and provide baseline data necessary to inform Agency decisions on exemption applications for alternative warning device products.

FMCSA published the 60-day **Federal Register** notice on January 8, 2025, and the comment period closed on March 10, 2025 (90 FR 1591). A total of nine comments were received from the public. These comments revolved around nine themes: regulatory considerations and impact, environment or condition-based study factors, study factors for other devices, automated vehicle considerations, safety benefits of

¹ Roberts, G. L., & Lynn, C. (2003). Passenger vehicle crashes into stationary large trucks: incidence and possible countermeasures (No. VTRC 03–CR17). Virginia Transportation Research Council.

² 49 CFR 393.95. (2024). Emergency equipment on all power units. <https://www.ecfr.gov/current/title-49/section-393.95>.

³ 49 CFR 392.22. (2024). Emergency signals; stopped commercial motor vehicles. <https://www.ecfr.gov/current/title-49/section-392.22>.

⁴ Placement of warning devices—Special rules. 49 CFR 392.22(b)(2) (1998). [https://www.ecfr.gov/current/title-49/part-392#p-392.22\(b\)\(2\)](https://www.ecfr.gov/current/title-49/part-392#p-392.22(b)(2)).

⁵ FMVSS no. 125; Warning devices. 49 CFR 571.125 (2012). <https://www.ecfr.gov/current/title-49/subtitle-B/chapter-V/part-571/subpart-B/section-571.125>.

⁶ FMVSS; Warning devices, 58 FR 27514 (May 10, 1993). https://archives.federalregister.gov/issue_slice/1993/5/10/27507-27517.pdf#page=8.

⁷ Kim, A., Perlman, D., Bogard, D., & Harrington, R. (2016). Review of federal motor vehicle safety standards (FMVSS) for automated vehicles. John A. Volpe National Transportation Systems Center, for NHTSA and USDOT Intelligent Transportation Systems Joint Program Office. <https://rosap.nhtl.bts.gov/view/dot/12260>.

⁸ Perlman, D., Bogard, D., Epstein, A., Santalucia, A., & Kim, A. (2018). Review of the federal motor carrier safety regulations for automated commercial vehicles: Preliminary assessment of interpretation and enforcement challenges, questions, and gaps (FMCSA–RRT–17–013). John A. Volpe National Transportation Systems Center. <https://rosap.nhtl.bts.gov/view/dot/35426>.

⁹ Parts and accessories necessary for safe operation; Pi Variables, Inc; Application for an exemption, 88 FR 40920 (June 22, 2023). <https://www.govinfo.gov/content/pkg/FR-2023-06-22/pdf/2023-13205.pdf>.

¹⁰ Parts and accessories necessary for safe operation; Exemption application from Waymo LLC, and Aurora Operations, Inc., 88 FR 13489 (Mar. 3, 2023). <https://www.govinfo.gov/content/pkg/FR-2023-03-03/pdf/2023-04385.pdf>.

¹¹ Lyles, R. W. (1980). Effective warning devices for parked/disabled vehicles (No. FHWA–RD–80–65 Final Rpt.). University of Maine, Orono, for Federal Highway Administration.

¹² Knoblauch, R.L., & Tobey, H.N. (1980). Safety aspects of using vehicle hazard warning lights, Volume 2 (No. FHWA/RD–80–102). Biotechnology, Inc., for Federal Highway Administration.

¹³ Allen, M.J., Miller, S.D., & Short, J.L. (1973). The effect of flares and triangular distress signals on

highway traffic. *Optometry and Vision Science*, 50(4), 305–315.

¹⁴ Federal motor vehicle safety standards; Warning devices, 59 FR 49586 (September 29, 1994). https://archives.federalregister.gov/issue_slice/1994/9/29/49585-49591.pdf#page=2.

and effectiveness of warning devices, and risks or challenges with warning devices. These are all important comments for FMCSA to consider while conducting the study or when making decisions based on the results of the study. However, none of the comments directly address the proposed information collection or its associated costs/impacts. As such, FMCSA summarizes the comments but provides no response. Many comments touched on multiple issues; however, the comments below are organized based on the primary feedback provided.

Regulatory Considerations and Impact

There is widespread recognition that regulatory gaps and complexities hinder effective deployment and use of warning devices. Commenters noted that current rules do not adequately address the overuse of warning lights, and that knowledge gaps continue to weaken the regulatory framework's effectiveness. Additionally, legal loopholes and the complexity of implementing regulations were seen as barriers to the adoption of improved safety measures. Nonetheless, many comments supported FMCSA's ongoing regulatory efforts and encouraged further research to improve and modernize safety rules.

Environment or Condition-Based Study Factors

Environmental factors were a consistent theme, with many comments highlighting how visibility issues—compounded by driver inattention, curves in the road, and lack of rumble strips—reduce the effectiveness of warning devices. Visibility varies significantly across road types, making it essential for studies to account for these conditions. Several comments advocated for studies to explicitly consider how different environmental scenarios impact both warning device performance and driver response.

Study Factors for Other Devices

The public expressed concerns about the reliability and effectiveness of alternative warning devices. Some noted that excessive or competing lights, such as flashing beacons, can confuse drivers and reduce recognition of genuine hazards. Others raised the issue of power failure risks in beacons and the failure of some warning devices in real-world conditions. There was strong support for the evaluation of new warning technologies and a call to remain open to innovative solutions that might enhance safety outcomes.

Automated Vehicle Considerations

With deployment nearing of driver-out ADS-equipped CMVs, commenters raised important questions about how these technologies interface with existing safety requirements. Many pointed out that automated vehicles (AVs) lack the ability to deploy warning devices which introduces new regulatory challenges. Concerns included the need for AVs to have redundant safety systems and the potential mismatch between other driver expectations and AV capabilities. The comments emphasized the need for additional human-factors research, particularly regarding how drivers maintain attention and readiness to assume control of ADS-equipped CMVs. There was also a call for developing specific safety solutions for ADS-equipped CMVs and addressing gaps in AV breakdown procedures.

Safety Benefits of and Effectiveness of Warning Devices

Despite some concerns, many commenters acknowledged the critical role of warning devices in preventing accidents. Proper use of these devices was praised for offering early hazard detection and for being simple yet effective. The comments reinforced the idea that even basic tools can provide significant safety benefits when deployed correctly. Public feedback also urged FMCSA to validate the effectiveness of these tools through research and ensure that any new safety technologies meet or exceed this benchmark.

Risks or Challenges With Warning Devices

The misuse or overuse of warning devices was a key concern, as it can reduce their clarity and effectiveness in signaling real hazards. Inattentive drivers, outdated devices, and the risk of device placement on the roadside were all cited as challenges. Some commenters also mentioned that certain warning devices may be dangerous, especially when their deployment puts drivers at risk. These concerns underscore the need for updated regulations and evaluations that reflect current and emerging road conditions and technologies.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) whether the proposed collection is necessary for the performance of FMCSA's functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected

information; and (4) ways that the burden could be minimized without reducing the quality of the collected information.

Issued under the authority of 49 CFR 1.87.

Jonathan Mueller,

Acting Associate Administrator, Office of Research and Registration.

[FR Doc. 2025–23762 Filed 12–22–25; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA 2025–0237]

Agency Information Collection Activity Under OMB Review: All Stations Accessibility Program (ASAP)

AGENCY: Federal Transit Administration, Department of Transportation.

ACTION: Notice of request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Federal Transit Administration (FTA) to request the Office of Management and Budget (OMB) to approve a request for an extension without change to an existing information collection: All Stations Accessibility Program (ASAP).

DATES: Comments must be submitted before February 23, 2026.

ADDRESSES: To ensure that your comments are not entered more than once into the docket, submit comments identified by the docket number by only one of the following methods:

1. **Website:** <https://www.regulations.gov>. Follow the instructions for submitting comments on the U.S. Government electronic docket site. All electronic submissions must be made to the U.S. Government electronic docket site at <https://www.regulations.gov>. Commenters should follow the directions below for mailed and hand-delivered comments.

2. **Fax:** 202–366–7951.

3. **Mail:** U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.

4. **Hand Delivery:** U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: You must include the agency name and docket number for this notice at the beginning of your comments. Submit two copies of your

comments if you submit them by mail. For confirmation that FTA has received your comments, include a self-addressed stamped postcard. Note that all comments received, including any personal information, will be posted and will be available to internet users, without change, to <https://www.regulations.gov>. You may review DOT's complete Privacy Act Statement in the **Federal Register** published April 11, 2000, (65 FR 19477), or you may visit <https://www.regulations.gov>. Docket: For access to the docket to read background documents and comments received, go to <https://www.regulations.gov> at any time. Background documents and comments received may also be viewed at the U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M-30, West Building, Ground Floor, Room W12-140, Washington, DC 20590-0001 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Thomas Wilson, Office of Program Management (202) 366-5279 or Thomas.Wilson@dot.gov.

SUPPLEMENTARY INFORMATION: Interested parties are invited to send comments regarding any aspect of this information collection, including: (1) the necessity and utility of the information collection for the proper performance of the functions of the FTA; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the collected information; and (4) ways to minimize the collection burden without reducing the quality of the collected information. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection.

Title: All Stations Accessibility Program (ASAP).

OMB Number: 2132-0582.

Background: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Federal Transit Administration (FTA) is requesting Office of Management and Budget (OMB) 3-year approval of an extension without change for a currently approved collection. FTA's All Stations Accessibility Program (ASAP) is a competitive grant program that helps transit agencies upgrade older rail and other fixed-guideway stations, so they are fully accessible to all riders. The program focuses on bringing legacy stations; especially those built before modern accessibility requirements into compliance by funding improvements such as elevators, ramps, level boarding,

and other accessibility features. ASAP supports transit systems in removing barriers to station access and ensuring that all passengers can use public transportation independently and reliably.

Respondents: Eligible applicants for ASAP include designated recipients that allocate funds to legacy rail fixed guideway public transportation systems, states (including territories and Washington, DC) or local governmental entities that operate legacy rail fixed guideway public transportation system.

Estimated Annual Number of Respondents: 20 respondents.

Estimated Annual Number of Responses: 40 responses.

Estimated Total Annual Burden: 280 hours.

Frequency: Annually.

Kusum Dhyani,

Director, Office of Management Planning.

[FR Doc. 2025-23675 Filed 12-22-25; 8:45 am]

BILLING CODE 4910-57-P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA 2025-0235]

Agency Information Collection Activity Under OMB Review: Transit Research, Development, Demonstration, Deployment and Training Projects

AGENCY: Federal Transit Administration, Department of Transportation.

ACTION: Notice of request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Federal Transit Administration (FTA) to request the Office of Management and Budget (OMB) to approve a request for an extension without change to an existing information collection: Transit Research, Development, Demonstration, Deployment and Training Projects.

DATES: Comments must be submitted before February 23, 2026.

ADDRESSES: To ensure that your comments are not entered more than once into the docket, submit comments identified by the docket number by only one of the following methods:

1. *Website:* <https://www.regulations.gov>. Follow the instructions for submitting comments on the U.S. Government electronic docket site. All electronic submissions must be made to the U.S. Government electronic docket site at <https://www.regulations.gov>. Commenters should follow the directions below for mailed and hand-delivered comments.

2. *Fax:* 202-366-7951.

3. *Mail:* U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M-30, West Building, Ground Floor, Room W12-140, Washington, DC 20590-0001.

4. *Hand Delivery:* U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M-30, West Building, Ground Floor, Room W12-140, Washington, DC 20590-0001 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: You must include the agency name and docket number for this notice at the beginning of your comments. Submit two copies of your comments if you submit them by mail. For confirmation that FTA has received your comments, include a self-addressed stamped postcard. Note that all comments received, including any personal information, will be posted and will be available to internet users, without change, to <https://www.regulations.gov>. You may review DOT's complete Privacy Act Statement in the **Federal Register** published April 11, 2000, (65 FR 19477), or you may visit <https://www.regulations.gov>. Docket: For access to the docket to read background documents and comments received, go to <https://www.regulations.gov> at any time. Background documents and comments received may also be viewed at the U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M-30, West Building, Ground Floor, Room W12-140, Washington, DC 20590-0001 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lisa Colbert, Office of Research and Innovation (202) 366-9261 or Lisa.Colbert@dot.gov.

SUPPLEMENTARY INFORMATION: Interested parties are invited to send comments regarding any aspect of this information collection, including: (1) the necessity and utility of the information collection for the proper performance of the functions of the FTA; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the collected information; and (4) ways to minimize the collection burden without reducing the quality of the collected information. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection.

Title: Transit Research, Development, Demonstration, Deployment and Training Projects.

OMB Number: 2132-0546.

Background: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Federal Transit Administration (FTA) is requesting Office of Management and Budget (OMB) 3-year approval of an extension without change for a currently approved collection. The Federal Transit Administration administers a suite of grant programs that support research, development, demonstration, deployment, cooperative research, technical assistance, standards development, and workforce training in public transportation. These programs provide funding for projects that advance new technologies and practices, address operational challenges, support national research efforts, offer technical assistance to the transit industry, and strengthen the public transportation workforce. Together, these programs help transit agencies improve service delivery, enhance safety, develop industry standards, and build the skills and capabilities needed across the transit workforce. Information collected through these programs is used to evaluate applications, select projects for funding, monitor progress, and share results with stakeholders.

Respondents: Federal Government Departments, agencies, and instrumentalities of the Government, including Federal laboratories; State and local governmental entities; providers of public transportation; private or non-profit organizations; institutions of higher education; and technical and community colleges.

Estimated Annual Number of Respondents: 175 respondents.

Estimated Annual Number of Responses: 775 responses.

Estimated Total Annual Burden: 20,550 hours.

Frequency: Every Two years.

Kusum Dhyani,

Director, Office of Management Planning.

[FR Doc. 2025-23677 Filed 12-22-25; 8:45 am]

BILLING CODE 4910-57-P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA 2025-0236]

Agency Information Collection Activity Under OMB Review: Public Transportation Emergency Relief Program

AGENCY: Federal Transit Administration, Department of Transportation.

ACTION: Notice of request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Federal Transit Administration (FTA) to request the Office of Management and Budget (OMB) to approve a request for an extension without change to an existing information collection: Public Transportation Emergency Relief Program.

DATES: Comments must be submitted before February 23, 2026.

ADDRESSES: To ensure that your comments are not entered more than once into the docket, submit comments identified by the docket number by only one of the following methods:

1. **Website:** <https://www.regulations.gov>. Follow the instructions for submitting comments on the U.S. Government electronic docket site. All electronic submissions must be made to the U.S. Government electronic docket site at <https://www.regulations.gov>. Commenters should follow the directions below for mailed and hand-delivered comments.

2. **Fax:** 202-366-7951.

3. **Mail:** U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M-30, West Building, Ground Floor, Room W12-140, Washington, DC 20590-0001.

4. **Hand Delivery:** U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M-30, West Building, Ground Floor, Room W12-140, Washington, DC 20590-0001 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: You must include the agency name and docket number for this notice at the beginning of your comments. Submit two copies of your comments if you submit them by mail. For confirmation that FTA has received your comments, include a self-addressed stamped postcard. Note that all comments received, including any personal information, will be posted and will be available to internet users, without change, to <https://www.regulations.gov>. You may review DOT's complete Privacy Act Statement in the **Federal Register** published April 11, 2000, (65 FR 19477), or you may visit <https://www.regulations.gov>. Docket: For access to the docket to read background documents and comments received, go to <https://www.regulations.gov> at any time. Background documents and comments received may also be viewed at the U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M-30, West Building, Ground Floor, Room W12-140, Washington, DC 20590-0001 between 9

a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Thomas Wilson, Office of Program Management (202) 366-5279 or Thomas.Wilson@dot.gov.

SUPPLEMENTARY INFORMATION: Interested parties are invited to send comments regarding any aspect of this information collection, including: (1) the necessity and utility of the information collection for the proper performance of the functions of the FTA; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the collected information; and (4) ways to minimize the collection burden without reducing the quality of the collected information. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection.

Title: Public Transportation Emergency Relief Program.

OMB Number: 2132-0575.

Background: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Federal Transit Administration (FTA) is requesting Office of Management and Budget (OMB) 3-year approval of an extension without change for a currently approved collection. The Federal Transit Administration's Emergency Relief program enables FTA to provide assistance to public transit operators in the aftermath of an emergency or major disaster. The program helps states and public transportation systems pay for protecting, repairing, and/or replacing equipment and facilities that may suffer or have suffered serious damage as a result of an emergency, including natural disasters such as floods, hurricanes, and tornadoes. The program can fund capital projects to protect, repair, or replace facilities or equipment that are in danger of suffering serious damage, or have suffered serious damage because of an emergency. The program can also fund the operating costs of evacuation, rescue operations, temporary public transportation service, or reestablishing, expanding, or relocating service before, during or after an emergency. Congress appropriates funding for FTA's Emergency Relief Program based on estimates of the funding needed to assist public transportation providers with capital projects to repair and rebuild after a disaster and to reimburse them for operating expenses incurred while preparing for and responding to disasters.

Respondents: Public transit agencies, States, federally recognized tribes, local

governmental authorities responsible for public transportation and other eligible public transportation providers designated by a State or local government.

Estimated Annual Number of Responses: 26 responses.

Estimated Total Annual Burden: 4,680 hours.

Frequency: Annually.

Kusum Dhyani,

Director, Office of Management Planning.

[FR Doc. 2025–23676 Filed 12–22–25; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2025–1158]

Request for Comments on the Revision of a Currently Approved Collection: Regulations for Making Excess or Surplus Federal Property Available to the U.S. Merchant Marine Academy, State Maritime Academies and Non-Profit Maritime Training Facilities

AGENCY: Maritime Administration (MARAD), U.S. Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: MARAD invites public comments on its intention to request Office of Management and Budget (OMB) approval to renew an information collection in accordance with the Paperwork Reduction Act of 1995. The proposed collection OMB 2133–0504 (Regulations for Making Excess or Surplus Federal Property Available to the U.S. Merchant Marine Academy, State Maritime Academies and Non-Profit Maritime Training Facilities) is used to determine compliance with applicable statutory requirements regarding surplus government property. This collection is being revised to include a new form MA–1073C Agreement for Donation of Federal Property for Historical Purposes. MARAD is required to publish this notice in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments must be submitted on or before *February 23, 2026*.

ADDRESSES: You may submit comments identified by Docket No. MARAD–2025–1158 through one of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov. Search using the above DOT docket number and follow

the online instructions for submitting comments.

- *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Instructions: All submissions must include the agency name and docket number for this rulemaking.

Note: All comments received will be posted without change to www.regulations.gov including any personal information provided.

Comments are invited on: (a) whether the proposed collection of information is reasonable for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility, and clarity of the information collection; and (d) ways that the burden could be lessened without reducing the quality of the collected information. The agency will summarize or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Katrina McRae, 202–366–3198, Office of Sealift Support, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Washington, DC 20590, Email: Katrina.mcrae@dot.gov.

SUPPLEMENTARY INFORMATION:

Title: Regulations for Making Excess or Surplus Federal Property Available to the U.S. Merchant Marine Academy, State Maritime Academies and Non-Profit Maritime Training Facilities.

OMB Control Number: 2133–0504.

Type of Request: Revision of a currently approved collection.

Abstract: MARAD requires approved maritime training institutions seeking excess or surplus government property to provide a statement of need/justification prior to acquiring the property, using this information collection.

Respondents: Maritime training institutions, such as the U.S. Merchant Marine Academy, State Maritime Academies and non-profit maritime institutions.

Affected Public: State, Local or Tribal Government.

Estimated Number of Respondents: 40.

Estimated Number of Responses: 360.

Estimated Hours per Response: Between 1 and 4.

Annual Estimated Total Annual Burden Hours: 360.

Frequency of Response: Annually.

(Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.49.)

By Order of the Maritime Administration.

Gabriel Chavez,

Secretary, Maritime Administration.

[FR Doc. 2025–23729 Filed 12–22–25; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2025–1159]

Request for Comments on the Renewal of a Previously Approved Information Collection: Ocean Shipments Moving Under Export-Import Bank Financing

AGENCY: Maritime Administration (MARAD), U.S. Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: MARAD invites public comments on its intention to request the Office of Management and Budget (OMB) approval to renew an information collection in accordance with the Paperwork Reduction Act of 1995. The proposed collection OMB 2133–0013 (Ocean Shipments Moving Under Export-Import (EXIM) Bank Financing) is used to document shipments made during the life of certain EXIM Bank financed projects. Collected information is necessary for MARAD to fulfill its legislative requirement to monitor the percentage of ocean freight revenues/tonnage. MARAD is required to publish this notice in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments must be submitted on or before *February 23, 2026*.

ADDRESSES: You may submit comments identified by Docket No. DOT–MARAD–2025–1159 through one of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov. Search using the above DOT docket number and follow the online instructions for submitting comments.

- *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Instructions: All submissions must include the agency name and docket number for this rulemaking.

Note: All comments received will be posted without change to

www.regulations.gov including any personal information provided.

Comments are invited on: (a) whether the proposed collection of information is necessary for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility, and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Lisa Burley, Office of Cargo and Commercial Sealift, Maritime Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, Email: cargo.marad@dot.gov.

SUPPLEMENTARY INFORMATION:

Title: Ocean Shipments Moving Under Export-Import Bank Financing.

OMB Control Number: 2133-0013.

Type of Request: Extension without change of a currently approved collection.

Abstract: MARAD uses this information collection to monitor compliance with the cargo preference laws by parties covered under PR 17 and 46 U.S.C. 55304, compile annual information on EXIM Bank-financed shipments, and when applicable, provide for an informal grievance procedure, in the event there is a question or complaint pertaining to cargo preference matters.

The monthly shipping reports, with substantiating documents provide the only basis for MARAD to exercise its legislative responsibility to monitor EXIM Bank-financed cargoes that are transported on U.S.-flag vessels, recipient flag vessels, and on third-flag vessels according to the determinations and certifications of vessel non-availability that have been granted. The compilation of the statistics from the shipping reports forms the basis for determining compliance with PR 17 for each loan participant. This information is also provided to the EXIM Bank and is the nucleus for conducting annual reviews of the shipping activities of the EXIM Bank programs.

MARAD uses the information collected as part of the Transparency Initiative with the EXIM Bank. MARAD also intends to use collected information to assist EXIM Bank shippers with finding suitable U.S.-flag vessels and resolving requests for certifications of non-availability.

Respondents: All EXIM Bank loan and certain loan guarantee recipients and designated representatives charged with

the responsibility of monthly and annual reporting. These can be a contractor, ocean transportation intermediary, supplier, etc.

Affected Public: EXIM Bank loan and certain loan guarantee recipients.

Estimated Number of Respondents: 30.

Estimated Number of Responses: 390.

Estimated Hours per Response: 0.5.

Annual Estimated Total Annual Burden Hours: 195.

Frequency of Response: Monthly and Annually.

(Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.49.)

By Order of the Maritime Administration.

Gabriel Chavez,

Secretary, Maritime Administration.

[FR Doc. 2025-23728 Filed 12-22-25; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2025-1125]

Request for Comments on the Renewal of a Previously Approved Information Collection: MARAD Exercise Breakout Survey

AGENCY: Maritime Administration (MARAD), U.S. Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: MARAD invites public comments on its intention to request Office of Management and Budget (OMB) approval to renew an information collection in accordance with the Paperwork Reduction Act of 1995. The proposed collection OMB 2133-0550 titled *MARAD Exercise Breakout Survey* is being renamed "MARAD Mariner Preparedness Exercise Survey (Mariner PrepEx Survey)" to reflect the new name of the exercise program, which includes this survey. Since the last renewal, survey questions 1 and 2 are being updated to include additional modes of communication that may be restricted. There was also an increase in the totals for respondents, responses, and burden hours. MARAD is required to publish this notice in the **Federal Register** to obtain comments from the public and affected agencies.

ADDRESSES: Written comments and recommendations for the proposed information collections should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular

information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Michael DaPonte, 202-366-7627, Division of Sealift Operations and Emergency Response (MAR-612), Maritime Administration, 1200 New Jersey Avenue SE, Washington, DC 20590, Email: michael.daponte@dot.gov.

SUPPLEMENTARY INFORMATION:

Title: MARAD Mariner Preparedness Exercise Survey (Mariner PrepEx Survey).

OMB Control Number: 2133-0550.

Type of Request: Extension with change of a currently approved information collection.

Abstract: The Mariner PrepEx Survey is a component of MARAD's Mariner Preparedness Exercise Program. The survey will be conducted on a voluntary basis and provide vital information to the Ready Reserve Force (RRF) program. Periodic surveying is necessary in view of the dynamics that affect the RRF program, which include changes in the RRF fleet composition, readiness status, ship location, as well as changes to the seafaring manpower base. The survey is an integral part of the Mariner Preparedness Exercise Program and is designed to gauge mariner's training and military experience levels, willingness to participate in time of national need, and awareness of working in a contested environment.

Respondents: Merchant Mariners.

Affected Public: Individuals and households.

Estimated Number of Respondents: 1,750.

Estimated Number of Responses: 1,750.

Estimated Hours per Response: 0.0833 (5 minutes).

Annual Estimated Total Annual Burden Hours: 145.83/146 hours.

Frequency of Response: Once Annually.

A 60-day **Federal Register** Notice soliciting comments on this information collection was published on October 2, 2025, (FR 47899, Vol. 90, No. 189). The posting received one non-substantive comment commending the minor changes to the survey and recommending a reduction of the reported public burden to ensure participation in the survey. In response, MARAD clarified that total respondents and burden hours were increased to reflect the potential expansion of the RRF fleet, which will require more mariners and crew aboard additional vessels. However, the total time taken to complete the survey (*i.e.*, five (5)

minutes) remains low to encourage maximum participation in the survey.
Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.49.

By Order of the Maritime Administration.
Gabriel Chavez,

Secretary, Maritime Administration.

[FR Doc. 2025–23726 Filed 12–22–25; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2025–1126]

Request for Comments on the Renewal of a Previously Approved Information Collection: Request for Transfer of Ownership, Registry, and Flag, or Charter, Lease, or Mortgage of U.S. Citizen Owned Documented Vessels

AGENCY: Maritime Administration (MARAD), U.S. Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: MARAD invites public comments on its intention to request Office of Management and Budget (OMB) approval to renew an information collection in accordance with the Paperwork Reduction Act of 1995. The proposed collection OMB 2133–0006 (Request for Transfer of Ownership, Registry, and Flag, or Charter, Lease, or Mortgage of U.S. Citizen Owned Documented Vessels) is used to determine if a proposed vessel for transfer will initially require retention under the U.S. flag statutory regulations. MARAD is required to publish this notice in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments must be submitted on or before February 23, 2026.

ADDRESSES: You may submit comments identified by Docket No. MARAD–2025–1126 through one of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov. Search using the above DOT docket number and follow the online instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Instructions: All submissions must include the agency name and docket number for this rulemaking.

Note: All comments received will be posted without change to www.regulations.gov including any personal information provided.

Comments are invited on: (a) whether the proposed collection of information is reasonable for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility, and clarity of the information collection; and (d) ways that the burden could be lessened without reducing the quality of the collected information. The agency will summarize or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Katrina McRae, 202–366–3198, Office of Sealift Support, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Washington, DC 20590, Email: Katrina.Mcrae@dot.gov.

SUPPLEMENTARY INFORMATION:

Title: Request for Transfer of Ownership, Registry, and Flag, or Charter, Lease, or Mortgage of U.S. Citizen Owned Documented Vessels.

OMB Control Number: 2133–0006.

Type of Request: Extension without change of currently approved collection.

Abstract: This collection provides information necessary for MARAD to approve the sale, transfer, charter, lease, or mortgage of U.S. documented vessels to non-citizens, or the transfer of such vessels by their owners to foreign registry and flag, as required by various contractual requirements. MARAD uses the compiled data to determine if the transfer is subject to retention under the U.S. flag statutory regulations.

Respondents: Vessel owners who have applied for foreign transfer of U.S. flag vessels.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 85.

Estimated Number of Responses: 85.

Estimated Hours per Response: 2.

Annual Estimated Total Annual Burden Hours: 170.

Frequency of Response: Annually.

(Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.49.)

By Order of the Maritime Administration.
Gabriel Chavez,

Secretary, Maritime Administration.

[FR Doc. 2025–23727 Filed 12–22–25; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2025–1092]

Request for Comments on the Renewal of a Previously Approved Information Collection: Effective U.S. Control (EUSC)/Parent Company

AGENCY: Maritime Administration (MARAD), U.S. Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: MARAD invites public comments on its intention to request Office of Management and Budget (OMB) approval to renew an information collection in accordance with the Paperwork Reduction Act of 1995. The proposed collection OMB 2133–0511 (Effective U.S. Control (EUSC)/Parent Company) is used to identify useful and available oceangoing vessels for the deployment of U.S. military equipment and supplies by the Department of Defense, which are necessary to sustain a force during a foreign theater of operations. MARAD is required to publish this notice in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments must be submitted on or before February 23, 2026.

ADDRESSES: You may submit comments identified by Docket No. MARAD–2025–1092 through one of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov. Search using the above DOT docket number and follow the online instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Instructions: All submissions must include the agency name and docket number for this rulemaking.

Note: All comments received will be posted without change to www.regulations.gov including any personal information provided.

Comments are invited on: (a) whether the proposed collection of information is reasonable for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility, and clarity of the information collection; and (d) ways that the burden could be lessened without reducing the quality of the collected information. The

agency will summarize or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT:

George Jackson, 202-366-4029, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Washington, DC 20590, Email: george.jackson@dot.gov.

SUPPLEMENTARY INFORMATION:

Title: Effective U.S. Control (EUSC)/ Parent Company.

OMB Control Number: 2133-0511.

Type of Request: Extension without change of a previously approved collection.

Abstract: This information collection includes a detailed inventory of foreign-registered vessels owned by U.S. citizens, which is essential to logistical support planning operations conducted by MARAD officials. Collected information could also be vital during national and international emergencies.

Respondents: U.S. citizens who own foreign-registered vessels.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 60.

Estimated Number of Responses: 60.

Estimated Hours per Response: 1.

Annual Estimated Total Annual Burden Hours: 60.

Frequency of Response: Annually.

(Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.49.)

By Order of the Maritime Administration.

Gabriel Chavez,

Secretary, Maritime Administration.

[FR Doc. 2025-23730 Filed 12-22-25; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Comment Request; Appraisals for Higher-Priced Mortgage Loans

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC may not conduct or

sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning the renewal of its information collection titled, "Appraisals for Higher-Priced Mortgage Loans."

DATES: Comments must be received by February 23, 2026.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email:* prainfo@occ.treas.gov.

- *Mail:* Chief Counsel's Office,

Attention: Comment Processing, Office of the Comptroller of the Currency, Attention: 1557-0313, 400 7th Street SW, Suite 3E-218, Washington, DC 20219.

- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E-218, Washington, DC 20219.

- *Fax:* (571) 293-4835.

Instructions: You must include "OCC" as the agency name and "1557-0313" in your comment. In general, the OCC will publish comments on www.reginfo.gov without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Following the close of this notice's 60-day comment period, the OCC will publish a second notice with a 30-day comment period. You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection by the method set forth in the next bullet.

- *Viewing Comments Electronically:* Go to www.reginfo.gov. Hover over the "Information Collection Review" tab and click on "Information Collection Review" from the drop-down menu. From the "Currently under Review" drop-down menu, select "Department of the Treasury" and then click "submit." This information collection can be located by searching OMB control number "1557-0313" or "Appraisals for Higher-Priced Mortgage Loans." Upon finding the appropriate information collection, click on the related "ICR Reference Number." On the next screen,

select "View Supporting Statement and Other Documents" and then click on the link to any comment listed at the bottom of the screen.

- For assistance in navigating www.reginfo.gov, please contact the Regulatory Information Service Center at (202) 482-7340.

FOR FURTHER INFORMATION CONTACT:

Shaquita Merritt, Clearance Officer, (202) 649-5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7-1-1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor.

"Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements, imposed on ten or more persons, that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of title 44 generally 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, the OCC is publishing notice of the renewal of this collection.

Title: "Appraisals of Higher-Priced Mortgage Loans." *OMB Control No.:* 1557-0313.

Type of Review: Regular.

Affected Public: Businesses or other for-profit. *Description:* This information collection relates to section 1471 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, which added a new section 129H to the Truth in Lending Act (TILA) establishing special appraisal requirements for "higher-risk mortgages." For certain mortgages with an annual percentage rate that exceeds the average prime offer rate by a specified percentage, creditors must obtain an appraisal or appraisals meeting certain specified standards, provide applicants with a notification regarding the use of the appraisals, and give applicants a copy of the written appraisals used to evaluate real estate collateral. The statute permits the OCC to issue a rule to include exemptions from these requirements.

The information collection requirements are found in 12 CFR 34.203(c)(1), (c)(2), (d), (e) and (f). This

information is required to protect consumers and promote the safety and soundness of creditors making higher-priced mortgage loans (HPMLs) subject to 12 CFR part 34, subpart G. This information is used by creditors to evaluate real estate collateral securing HPMLs subject to 12 CFR 34.203(c) and by consumers entering these transactions. The collections of information are mandatory for creditors making HPMLs subject to 12 CFR part 34, subpart G.

Under 12 CFR 34.203(e) and (f), a creditor must, no later than the third business day after the creditor receives a consumer's application for an HPML, provide the consumer with a disclosure that informs the consumer that the creditor may order an appraisal to determine the value of the property and charge the consumer for that appraisal, that the creditor will provide the consumer with a copy of any appraisal, and that the consumer may choose to have an additional appraisal conducted at the expense of the consumer. If a loan is an HPML subject to 12 CFR 34.203(c), then, under 12 CFR 34.203(c)(1) and (2), the creditor is required to obtain a written appraisal prepared by a certified or licensed appraiser who conducts a physical visit of the interior of the property that will secure the transaction (Written Appraisal). Under 12 CFR 34.203(d)(1), a creditor is required to obtain an additional appraisal (Additional Written Appraisal) for an HPML that is subject to 12 CFR part 34, subpart G if: (1) the seller acquired the property securing the loan 90 or fewer days prior to the date of the consumer's agreement to acquire the property and the price in the consumer's agreement to acquire the property exceeds the seller's acquisition price by more than 10 percent; or (2) the seller acquired the property securing the loan 91 to 180 days prior to the date of the consumer's agreement to acquire the property and the price in the consumer's agreement to acquire the property exceeds the seller's acquisition price by more than 20 percent.

Under 12 CFR 34.203(d)(3) and (4), the Additional Written Appraisal must meet the requirements described in 12 CFR 34.203(c)(1) and also include an analysis of: (1) the difference between the price at which the seller acquired the property and the price the consumer is obligated to pay to acquire the property; (2) changes in market conditions between the date the seller acquired the property and the date of the consumer's agreement to acquire the property; and (3) any improvements made to the property between the date the seller acquired the property and the

date of the consumer's agreement to acquire the property. Under 12 CFR 34.203(f), a creditor is required to provide the consumer with a copy of the Written Appraisal or Additional Written Appraisal, as applicable.

Estimated Burden

Estimated Frequency of Response: On occasion.

Estimated Number of Respondents: 1,011.

Estimated Total Annual Burden: 261 hours.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Carl Kaminski,

Assistant Director, Office of the Comptroller of the Currency.

[FR Doc. 2025-23731 Filed 12-22-25; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Comment Request; OCC Supplier Registration Form

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the

PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning a revision to its information collection titled, "OCC Supplier Registration Form."

DATES: Comments must be received by February 23, 2026.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

• *Email:* prainfo@occ.treas.gov.

• *Mail:* Chief Counsel's Office,

Attention: Comment Processing, Office of the Comptroller of the Currency, Attention: 1557-0316, 400 7th Street SW, Suite 3E-218, Washington, DC 20219.

• *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E-218, Washington, DC 20219.

• *Fax:* (571) 293-4835.

Instructions: You must include "OCC" as the agency name and "1557-0316" in your comment. In general, the OCC will publish comments on www.reginfo.gov without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Following the close of this notice's 60-day comment period, the OCC will publish a second notice with a 30-day comment period. You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection by the method set forth in the next bullet.

• **Viewing Comments Electronically:** Go to www.reginfo.gov. Hover over the "Information Collection Review" tab and click on "Information Collection Review" from the drop-down menu. From the "Currently under Review" drop-down menu, select "Department of the Treasury" and then click "submit." This information collection can be located by searching OMB control number "1557-0316" or "OCC Supplier Registration Form." Upon finding the appropriate information collection, click on the related "ICR Reference Number."

On the next screen, select “View Supporting Statement and Other Documents” and then click on the link to any comment listed at the bottom of the screen.

- For assistance in navigating www.reginfo.gov, please contact the Regulatory Information Service Center at (202) 482-7340.

FOR FURTHER INFORMATION CONTACT:

Shaquita Merritt, Clearance Officer, (202) 649-5490, Chief Counsel’s Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7-1-1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements, imposed on ten or more persons, that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of title 44 generally 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, the OCC is publishing notice of the revision of this collection.

Title: OCC Supplier Registration Form.

OMB Control No.: 1557-0316.

Type of Review: Regular.

Affected Public: Businesses or other for-profit.

Description: The OCC Supplier Registration Form is used to update and enhance an internal database of entities interested in doing business with the agency. This collection of information from interested suppliers facilitates early market research by allowing businesses to provide specific information to the OCC about capabilities that meet the OCC’s needs and in specific purchasing areas.

The collection also allows the OCC to build a robust internal database of interested small businesses. In collaboration with the U.S. Department of the Treasury and U.S. Small Business Administration, the OCC establishes annual small business contracting goals. This collection helps ensure the maximum participation of small business concerns in the OCC’s procurement process.

The OCC is revising the Supplier Registration Form by changing the format of the business classification information requested on the form; however, this revision will not impact the ability of suppliers to provide business classification information or otherwise continue submitting expressions of interest in doing business with the agency.

Estimated Burden

Estimated Frequency of Response: On occasion.

Estimated Number of Respondents: 100.

Estimated Burden per Response: 10 minutes.

Estimated Total Annual Burden: 17 hours.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC’s estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Charles A. Davis,

Assistant Director, Office of the Comptroller of the Currency.

[FR Doc. 2025-23769 Filed 12-22-25; 8:45 am]

BILLING CODE 4810-33-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Internal Revenue Service Advisory Council; Public Meeting

AGENCY: Internal Revenue Service, Department of Treasury.

ACTION: Notice of public meeting.

SUMMARY: The Internal Revenue Service Advisory Council will hold a public meeting.

DATES: Wednesday, January 14, 2026.

ADDRESSES: 1111 Constitution Ave. NW, Washington, DC 20224. This meeting will also be held virtually via Microsoft Teams.

FOR FURTHER INFORMATION CONTACT:

Anna Millikan, Office of National Public Liaison, at 202-317-6564 or send an email to PublicLiaison@irs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, the Internal Revenue Service announces the Internal Revenue Service Advisory Council (IRSAC) will hold a public meeting on Wednesday, January 14, 2026, from 9:00 a.m. to 12:30 p.m. Eastern.

The meeting will be held in person at 1111 Constitution Ave. NW, Washington, DC as well as virtually via Microsoft Teams. Members of the public planning to attend should register by January 9 by contacting Anna Millikan at 202-317-6564 or sending an email to PublicLiaison@irs.gov.

Issues to be discussed may include, but are not limited to: *IRS Funding; Recommendation that the IRS Actively Take Steps to Education the Public About its Crucial Role in the U.S. and Address Misinformation Spread About its Operations; Updating and Maximizing Usefulness of IRS websites; Accounting Method Change Requests; Simplify Use of Online Tax Services; Processing of Form 730 and Excise Tax Payments; Address Changes for Large Businesses; Non-tax-related Identity Theft and Account Takeover Fraud; De Minimis Threshold for Reconciling Form 1042 and Form 1042-S; Character and Source of Staking Income; Recommendations for Increasing the Tax Information Reporting Threshold for Slot Machine Jackpot Winnings; Comments Regarding Changed E-filing Requirements; Recommendations for Modernizing Form 1065, U.S. Return of Partnership Income; IRS Sections 6038 and 6038A Penalty Administration; Broadening and Promoting Settlement Programs; Enhancing Digital Tools for Taxpayer Engagement; Expanding ADR and the Pool of Eligible Mediators; Using Proactive Prompts to Improve Small Business Voluntary Compliance; Expanding and Developing Resources to Increase Tax Literacy for Small Business Owners; Update Guidance on the Interpretation of “Essential Government Function” for Tribal Governments; High Cost for Exempt Organizations to Use the PLR Process; Implementation of the Saver’s Match; Defining Identical Terms Identically for Purposes of the Unrelated Business Income Tax (UBIT) and Real Estate Investment Trusts (REITs) to Avoid Confusion and Facilitate the Effective Administration of Tax Law;*

CAF Authorization Process Improvements; Access to Entire Electronically Filed 1040 Tax Return Data; Amended Return Processing and Time; Leveraging Social Media to Improve Service and Compliance; Pre-Launch Testing and Post-Launch Support; and Supporting Live Chat for Tax Professionals. The meeting agenda will be posted online prior to the meeting at the IRSAC web page, www.irs.gov/irsac.

Should you wish the IRSAC to consider a written statement germane to the Council's work, file the statement by sending an email to PublicLiaison@irs.gov by January 9, 2026.

Dated: December 19, 2025.

John A. Lipold,

Designated Federal Official, Office of National Public Liaison, Internal Revenue Service.

[FR Doc. 2025–23724 Filed 12–22–25; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Information Sharing Between Government Agencies and Financial Institutions

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice of information collection; request for comment.

SUMMARY: The Department of the Treasury will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on this request.

DATES: Comments should be received on or before December 23, 2025 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Spencer W. Clark by emailing PRA@treasury.gov, calling (202) 927–5331, or viewing the entire

information collection request at www.reginfo.gov.

SUPPLEMENTARY INFORMATION:

Financial Crimes Enforcement Network (FinCEN)

Title: Information sharing between government agencies and financial institutions.

OMB Control Number: 1506–0049.

Type of Review: Extension without change of a currently approved collection.

Description: The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act) charged the Department of the Treasury (Treasury) with developing regulations to facilitate information sharing among government entities and financial institutions for the purpose of combatting terrorism and money laundering.¹ In 2002, FinCEN published a final rule implementing the authority contained in section 314(a) of the USA PATRIOT Act (the Section 314(a) Rule).² The rule required financial institutions, upon FinCEN's request (a “Section 314(a) Request”), to search their records to determine whether they have maintained an account or conducted a transaction with a specified individual, entity, or organization that a Federal law enforcement agency has certified is suspected, based on credible evidence, of engaging in terrorist activity or money laundering. The rule enables certain foreign law enforcement agencies, state and local law enforcement agencies, and FinCEN itself, on its own behalf and on behalf of appropriate components of Treasury, to initiate Section 314(a) Requests.³ Before processing a request, FinCEN requires the requesting agency to certify that, in the case of money laundering, the matter is significant, and that the requesting agency has been unable to locate the information sought through traditional methods of investigation and analysis. The regulations implementing the rules are found at 31 CFR 1010.520.

Form: Not applicable.

Affected Public: Businesses or other for profit and non-profit institutions.

Estimated Number of Potential Respondents: 575,873 financial institutions.

¹ Public Law 107–56, 115 Stat. 272 (Oct. 26, 2001).

² FinCEN, *Final Rule—Special Information Sharing Procedures to Deter Money Laundering and Terrorist Activity*, 67 FR 60579, (Sept. 26, 2002).

³ FinCEN, *Final Rule—Expansion of Special Information Sharing Procedures To Deter Money Laundering and Terrorist Activity*, 75 FR 6560, (Feb. 10, 2010).

Estimated Number of Expected Respondents: 12,726 financial institutions.

Frequency of Response: As required.

Estimated Total Number of Annual Responses: 7,381,080.

Estimated Burden Hours per Respondent: Approximately 44 hours.

Estimated Total Annual Burden Hours: 555,702.

Authority: 44 U.S.C. 3501 *et seq.*

Spencer W. Clark,

Treasury PRA Clearance Officer.

[FR Doc. 2025–23743 Filed 12–22–25; 8:45 am]

BILLING CODE 4810–02–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Internal Revenue Service (IRS) Information Collection Requests

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice of information collection; request for comment.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before January 22, 2026 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Copies of the submissions may be obtained from Spencer W. Clark by emailing PRA@treasury.gov, calling (202) 927–5331, or viewing the entire information collection request at www.reginfo.gov.

SUPPLEMENTARY INFORMATION:

Internal Revenue Service (IRS)

1. Title: Returns Required on Magnetic Media.

OMB Control Number: 1545–0957.

Type of Request: Extension without change of a currently approved collection.

Description: Certain filers of information returns are required by law to file on magnetic media. In some instances, waivers from this requirement are necessary and justified. Form 8508 is submitted by the filer and provides information on which IRS will base its waiver determination.

Form: 8508.

Affected Public: Private Sector, Federal, State and local governments.

Estimated Number of Respondents: 1,000.

Frequency of Response: On Occasion.

Estimated Total Number of Annual Responses: 1,000.

Estimated Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 750.

2. *Title:* TD 8458, Real Estate Mortgage Investment Conduits.

OMB Control Number: 1545–1276.

Type of Request: Extension of a currently approved collection.

Description: Internal Revenue Code (IRC) section 860E(e) imposes an excise tax on any transfer of a residual interest in a Real Estate Mortgage Investment Conduits (REMIC) to a disqualified organization. IRC sections 860E(e)(4) and 860E(e)(6)(D) provide relief of the excise tax when the transferee or record holder of the residual interest furnishes an affidavit to the transferor or pass-thru entity stating that they are not a disqualified organization. Treasury Decision (TD) 8458 contains final regulations and guidance relating to the IRC requirements for a REMIC. Treasury Regulations section 1.860E–2(a)(5) requires the REMIC, upon request of the party responsible for the tax liability, to furnish information sufficient to compute the present value of the anticipated excess inclusions. Treasury Regulations sections 1.860E–2(a)(7) and 1.860E–2(b)(2) provide requirements for the affidavits provided by the transferee or record holder of a residual interest in a REMIC as required by IRC sections 860E(e)(4) and 860E(e)(6)(D).

Regulation Project Number: TD 8458.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 1,600.

Frequency of Response: On occasion.

Estimated Total Number of Annual Responses: 1,600.

Estimated Time per Response: 20 minutes.

Estimated Total Annual Burden Hours: 525.

3. *Title:* Aid of Construction Under Section 118(c).

OMB Control Number: 1545–1639.

Type of Request: Extension of a currently approved collection.

Description: TD 8936 contains final regulations concerning an exclusion from gross income for a contribution in aid of construction under section 118(c) that is treated as a contribution to capital under section 118(a). The final regulations affect a regulated public utility that provides water or sewerage services because a qualifying contribution in aid of construction is treated as a contribution to the capital of the utility and excluded from gross income. The final regulations provide guidance on the definition of a contribution in aid of construction, the adjusted basis of any property acquired with a contribution in aid of construction, the information relating to a contribution in aid of construction required to be furnished by the utility, and the time and manner for providing that information to the IRS.

Regulation Project Number: TD 8936.

Affected Public: Businesses and other for-profit organizations.

Estimated Number of Respondents: 300.

Frequency of Response: On Occasion.

Estimated Time per Response: 60 minutes.

Estimated Total Annual Burden Hours: 300.

(Authority: 44 U.S.C. 3501 *et seq.*)

Spencer W. Clark,

Treasury PRA Clearance Officer.

[FR Doc. 2025–23740 Filed 12–22–25; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Alcohol and Tobacco Tax and Trade Bureau Information Collection Requests

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice of information collection; request for comment.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before January 22, 2026 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed

information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Copies of the submissions may be obtained from Spencer W. Clark by emailing PRA@treasury.gov, calling (202) 927–5331, or viewing the entire information collection request at www.reginfo.gov.

SUPPLEMENTARY INFORMATION:

Alcohol and Tobacco Tax and Trade Bureau (TTB)

1. *Title:* Distilled Spirits Plants—Excise Taxes (TTB REC 5110/06).

OMB Control Number: 1513–00445.

Type of Request: Extension without change of a currently approved collection.

Description: Under chapter 51 of the Internal Revenue Code (IRC), distilled spirits produced or imported into the United States are subject to Federal excise tax, which is determined at the time the spirits are withdrawn from bond, and which is paid by return, subject to regulations prescribed by the Secretary of the Treasury (the Secretary). In addition, a credit may be taken against that tax for the portion of a distilled spirits product’s alcohol content derived from wine or flavors. The TTB regulations in 27 CFR parts 19 and 26 require distilled spirits excise taxpayers to keep certain records in support of the information provided on their excise tax returns, including information on the distilled spirits removed from their premises and the products’ applicable tax rates. TTB uses the collected information to ensure that the relevant provisions of the IRC are appropriately applied, verify claims for refunds or remission of tax, and account for the transfer of certain distilled spirits excise taxes to the governments of Puerto Rico and the U.S. Virgin Islands.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 5,700.

Frequency of Response: Average of 9.2105 per year.

Estimated Total Number of Annual Responses: 52,000.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 52,000 hours.

2. *Title:* Retail Liquor Dealers Records of Receipts of Alcoholic Beverages and Commercial Invoices (TTB REC 5170/03).

OMB Control Number: 1513–0066.

Type of Request: Extension without change of a currently approved collection.

Description: Under the authority of the IRC at 26 U.S.C. 5122, the TTB regulations in 27 CFR part 31 require retail alcohol beverage dealers to keep records showing the quantities of all distilled spirits, wines, and beer received, including information on from whom and when the products were received. Those regulations also require dealers to keep records of all alcohol beverage sales of 20 or more wine gallons made to the same person at the same time. At the respondent's discretion, those records may consist of usual and customary business records such as commercial invoices, unless the respondent prefers maintaining the information by other means, maintained at their place of business or at an alternate location under the dealer's control approved by TTB. Additionally, under the IRC at 26 U.S.C. 5123, the TTB regulations require retail dealers to maintain those records for at least 3 years, available for TTB inspection during business hours. TTB uses the required information to ensure that the relevant provisions of the IRC are appropriately applied.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 480,000.

Frequency of Response: Once annually.

Estimated Total Number of Annual Responses: 480,000.

Estimated Time per Response: None.

Estimated Total Annual Burden Hours: None. This information collection consists of usual and customary records kept by respondents during the normal course of business, regardless of any regulatory requirement to do so, and it therefore imposes no additional annual burden on its respondents, per the OMB regulations at 5 CFR 1320.3(b)(2).

3. Title: Records of Operations—Manufacturer of Tobacco Products or Processed Tobacco (TTB REC 5210/1).

OMB Control Number: 1513–0068.

Type of Request: Extension without change of a currently approved collection.

Description: The IRC at 26 U.S.C. 5741 requires manufacturers of tobacco products, cigarette papers or tubes, or processed tobacco to keep records as the Secretary prescribes by regulation.

Under that authority, the TTB regulations in 27 CFR part 40 require such manufacturers to keep daily records regarding products manufactured, removed, returned, consumed, transferred, destroyed, lost, or disclosed as shortages. Those regulations provide that manufacturers may use usual and customary commercial records, where possible, to keep and maintain the required data, which must be maintained for 3 years, subject to TTB inspection upon request. TTB uses the required information to ensure compliance with the tax provisions of the IRC regarding tobacco products and processed tobacco.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 235.

Frequency of Response: Once annually.

Estimated Total Number of Annual Responses: 235.

Estimated Time per Response: 2 hours.

Estimated Total Annual Burden Hours: 470 hours.

4. Title: Tobacco Export Warehouse—Records of Operations.

OMB Control Number: 1513–0070.

Type of Request: Extension without change of a currently approved collection.

Description: In general, chapter 52 of the IRC imposes Federal excise tax on all tobacco products and cigarette papers and tubes manufactured in, or imported into, the United States, while exempting such products removed for export, as well as all processed tobacco, from that tax. Export warehouses receive and store such non-taxpaid products until they are removed without payment of tax for export to a foreign country, Puerto Rico, or the U.S. Virgin Islands, or for consumption beyond the internal revenue laws of the United States. As authorized by the IRC at 26 U.S.C. 5741, the TTB regulations in 27 CFR part 44 require export warehouse proprietors to keep usual and customary business records showing the date, kind, quantity, and manufacturer of all tobacco products, cigarette papers and tubes, and processed tobacco received, removed, transferred, destroyed, lost, or returned to the manufacturer or to a customs bonded warehouse proprietor. TTB uses the collected information to ensure untaxed products are accounted for to detect diversion of untaxed products.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 65.

Frequency of Response: Once annually.

Estimated Total Number of Annual Responses: 65.

Estimated Time per Response: None.

Estimated Total Annual Burden

Hours: None. This information collection consists of usual and customary records kept by respondents during the normal course of business, regardless of any regulatory requirement to do so, and it therefore imposes no additional annual burden on its respondents, per the OMB regulations at 5 CFR 1320.3(b)(2).

5. Title: Notices Relating to Payment of Firearms and Ammunition Excise Tax by Electronic Fund Transfer.

OMB Control Number: 1513–0097.

Type of Request: Extension without change of a currently approved collection.

Description: Under the IRC at 26 U.S.C. 6302, TTB collects the firearms and ammunition excise tax imposed by 26 U.S.C. 4181 on the basis of a return that taxpayers file on a quarterly basis. That section also authorizes the Secretary to issue regulations concerning the payment of taxes by electronic funds transfer (EFT). Under the TTB regulations in 27 CFR part 53, persons who elect to begin or discontinue payment of firearms and ammunition excise taxes by EFT must submit a written notice to TTB regarding such actions. TTB uses those notifications to administer the firearms and ammunition excise tax payment provisions related to the use of EFT.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 10.

Frequency of Response: On occasion.

Estimated Total Number of Annual Responses: 10.

Estimated Time per Response: 24 minutes. None.

Estimated Total Annual Burden Hours: 4 hours.

Authority: 44 U.S.C. 3501 *et seq.*

Spencer W. Clark,

Treasury PRA Clearance Officer.

[FR Doc. 2025–23741 Filed 12–22–25; 8:45 am]

BILLING CODE 4810–31–P



FEDERAL REGISTER

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Tuesday,

No. 244

December 23, 2025

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 513

Global Benchmark for Efficient Drug Pricing (GLOBE) Model; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 513

[CMS–5545–P]

RIN 0938–AV66

Global Benchmark for Efficient Drug Pricing (GLOBE) Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule proposes to implement the Global Benchmark for Efficient Drug Pricing Model (“GLOBE Model”), a new Medicare payment model under section 1115A of the Social Security Act (the Act). The GLOBE Model would test whether a payment model that uses an alternative method for calculating Part B inflation rebate amounts for certain separately payable Part B drugs and biologicals products reduces costs for Medicare fee-for-service (FFS) beneficiaries and the Medicare program while preserving quality of care.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by February 23, 2026.

ADDRESSES: In commenting, please refer to file code CMS–5545–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–5545–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 to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5545–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:

Vinod Mitta, (667) 290–8712 or GLOBEmodel@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: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments. We encourage commenters to include supporting facts, research, and evidence in their comments. When doing so, commenters are encouraged to provide citations to the published materials referenced, including active hyperlinks. Likewise, commenters who reference materials which have not been published are encouraged to upload relevant data collection instruments, data sets, and detailed findings as a part of their comment. Providing such citations and documentation will assist us in analyzing the 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/>.

I. Executive Summary and Background

A. Executive Summary

1. Purpose

The purpose of this proposed rule is to propose the implementation and testing of a new mandatory model under the authority of the Centers for Medicare & Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (CMMI) (Innovation Center). Section 1115A of the Social Security Act (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 such programs.

2. Summary of Major Provisions

a. Proposed GLOBE Model Drugs

The proposed Global Benchmark for Efficient Drug Pricing Model (“GLOBE Model”) would focus on a set of Part B rebatable drugs that are single source drugs and sole source biological products that are furnished to a cohort of beneficiaries in the traditional Medicare program. The set of included drugs, as proposed in section II.B. of this proposed rule, would include certain Part B rebatable drugs as identified in 42 CFR 427.101 for the purpose of the Medicare Part B Drug Inflation Rebate Program and that meet the proposed definition of GLOBE Model drugs in proposed 42 CFR 513.130. Drug selection (and removal, if applicable) for the model test would be determined by CMS based on the eligibility criteria and would not be subject to appeal.

b. Proposed Defined Population and Intervention

The proposed cohort of beneficiaries is described in section II.C. of this proposed rule. This cohort would be identified from approximately 25 percent of beneficiaries who are enrolled in traditional Medicare Part B and meet certain criteria (as determined by CMS as set forth in proposed 42 CFR 513.120). These beneficiaries are traditional Medicare Part B as their primary payer, as defined by a beneficiary being enrolled in Medicare Part B fee-for-service (FFS), and must not be enrolled in a Medicare Advantage plan, section 1876 cost plan,¹ or section 1833 healthcare prepayment plan.² Beneficiaries must not have other group health coverage that is a primary payer (such as employer-sponsored health insurance). Finally, beneficiaries must be identified by CMS for inclusion in the model (based on the beneficiary’s address of record at a certain point in time being within the GLOBE Model geographic areas) and must not be identified by CMS for inclusion in the comparison group or otherwise not eligible for inclusion. Medicare beneficiaries who are in the selected cohort, or “GLOBE Model beneficiaries,” would not be model participants³ but would benefit from reduced coinsurance, as applicable, when they receive a GLOBE Model drug as described in section II.G.7. of this

¹ As established in section 1876 of the Act (42 U.S.C. 1395mm).

² As established in section 1833 of the Act (42 U.S.C. 1395l).

³ As proposed in section II.E. of this proposed rule, manufacturers of GLOBE Model drugs would be model participants.

proposed rule. When a GLOBE Model beneficiary receives a GLOBE Model drug on a date of service where they are identified as a GLOBE Model beneficiary, separately payable claim lines for that service would be included in the calculation of GLOBE Model billing units as described in section II.G.4. of this proposed rule. Beneficiary selection for the model cohort and comparison group (and removal, if applicable) would be solely determined by CMS and would not be subject to appeal. Providers and suppliers who furnish GLOBE Model drugs to Medicare FFS beneficiaries who are in the model cohort would not be model participants and would continue to buy and bill for GLOBE Model drugs as usual and receive separate payment under Medicare Part B (if applicable). These providers and suppliers include, but may not be limited to, hospital outpatient departments, physician practices, ambulatory surgical centers, pharmacies enrolled as durable medical equipment (DME) suppliers. When the GLOBE Model reduced beneficiary coinsurance applies to units of GLOBE Model drugs furnished to Medicare Part B FFS beneficiaries who are included in the GLOBE Model beneficiary cohort, the provider or supplier would reduce the amount of coinsurance charged to the beneficiary and the portion of the Medicare Part B allowed amount that would be payable by Medicare Part B would be adjusted upwards. For example, if the Medicare Part B allowed amount under the GLOBE Model is \$100 and the GLOBE Model beneficiary coinsurance percentage is reduced to 10 percent (instead of the usual 20 percent), the Medicare Part B program payment to the provider or supplier would be adjusted upward and would be \$90 (instead of the usual \$80) and the beneficiary coinsurance financial responsibility would be \$10.

c. Proposed Manufacturer Participation

The proposed GLOBE Model would require mandatory participation for all manufacturers (as defined in 42 CFR 427.20) of Part B rebatable drugs that are also GLOBE Model drugs (as identified in proposed 42 CFR 513.130 and discussed in section II.B. of this proposed rule). When Part B rebatable drugs subject to the GLOBE Model are furnished to Medicare FFS beneficiaries who are in the model cohort, manufacturers that are GLOBE Model participants would pay GLOBE Model rebates to the Medicare Part B account in the Federal Supplementary Medical Insurance Trust Fund if the amount specified in section 1847A(i)(3)(A)(ii)(I) of the Act for the GLOBE Model drug

exceeds a benchmark amount that would be based on available international drug pricing information (as described in section II.G. of this proposed rule), which would not be less than any rebates owed under the Medicare Part B Drug Inflation Rebate Program. The total GLOBE Model rebate amount would only apply to certain units of the GLOBE Model drugs (as identified in proposed 42 CFR 513.520) and would be solely determined by CMS and would not be subject to appeal. Manufacturers would have the opportunity to submit a Suggestion of Error if the manufacturer believes that there is a mathematical error or errors to be corrected.

d. Model Purpose

The intent of the proposed GLOBE Model is to test an innovative payment model that modifies the Part B inflation rebate amount for GLOBE Model drugs using international drug pricing information to identify a benchmark that reflects prices paid in a set of economically comparable countries (as discussed in section II.G.1.e. of this proposed rule), which CMS expects would reduce program expenditures for Medicare Part B while preserving or enhancing beneficiaries' quality of care. As described in section II.G.2. of this proposed rule, CMS proposes that the model test would include two approaches for identifying a benchmark amount for the modified rebate calculation—using differently sourced international drug pricing information and different calculations—and the model evaluation would assess the impacts of testing these different approaches for identifying a benchmark amount for the modified rebate calculation. One approach, described in section II.G.2.a. of this proposed rule (Method I), would use existing international drug pricing information to identify a benchmark based on an estimation of the lowest international price among the set of economically comparable countries, which may be tied to pricing data that represent list, invoice, ex-manufacturer sales, other prices, or a combination of such prices as available in commercially-available data sources. The other approach, described in section II.G.2.b. of this proposed rule (Method II), would use voluntary manufacturer-submitted international drug net pricing data to estimate a benchmark based on an average international price among the set of economically comparable countries, which would reflect net prices realized by a manufacturer.

In this proposed rule, we propose to test the GLOBE Model in a manner that

captures all applicable billing units for all separately payable Medicare Part B FFS claims for GLOBE Model drugs that are furnished to Medicare Part B FFS beneficiaries who are in the model cohort (on the date of service) and that are paid under the GLOBE Model for dates of service during a performance year and for which the GLOBE Model beneficiary coinsurance and adjusted payments to providers and suppliers could apply. For purposes of calculating the total GLOBE Model rebate amount, applicable billing units would be identified by CMS several months after the end of a calendar quarter (as described in section II.G. of this proposed rule) and additional time is necessary for calculations of rebate amounts and creating invoices. This means that GLOBE Model test processes for claims processing, data collection, invoicing, payment of GLOBE Model rebates, and reconciliation would occur concurrently with and continue after the end of a performance year and subsequent years after the last performance year.

e. Proposed Model Performance Period

The proposed GLOBE Model would have a 7-year test period that includes 5 performance years, beginning October 1, 2026, and ending September 30, 2031, during which the GLOBE Model beneficiary coinsurance and adjusted payments to providers and suppliers could apply and monitoring activities would occur, and 7 payment years, beginning October 1, 2026, and ending September 30, 2033, during which CMS would calculate, invoice, collect, and reconcile the GLOBE Model rebates for a performance year. The model evaluation would encompass the 7-year test period.

f. Proposed Model Waivers

We believe it would be necessary to waive certain requirements of title XVIII of the Act and related program requirements codified in regulations solely for purposes of carrying out the testing of the GLOBE Model under section 1115A(b) of the Act. Specifically, as further described in section II.O. of this proposed rule, we propose to waive provisions in section 1847A(i), 1833(a), and 1833(t) of the Act to the extent necessary to permit testing of an alternative rebate calculation for certain units of GLOBE Model drugs and collect GLOBE Model rebate amounts. We propose to issue waivers using the waiver authority under section 1115A(d)(1) of the Act. Each of the proposed waivers is discussed in detail in section II.O. of this proposed rule.

We propose to codify the requirements of the GLOBE Model at 42 CFR part 513. We propose at § 513.800 that should any provision of the proposed part 513 be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provisions would be severable from the remainder of part 513 and the invalidity or unenforceability would not affect the remainder of the provisions of part 513. For example, should the proposed alternate rebate calculation payment methodology in this proposed rule be deemed invalid or unenforceable, the underlying obligation under current statute will continue. We seek comment on our proposed severability policies.

3. Summary of Costs and Benefits

In section IV. of this proposed rule, we set forth a detailed analysis of the regulatory and Federalism impacts that the proposed GLOBE Model would have on affected entities and beneficiaries. As detailed in section II.A. of this proposed rule, this proposed rule would establish a 7-year GLOBE Model alternative payment test for certain separately payable Medicare Part B rebatable drugs furnished in the outpatient setting to Medicare FFS beneficiaries in the model cohort and that are paid under the GLOBE Model. Tables 13, 14, and 15 in section IV.D. of this proposed rule display the estimated overall impact of the proposed GLOBE Model on the Medicare and Medicaid programs.

We estimate that the GLOBE Model would result in overall savings of \$11.9 billion in Medicare Part B net spending during the 7-year model, inclusive of \$8.4 billion in Medicare Part B FFS, 7.5 billion in Medicare Advantage (MA) savings, and \$4 billion in premium offset impacts. In this estimate, we assume manufacturer behavioral changes and beneficiary utilization changes, as described in section IV. of this proposed rule. We estimate savings for the MA program of \$7.5 billion due to the way CMS calculates MA rates using Medicare FFS claims, which would include claims paid under the GLOBE Model beginning with rate setting for 2028, and savings for the Medicaid program of around \$1.0 billion, of which roughly \$0.7 billion would be federal savings and roughly \$0.3 billion would be state savings.⁴ When annualized over the 7-year period, we estimate that the GLOBE Model would result in overall cost savings in Medicare Part B FFS net spending of approximately \$2.3 billion

at both the 3 and 7 percent rates of discount.

B. Background

A 2024 report from the Office of the Assistant Secretary for Planning and Evaluation (ASPE) revealed that U.S. prices for U.S. originator drugs were 422 percent higher than other countries.^{5 6} A number of studies have also demonstrated observable differences in pricing dynamics of single source⁷ versus multi-source,⁸ where multi-source drugs and biological products typically have higher price concessions and manufacturer discounts than single source drugs and sole source^{9 10 11} biologics.

Recent CMS analysis of claims data for 2024 shows that total Medicare spending is at \$70.71 billion, with more than two-thirds (\$46.38 billion) of this spend being attributed to Medicare Part B rebatable drugs. Research has shown Medicare Part B drug spending is also concentrated among a small number of drugs. In 2021, the top 20 drugs accounted for over half of total Medicare Part B FFS drug spending, with the top

⁵ This study reports unadjusted ratios, meaning they have not been adjusted to account for GDP per capita. Available at: <https://aspe.hhs.gov/sites/default/files/documents/f96a072f8f32f3ba546abd52bfcae57/aspe-cover-idr-pricing-availability.pdf>.

⁶ U.S. originator drugs are the original biological products and drugs developed and licensed or approved via section 351(a) of the Public Health Services Act or submitted under section 505(b) and approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). U.S. originator drugs are also sometimes called brand name drugs, reference listed drug, or reference products.

⁷ Single source drugs and biological products in this sentence refers to drugs without generic competition (drugs approved under section 505(j) of the FD&C Act) and biological products without biosimilar competition (biological products licensed under 351(k) of the Public Health Service Act).

⁸ Multi-source refers to drugs and biological product with generic (drug approved under section 505(j) of the FD&C Act) or biosimilar competition (biological products licensed under 351(k) of the Public Health Service Act).

⁹ Jofre-Bonet, Mireia, et al. "The Price Effects of Biosimilars in the United States." *Value in health: the journal of the International Society for Pharmacoeconomics and Outcomes Research* vol. 28,5 (2025): 742–750. doi: 10.1016/j.jval.2025.02.008.

¹⁰ Changes in the List Prices of Prescription Drugs, 2017 to 2023, Office of the Assistant Secretary for Planning and Evaluation (October 6, 2023). Available at: <https://aspe.hhs.gov/sites/default/files/documents/e24f630a33f0a0585337c65745904487/aspe-drug-price-tracking-brief.pdf>.

¹¹ San-Juan-Rodriguez, A, et al. Trends in List Prices, Net Prices, and Discounts for Originator Biologics Facing Biosimilar Competition. *JAMA Netw Open*. 2019;2(12): e1917379. doi:10.1001/jamanetworkopen.2019.17379.

10 representing 40 percent.¹² Notably, all 20 drugs were biological products.

To discourage drug manufacturers from increasing drug prices faster than the rate of inflation and to improve access to affordable treatments for Medicare beneficiaries, the Inflation Reduction Act of 2022 created the Medicare Part B Drug Inflation Rebate Program. If drug manufacturers raise prices for certain drugs faster than the rate of inflation for a calendar quarter beginning with the first quarter of 2023, manufacturers must pay a rebate to the Medicare Part B account in the Federal Supplementary Medical Insurance Trust Fund and Medicare lowers beneficiary coinsurance amounts for applicable drugs accordingly.

Medicare Part B FFS drug spending¹³ has grown by 85.8 percent (\$18.7 billion)¹⁴ from 2014 to 2021 with the standard monthly Medicare Part B premium for beneficiaries increasing by 41.5 percent (\$104.90¹⁵ to \$148.50¹⁶). Based on the increasing Medicare Part B FFS and beneficiary drug spending, we propose to test a model that reduces Medicare Part B FFS drug spending and beneficiary coinsurance amounts using international drug pricing information as a benchmark to test an alternative Part B inflation rebate amount calculation for certain single source drugs and sole source biological products that would reduce Medicare program expenditures while preserving or enhancing quality of care.

The pace of growth in drug prices varies across disease categories. A report by the Healthcare Distribution Alliance (HDA) Research Foundation, showed that drugs classified in immunology, oncology, rheumatology, endocrinology and ophthalmology are among the top 20 therapeutic classes based on spending or prescriptions volume in the United States and that most of these categories have shown notable growth

¹² Medicare Part B Drug Pricing, Office of the Assistant Secretary for Planning and Evaluation (June 9, 2023).

Available at: <https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf>.

¹³ Measured by drug allowed charges.

¹⁴ Medicare Part B Drug Pricing, Office of the Assistant Secretary for Planning and Evaluation (June 9, 2023).

Available at: <https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf>.

¹⁵ CMS announces major savings for Medicare beneficiaries. Available at: <https://www.cms.gov/newsroom/press-releases/cms-announces-major-savings-medicare-beneficiaries>.

¹⁶ 2021 Medicare Parts A & B Premiums and Deductibles. Available at: <https://www.cms.gov/newsroom/fact-sheets/2021-medicare-parts-b-premiums-and-deductibles>.

⁴ Note: Totals do not add up due to rounding. See section IV. of this proposed rule for the Regulatory Impact Analysis.

between 2023 and 2024.¹⁷ This trend is also observed in Medicare Part B FFS drugs, where these five therapeutic classes represent at least \$24 billion in Medicare Part B FFS allowed charges in 2024.^{18 19 20}

Increasingly high drug costs limit access to care and treatment which in turn results in complications that can lead to worse health outcomes and premature death. This results in increased medical spending to treat patients' conditions and potentially avoidable expenditures for all payers, including CMS.²¹ Results from recent surveys revealed that many Americans, including Medicare beneficiaries, face significant financial burden of care that results in skipping or rationing medication due to cost.²² A survey conducted in June 2025 showed that one quarter of adults reported not filling their prescription in 2024 because of cost; among those who had taken a prescription, one in three stated they did not fill at least one prescription because of the cost.²³ Financial toxicity, or the negative impact that the monetary burden of medical care can have on patients' well-being, fiscal security, and overall health,²⁴ can be most pronounced among the elderly population and among patients where the cost of treatment is high and with low income. One in four adults taking

prescriptions report difficulty affording their medication, including 40 percent of those with household income of less than \$40,000 per year.²⁵ A separate survey conducted concluded that about 4 in 10 older adults with Medicare reported problems accessing healthcare because of its costs, and that 14 percent of Medicare beneficiaries stated they skipped taking or sometimes did not even fill their prescription because of the expense.²⁶ Studies show that Medicare patients with cancer and certain chronic conditions are more likely to report cost-related medication non-adherence (that is, not taking medications as prescribed or indicated by a physician due to cost).^{27 28 29}

Studies have also shown that the impacts on access to care due to costs can be significant. A literature review concluded that annual costs of medication non-adherence are up to \$290 billion, that 10 percent of hospitalizations in adults are attributed to medication non-adherence, with the typical non-adherent patient requiring three extra visits per year leading to \$2,000 in increased treatment costs per year.³⁰ This paper also found that cancer patients experience more than double the cost variation compared to other disease groups. Further, a 2020 report estimated that up to 112,000 seniors could die prematurely because drug prices are so high that they cannot afford their medication, and that Medicare could be spending \$17.7 billion annually on avoidable medical spending because of complications

associated with cost-related medication non-adherence.³¹

1. Medicare Part B Drug Benefit

a. Medicare Payment for Separately Payable Under Medicare Part B Drugs

The majority of drugs covered under Medicare Part B generally fall into three categories: drugs furnished incident to a physician's service which are not usually self-administered by the patient (section 1861(s)(2)(A) and (B) of the Act), drugs administered via a covered item of durable medical equipment (DME) (section 1861(s)(6) of the Act), and drugs specified by statute (for example, vaccines (section 1861(s)(10)(A) and (B) of the Act), oral cancer drugs (section 1861(s)(2)(Q) of the Act), oral antiemetics (section 1861(s)(2)(T) of the Act), and immunosuppressive therapy (section 1861(s)(2)(J) of the Act)).

Many drugs payable under Medicare Part B are administered via injection or infusion in a physician office, a Hospital Outpatient Department (HOPD), and certain other outpatient settings, such as ambulatory surgery centers (ASCs), and, when Medicare allows separate payment for these drugs, the payment limit is typically based on the methodology described in section 1847A of the Act. Payment for these drugs does not include payment for administration; payment for drug administration services is made in accordance with the applicable payment policy for the setting in which the drug was furnished, such as the Physician Fee Schedule (PFS), the Hospital Outpatient Prospective Payment System (OPPS), or the Ambulatory Surgical Center Payment System. Medicare Part B also allows separate payment for drugs in less common situations such as osteoporosis drugs furnished by a home health agency, and when a beneficiary does not have benefits available under the Medicare Part A program.

The payment methodology described in section 1847A of the Act is generally based on the volume-weighted average sales price (ASP) for all National Drug Codes (NDCs) that are assigned to a Healthcare Common Procedure Coding System (HCPCS) Level II code for the drug plus an add-on percentage. For most HCPCS Level II codes, the add-on percentage is 6 percent except during the initial sales period when ASP is not yet available, for certain qualifying

¹⁷ HDA Research Foundation. HDA 96th Edition HDA Factbook. The Facts, Figures, and Trends in Healthcare (2025–2026). Available at: <https://www.hda.org/publications/>.

¹⁸ CMS. Medicare Utilization for Medicare Part B FFS. Available at: <https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-fee-for-service-parts-a-b/medicare-utilization-part-b>.

¹⁹ Dickson, S.R., and James, K.E. Treatments Associated with Manufacturer Payments to Ophthalmologists. *JAMA Health Forum*, 2023, 4 (9): e232951. doi:10.1001/jamahealthforum.2023.2951.

²⁰ Desai S., Sekimitsu, S., Rossin, E.J., Zebardast, N. Trends in Anti-Vascular Endothelial Growth Factor Original Medicare Part B Claims in the United States, 2014–2019. *Ophthalmic Epidemiology*, 2024, 31(5): 468–477. doi: 10.1080/09286586.2024.2310854.

²¹ Nekui F., Galbraith A.A., Briesacher B.A., Zhang F., Soumerai S.B., Ross-Degnan D., Gurwitz J.H., Madden J.M. *Cost-related Medication Nonadherence and Its Risk Factors Among Medicare Beneficiaries*. Medical Care. 2021;59(1):13–21. <https://doi.org/10.1097/MLR.0000000000001458>.

²² Arnold Ventures, Commonwealth Fund, and PerryUndem. Drug Costs and Their Impact on Care. February 10, 2025. Available at: <https://www.arnoldventures.org/stories/drug-costs-and-their-impact-on-care>.

²³ Center for Opinion Research and I–MAK Survey. Understanding Americans' Top Concerns on Drug Pricing: Corporate Greed and Patent Reform. Available at: <https://www.i-mak.org/survey/>.

²⁴ Ehsan AN, Wu CA, Minasian A, et al. Financial Toxicity Among Patients With Breast Cancer Worldwide: A Systematic Review and Meta-analysis. *JAMA Netw Open*. 2023;6(2):e2255388. doi:10.1001/jamanetworkopen.2022.55388.

²⁵ Sparks, G., Kirzinger, A., Montero, A., et al. Public Opinion on Prescription Drugs and Their Prices. KFF Poll Finding, October 4, 2024. Available at: <https://www.kff.org/health-costs/public-opinion-on-prescription-drugs-and-their-prices/>.

²⁶ The Commonwealth Fund. Medicare's Affordability Problem: A Look at the Cost Burdens Faced by Older Enrollees. Issue Briefs, September 19, 2023. Available at: <https://www.commonwealthfund.org/publications/issue-briefs/2023/sep/medicare-affordability-problem-cost-burdens-biennial>.

²⁷ Zhang, J.X., and Meltzer, D.O. Prevalence and Persistence of Cost-related Medication Non-Adherence Before and During the COVID–19 Pandemic Among Medicare Patients at High Risk of Hospitalization. *PLoS One*, 2023, 18(8): e0289608. doi: 10.1371/journal.pone.0289608.

²⁸ Zhang, J.X., and Meltzer, D.O. Longitudinal Progression of Cost-related Medication Non-Adherence Among Medicare Patients with Diabetes at High Risk of Hospitalization: The Role of Dual Eligibility. *PLoS One*, 2025, 20(8): e0329031. doi: 10.1371/journal.pone.0329031.

²⁹ Cutler, R.L., Fernandez-Llimos, F., Frommer, M., Benrimoj, C., et al. Economic Impact of Medication Non-adherence by Disease Groups: A Systematic Review. *BMJ Open*, 2018, 8(1): e016982. DOI: 10.1136/bmjopen-2017–016982.

³⁰ Cutler, R.L., Fernandez-Llimos, F., Frommer, M., Benrimoj, C., et al. Economic Impact of Medication Non-adherence by Disease Groups: A Systematic Review. *BMJ Open*, 2018, 8(1): e016982. DOI: 10.1136/bmjopen-2017–016982.

³¹ Xcenda. Modeling the Population Outcomes of Cost-Related Non-adherence: Model Report. September 21, 2020. Available at: https://global-uploads.webflow.com/5e5972d438ab930a0612707f/5fa9bf4419f4da03a7daf190_WHPC-Xcenda_NonAdherence%20Population%20Model_Report_22Oct2020r.pdf.

biosimilar biological products, and in certain circumstances specified within section 1847A(d)(3)(C) of the Act. When ASP is not yet available and the wholesale acquisition cost (WAC) is used, the add-on is 3 percent. Section 11403 of the Inflation Reduction Act of 2022 requires a temporary, 5-year increase for qualifying biosimilar biological products (as defined in section 1847A(b)(8)(iii) of the Act) that have an ASP less than the ASP of the reference biological product. In these cases, the add-on is 8 percent of the reference biological product's ASP. Following the applicable five-year period (as described in section 1847A(b)(8)(ii) of the Act) for these qualifying biosimilar biological products, the add-on percentage reverts back to 6 percent of the reference biological product's ASP.

The volume-weighted ASP for a HCPCS Level II code is calculated by CMS quarterly using manufacturer-submitted data on sales to all purchasers (with limited exceptions as articulated in section 1847A(c)(2) of the Act,³² such as sales at nominal charge and sales exempt from Medicaid best price)³³ with manufacturer rebates, discounts, and price concessions included in the ASP calculation (that is, the sales price is net of these rebates, discounts, and price concessions). The ASP-based payment limit that Medicare pays for a separately payable Medicare Part B FFS drug claim does not vary based on the exact price an individual provider or supplier pays to acquire the drug. This payment methodology may create an incentive for the use of more expensive drugs. Although the statute does not specifically state what the add-on represents, as noted in the MedPAC report,³⁴ it may be needed to account for handling and overhead costs and additional mark-up in U.S. distribution channels that are not captured in the manufacturer-reported ASP.

Currently, under Medicare Part B, beneficiary cost-sharing³⁵ is generally 20 percent of the Medicare-allowed amount. The term "Medicare-allowed amount" means the maximum amount that a provider or supplier would be paid for a covered health care service or drug. However, for items and services paid under the OPPTS, beneficiaries are

only financially responsible for a copayment amount up to the amount of the inpatient hospital deductible.³⁶ Medicare pays for the remaining portion of the Medicare allowed amount.³⁷

b. Medicare Part B Drug Inflation Rebate Program

Section 11101 of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, enacted August 16, 2022) established requirements under which drug manufacturers must pay Part B inflation rebate amounts if they raise their prices for certain drugs payable under Medicare Part B faster than the rate of inflation. Specifically, section 11101 of the IRA amended section 1847A of the Act by adding new subsection (i) which establishes a requirement for drug manufacturers to pay rebates into the Medicare Part B account in the Federal Supplementary Medical Insurance Trust Fund for Part B rebatable drugs for each calendar quarter beginning on or after January 1, 2023, if the amount specified, as determined under section 1847A(i)(3)(A)(ii) of the Act exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. The IRA also provides for an adjustment to the beneficiary coinsurance amount in cases where the price of a Part B rebatable drug increases faster than the rate of inflation such that the beneficiary coinsurance is calculated based on the lower inflation-adjusted payment amount instead of the applicable payment amount, resulting in a coinsurance percentage that is equal to 20 percent of the inflation-adjusted payment amount as described in section 1847A(i)(3)(C) of the Act for a calendar quarter. Section 1847A(i)(2) of the Act defines a "Part B rebatable drug," in part, as a single source drug or biological product (as defined in section 1847A(c)(6)(D) of the Act), including a biosimilar biological product (as defined in section 1847A(c)(6)(H) of the Act), for which payment is made under Medicare Part B. Certain product categories are excluded from the definition of a Part B rebatable drug pursuant to 42 CFR 427.101(b). Currently excluded product categories include: (1) qualifying

biosimilar biological products;³⁸ (2) products with historically excepted grouped billing and payment codes; (3) products billed under a "not otherwise classified" (NOC) code; (4) radiopharmaceutical drugs and biological products; (5) skin substitutes; (6) drugs with average total allowed charges under the applicable threshold; (7) certain vaccines and other products;³⁹ and (8) generic drugs.⁴⁰ The applicable threshold specified in section 1847A(i)(2) of the Act was equal to \$100 for applicable calendar quarters in 2023. Thereafter, CMS calculates the applicable threshold as equal to the unrounded applicable threshold calculated for the prior calendar year increased by the percentage increase in the consumer price index for all urban customers (CPI-U) for the 12-month period ending with June of the previous year, rounded to the nearest multiple of \$10.⁴¹

For each calendar quarter beginning on or after January 1, 2023, the manufacturer of a Part B rebatable drug is required, for such drug, not later than 30 days after date of receipt (as defined in 42 CFR 427.505) of the Rebate Report from CMS, to pay a rebate into the Medicare Part B account in the Federal Supplementary Medical Insurance Trust Fund if the amount specified in section 1847A(i)(3)(A)(ii) of the Act exceeds the inflation-adjusted payment amount (calculated as set forth in section 1847A(i)(3)(C) of the Act) for an applicable calendar quarter. With respect to invoicing manufacturers for the rebate amount owed, under section 1847A(i)(1) of the Act, CMS must report rebate amounts to each manufacturer of a Part B rebatable drug no later than 6 months after the end of each calendar quarter, except that for calendar quarters beginning in 2023 and 2024, CMS had until September 30, 2025, to invoice manufacturers for rebates. In the CY 2025 Physician Fee Schedule (PFS) final

³⁸ Qualifying biosimilar biological products are defined under section 1847A(b)(8)(B)(iii) of the Act and, during the applicable 5-year period, must have an ASP that is not more than the ASP of the reference biological product for a calendar quarter to qualify for an add-on amount equal to 8 percent of the payment amount calculated under section 1847A(b)(4) of the Act for the reference biological product.

³⁹ This includes influenza, pneumococcal, hepatitis B, and COVID-19 vaccines, and monoclonal antibodies used for treatment or post-exposure prophylaxis of COVID-19.

⁴⁰ Part B drugs submitted in an Abbreviated New Drug Application (ANDA) and approved under section 505(j) of the FD&C Act.

⁴¹ 42 CFR 427 Subpart B, Electronic Code of Federal Regulations. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-427>. For applicable calendar quarters during 2023, the applicable threshold was \$100.

³² OMB Control Number 0938–0921, Centers for Medicare & Medicaid Services.

³³ Best price is defined in section 1927(c)(1)(C) of the Act.

³⁴ MedPAC, June 2017, "Medicare Part B Drug Payment Policy Issues," accessed via https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun17_ch2.pdf.

³⁵ Not including the annual deductible.

³⁶ Section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year. This limit is \$1,676 in 2025.

³⁷ Centers for Medicare & Medicaid Services. Outpatient Services Payment for People with Medicare Part B, Revised May 2021. Available at: <https://www.medicare.gov/publications/02118-Part-B-Outpatient-Services-Payment.pdf>.

rule (89 FR 98228 through 98313)⁴² to implement section 11101 of the IRA, CMS codified these requirements and established other policies at 42 CFR part 427. In the CY 2026 PFS final rule (90 FR 49733 through 49739),⁴³ CMS adopted certain limited modifications to the policies for the Medicare Prescription Drug Inflation Rebate Program set forth in part 427 under title 42, chapter IV of the Code of Federal Regulations (CFR) for Part B. For example, at 42 CFR 427.302(c)(5) described how CMS identifies the payment amount benchmark quarter in certain instances and the calculation for the Part B rebate amount in such instances.

c. Medicare Drug Price Negotiation Program

Sections 11001 and 11002 of IRA establish the Medicare Drug Price Negotiation Program (hereinafter the “Negotiation Program”) to negotiate maximum fair prices (MFPs)⁴⁴ for certain high expenditure, single source drugs and biological products. The requirements for this program are described in sections 1191 through 1198 of the Act, as added by sections 11001 and 11002 of the IRA. Additionally, on July 4, 2025, the Working Families Tax Cuts Act (Pub. L. 119–21) was signed into law. Section 71203 of the Working Families Tax Cuts Act expanded protections for certain orphan drugs in section 1192(e) of the Act. Drugs payable under Medicare Part B are eligible to be selected for negotiation for initial price applicability year 2028.

2. Medicare and Beneficiary Spending

a. Historical Trending

An Issue Brief from ASPE evaluated Medicare Part B total spending and fee-for-service (FFS) drug allowed charges from 2014 to 2021.⁴⁵ Medicare Part B

total spending increased from \$265.9 billion in 2014 to \$405.5 billion in 2021, representing an increase of \$139.6 billion. Medicare Part B FFS drug allowed charges increased from \$21.8 billion in 2014 to \$40.5 billion in 2021, an increase of \$16.4 billion. While total spending and drug allowed charges have both increased significantly, Medicare Part B FFS drug allowed charges have seen higher spending growth. In 2014, Medicare Part B FFS drug allowed charges represented about 12.1 percent of Medicare Part B FFS spending but grew to approximately 20 percent in 2021.⁴⁶

The same report also found that between 2014 and 2021, Medicare Part B FFS drug spending per enrollee grew on “average at 9.2 percent annually” more than three times the rate of Medicare Part D (2.6 percent) and nearly four times as high as the rate of per capita annual prescription drug spending (2.4 percent). Medicare Part B FFS drug spending was also concentrated among a few drugs where the top 20 drugs accounted for greater than 50 percent of drug spending in 2021 and the top 10 drugs accounted for 40 percent of drug spending in the same period. When comparing biological products to non-biologicals, biological products accounted for 89 percent of the Medicare Part B FFS drug spending growth between 2008 and 2021 and 79 percent of Medicare Part B FFS drug spending in 2021. When reviewing Medicare Part B FFS spending on multi-source drugs and biological products in 2021, generic drugs⁴⁷ accounted for only 2 percent of spending and only 3 of the top 20 drugs by spend⁴⁸ (all biological products) were multi-source. Therefore, the majority of Medicare Part B FFS drug expenditures in 2021 were attributable to single source drugs and sole source biological products.

An ASPE report evaluating Medicare Part B FFS spending from 2018 to 2023 estimated biosimilar biological product

competition (multi-source biological products) reduced spending by \$12.9 billion, a 31 percent decrease compared to projected spending if only the reference biological product existed.⁴⁹ Savings after biosimilar biological product competition entered the market were driven by a mix of beneficiary switches to a lower-priced biosimilar biological product and price reductions in the reference biological products.

It is also important to note that the number of enrollees for Medicare Part B FFS has decreased (8.8 percent) between 2016 to 2021 (34 million to 31 million),⁵⁰ while Medicare Part B FFS drug allowed charges has increased (47 percent) for the same time period.⁵¹ Therefore, this increase in Medicare Part B FFS spending for drugs during this period is likely explained more by increases in the prices of drugs, introduction of new drugs,⁵² changes in utilization of drugs, and changes in the mix of drugs for those beneficiaries who received them more so than the changes in Medicare Part B enrollment.⁵³

b. Impact on Premiums, Beneficiaries, and Taxpayers

Medicare Part B is funded by premiums paid by beneficiaries and general federal revenues. Total Medicare Part B Premium amounts increased from \$74 billion in 2016 to \$113 billion in 2021, representing an increase of \$39

⁴⁹ Medicare Part B Enrollee Use and Spending on Biosimilars, 2018–2023, Office of the Assistant Secretary for Planning and Evaluation (January 2025). Available at: <https://aspe.hhs.gov/sites/default/files/documents/be065dbbd1f866c65cf627995bd2ea56/biosimilars-medicare-part-b.pdf>.

⁵⁰ Medicare Part B FFS enrollment derived from Table V.B3 of the 2023 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Trust Funds. Available at: <https://www.cms.gov/oact/tr/2023>.

⁵¹ Medicare Part B Drug Pricing, Office of the Assistant Secretary for Planning and Evaluation (June 9, 2023). Exhibit 3: Part B FFS drugs’ share of Part B FFS spending, 2014 to 2021. Available at: <https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf>.

⁵² Hyland MF, Sachs RM, Robillard L., Hayford TB, Bai G. Spending on and Use of Clinician-Administered Drugs in Medicare. JAMA Health Forum. September 8, 2023. Available at: <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2809283>.

⁵³ The average annual growth in number of Medicare Part B FFS beneficiaries was less than 2.5 percent from 2014 to 2021, so the change in Medicare Part B beneficiaries does not fully account for the average annual growth in Medicare Part B drug spending (9.2 percent annual growth). Instead, the increase during this period is more fully explained by increases in the prices of drugs, introduction of new drugs, changes in drug utilization, and changes in the mix of drugs than by increases in Medicare enrollment.

⁴² “Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments,” 89 FR 98228–98313 (December 9, 2024).

⁴³ “Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program,” 90 FR 49266–50481 (November 5, 2025).

⁴⁴ In accordance with section 1191(c)(3) of the Act, MFP means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1192(c) of the Act) with respect to such period, the price negotiated pursuant to section 1194 of the Act, and updated pursuant to section 1195(b) of the Act, as applicable, for such drug and year.

⁴⁵ Medicare Part B Drug Pricing, Office of the Assistant Secretary for Planning and Evaluation

(June 9, 2023). Available at: <https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf>.

⁴⁶ Medicare Part B Drug Pricing, Office of the Assistant Secretary for Planning and Evaluation (June 9, 2023). Exhibit 3: Part B FFS drugs’ share of Part B FFS spending, 2014 to 2021 from <https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf>.

⁴⁷ Generic drugs are submitted in an Abbreviated New Drug Application (ANDA) and approved under section 505(j) of the FD&C Act. For Medicare Part B FFS, generic drugs share the same HCPCS Level II code as the originator drug.

⁴⁸ The three multi-source biological products in the top 20 Part B drugs by total Medicare Payments were Rituxan (rituximab), Remicade (infliximab), and Neulasta (pegfilgrastim).

billion.⁵⁴ While this increase in total Medicare Part B premiums is partially attributable to the increase in beneficiaries from 52 million to 58 million,⁵⁵ there was also a rise in premium amount per enrollee from \$1,423 in 2016 to \$1,942 in 2021. A research study found the 2024 Medicare Part B premiums accounted for more than 10 percent of annual per capita income for 12 percent of Medicare Part B beneficiaries—approximately 7.4 million of the 61 million Medicare Part B beneficiaries.⁵⁶ The rise in premiums is partly due to projected costs for new drugs, price changes for health care services, new technologies, and assumed utilization increases.^{57 58 59}

In addition to a monthly premium, Medicare Part B FFS beneficiaries typically need to cover 20 percent of the cost of a Medicare Part B drug once their Medicare Part B deductible is met. Medicare Part B FFS does not have an out-of-pocket maximum, whereas other forms of coverage such as MA plans and Medigap policies may have a maximum. While the IRA has reduced beneficiary coinsurance for certain Medicare Part B drugs whose prices have risen faster than inflation, beneficiaries may continue to experience significant cost sharing as overall Medicare Part B FFS spending has increased. As previously discussed, this increase is likely driven

by high overall prices and the introduction of new drugs.^{60 61}

Further, as discussed earlier in this section, increasing high drug costs limit access to care and treatment which in turn results in complications that can lead to worse health outcomes and increased medical spending. For example, though not specific to Medicare Part B, the national healthcare expenditure (NHE) out-of-pocket (OOP) spending increased by 25.5 percent (\$102.7 billion) between 2019 to 2023.⁶² High OOP costs have been shown to reduce medication adherence. A study on specialty drugs found that 30 percent of new cancer drug prescriptions went unfilled among patients without low-income subsidies, while another showed that 7 percent of adults 65 and older skipped or did not take their medications as prescribed because of cost.^{63 64} Research has also found multiple indications of worse health status were associated with a higher likelihood of cost-related nonadherence to medications.⁶⁵

The second source for Medicare Part B funding comes from general federal revenues, which taxpayers primarily finance. General revenues fund approximately 75 percent of Medicare Part B expenditures, with beneficiary premiums accounting for the remaining 25 percent of projected expenditures.⁶⁶

⁶⁰ Hyland MF, et al. Spending on and Use of Clinician-Administered Drugs in Medicare. JAMA Health Forum. 2023;4(9):e232941. doi:10.1001/jamahealthforum.2023.2941.

⁶¹ Changes in the List Prices of Prescription Drugs, 2017 to 2023, Office of the Assistant Secretary for Planning and Evaluation (October 6, 2023). Available at: <https://aspe.hhs.gov/sites/default/files/documents/e24f630a33f0a0585337c65745904487/aspe-drug-price-tracking-brief.pdf>.

⁶² The 25.5 percent and \$102.7 billion was calculated using NHE Table 3: National Health Expenditures, by Source of Funds for out of pockets costs for years 2019 and 2023. Available at: <https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet>.

⁶³ Dusetzina SB, Huskamp HA, Rothman RL, Pinheiro LC, Roberts AW, Shah ND, Walunas TL, Wood WA, Zuckerman AD, Zullig LL, Keating NL. Many Medicare Beneficiaries Do Not Fill High-Price Specialty Drug Prescriptions. Health Affairs (December 2021). <https://doi.org/10.1377/hlthaff.2021.01742>.

⁶⁴ Anderer S. High Drug Costs Influence Nonadherence to Medications Among Older Adults. JAMA. Published online October 4, 2024; 332(16):1323. <https://doi.org/10.1001/jama.2024.19690>.

⁶⁵ Nekui F, Galbraith AA, Briesacher BA, Zhang F, Soumerai SB, Ross-Degnan D, Gurwitz JH, Madden JM. Cost-related Medication Nonadherence and Its Risk Factors Among Medicare Beneficiaries. Medical Care. 2021;59(1):13–21. <https://doi.org/10.1097/MLR.0000000000001458>.

⁶⁶ U.S. Government Accountability Office. Federal Trust Funds and Other Dedicated Funds: Fiscal Sustainability Is a Growing Concern for Some Key Funds. GAO–20–156. Washington, DC: GAO,

Historical trend analysis on Medicare Part B spending has shown an increase in annual federal revenue contribution from \$235.6 billion in 2016 to \$386.0 billion in 2024, illustrating the growth in general federal revenues in Medicare Part B financing.⁶⁷

c. Relative High Price of Medicare Part B Drugs

Research from ASPE and RAND provides comparative data on U.S. prescription drug prices relative to 32 other Organisation for Economic Co-operation and Development (OECD) countries.⁶⁸ These studies examine pricing patterns of prescription drugs and present findings on how U.S. prescription drug costs compare to international benchmarks. OECD countries are generally developed, high-income nations, making them suitable comparators for evaluating drug prices.

ASPE funded research published in July 2022 indicated that U.S. prescription drugs prices exceeded those of non-U.S. OECD countries combined by 256 percent⁶⁹ using 2018 data.⁷⁰ In 2024, the study was updated with pricing information from 2022 and showed an even larger gap of 278 percent compared to non-U.S. OECD countries combined.⁷¹ When comparing the U.S. against individual G7 countries,⁷² the price differential ranged from 229 percent higher than Canada to 347 percent higher than Japan.

This analysis reveals even larger pricing differences when examining

January 2020. Available at: <https://www.gao.gov/assets/gao-20-156.pdf>.

⁶⁷ 2025 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. Centers for Medicare & Medicaid Services, Office of the Actuary. June 2025. Available at: <https://www.cms.gov/oact/tr/2025>.

⁶⁸ The 32 countries compared to were Australia, Austria, Belgium, Canada, Chile, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Mexico, Netherlands, New Zealand, Norway, Poland, Portugal, Slovakia, Slovenia, South Korea, Spain, Sweden, Switzerland, Turkey, and United Kingdom.

⁶⁹ Authors calculated price indexes using U.S. volume weights to account for differences in volume and mix of drugs across countries.

⁷⁰ Ratios from this study are not adjusted for differences in purchasing power-adjusted GDP per capita. See Andrew W. Mulcahy, Christopher M. Whaley, Mahlet Gizaw, Daniel Schwam, Nathaniel Edenfield, and Alejandro Uriel Becerra-Ornelas, *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies*, RAND Corporation, RR–2956–ASPEC, 2021. Available at: https://www.rand.org/pubs/research_reports/RR2956.html.

⁷¹ Ratios from this study are not adjusted for differences in purchasing power-adjusted GDP per capita. Available at: <https://pmc.ncbi.nlm.nih.gov/articles/PMC11147645/>.

⁷² The G7 countries are Canada, France, Germany, Italy, Japan the United Kingdom, and the U.S.

⁵⁴ CMS Program Statistics—Medicare Premiums, Centers for Medicare & Medicaid Services. Medicare Part B Premiums are from Table, MDCR Premiums 4. Available at: <https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-premium-reports/cms-program-statistics-medicare-premiums>.

⁵⁵ These enrollment numbers include total Medicare Part B beneficiaries in Medicare Part B FFS, Medicare Advantage plans, section 1876 cost plans, and section 1833 healthcare prepayment plans. Medicare Part FFS enrollment for 2016 and 2021 were 34 million and 31 million, respectively.

⁵⁶ Cottrill A, Cubanski J, Neuman T, Smith K. Seven Million People with Medicare Spend More Than 10% of Income on Part B Premiums—The Reconciliation Bill Could Drive the Number Higher. Kaiser Family Foundation (June 23, 2025). Available at: <https://www.kff.org/medicare/issue-brief/seven-million-people-with-medicare-spend-more-than-10-of-income-on-part-b-premiums-the-reconciliation-bill-could-drive-the-number-higher/>.

⁵⁷ 2025 Medicare Parts A & B Premiums and Deductibles, Centers for Medicare & Medicaid Services (November 8, 2024). Available at: <https://www.cms.gov/newsroom/fact-sheets/2025-medicare-parts-b-premiums-and-deductibles>.

⁵⁸ Neuman T, Cubanski J, Freed M. Monthly Part B Premiums and Annual Percentage Increases. Kaiser Family Foundation (January 12, 2022). Available at: <https://www.kff.org/medicare/slide-monthly-part-b-premiums-and-annual-percentage-increases/>.

⁵⁹ Congressional Research Service. Medicare: Part B Premiums. CRS Report R40082. Washington, DC: Library of Congress, 2021. Available at: https://www.congress.gov/crs_external_products/R/PDF/R40082/R40082.48.pdf.

originator drugs separately. U.S. originator drug prices are 422 percent higher than non-U.S. OECD countries combined. Among individual G7 countries, the difference between U.S. and the international prices ranged from 324 percent higher than Canada to 464 percent higher than Japan. These data points indicate there are significant cost differences within the global pharmaceutical market for U.S. originator drugs and international originator drugs.⁷³

In contrast, the unbranded generic drug market, not including biologics such as biosimilar biological products, shows different pricing dynamics. The same study showed U.S. unbranded generic pricing was 67 percent of the average price among non-U.S. OECD countries. The comparison of U.S. prices to individual G7 countries for unbranded generic drugs shows pricing that is 39 percent lower than Canada and 46 percent lower than Germany. This indicates that pricing patterns vary significantly between originator drugs and generic drugs in the U.S. market.

A separate ASPE analysis examined Medicare Part B drugs. The study evaluated drug prices for the top 50 Part B drugs against non-U.S. OECD countries using 2018 drug spending data.⁷⁴ Although this report included only 50 drugs, those drugs accounted for 80 percent of the total 2018 Medicare Part B drug spending. The analysis found that U.S. prices were 211 percent higher than other OECD countries on average.⁷⁵ In G7 country comparisons,

the difference between the U.S. and individual countries for U.S. originators and international originators drugs ranged from 148 percent higher than Japan to 225 percent higher than France.⁷⁶

The research findings indicate that U.S. prices used to calculate ASP rates for Medicare Part B FFS payment limits are different from prices in international comparator countries. This price differential has led to recurring policy discussions about potential approaches for reducing Medicare Part B drug and biological product spending by reviewing international prices. Research from the Brookings Institute indicates that many non-U.S. OECD countries use international reference pricing as a benchmark when negotiating with prescription drug manufacturers, demonstrating that this practice is established among manufacturers.⁷⁷

The data shows that U.S. prescription drug prices, particularly for U.S. originator drugs,⁷⁸ exceed those found in other OECD countries. In addition, prior studies on generic drug pricing in the U.S. have shown that generic drug prices generally compare to or fall below international comparisons; suggesting that high overall drug costs are primarily driven by originator, single source drugs or sole source biological products. Based on the high spending by Medicare Part FFS and Medicare Part B beneficiaries on single source drugs and sole source biological products, in this proposed rule, we propose the GLOBE Model to test the impact of using international drug pricing information as a benchmark for an alternative Part B inflation rebate amount calculation for a subset of Medicare Part B rebatable drugs (certain single source drugs and sole source biological products) on Medicare

program expenditures and quality of care.

II. Provisions of the Proposed Regulations

In this proposed rule, we propose our policies for the GLOBE Model, including the general framework for implementing and evaluating the GLOBE Model and model-specific parameters, requirements, and definitions. We note that section 1115A(b) of the Act gives the Secretary discretion in the design of models. In accordance with section 1115A(a)(3) of the Act, through this proposed rule, CMS seeks input from interested parties and welcomes comments on the proposed GLOBE Model.

The proposed model-specific parameters, requirements, and definitions are described in subsections of this section of this proposed rule and we propose to codify them at proposed 42 CFR 513. In addition, for purposes of this proposed rule and the proposed GLOBE Model, we propose that the following terms would have the same meaning as set forth for the Medicare Part B Drug Inflation Rebate Program in 42 CFR 427.20: allowed charges, applicable calendar quarter, average sales price, billing and payment code, billing unit, biosimilar biological product, final action claim, inflation-adjusted payment amount, manufacturer, National Drug Code (NDC), Not Otherwise Classified (NOC) code, Part B rebatable drug, single source drug, specified amount, and unit (with respect to a Part B rebatable drug). We propose that the following terms would have the same meaning as set forth in 42 CFR 427.400: currently in shortage, drug shortage or shortage, natural disaster, other unique or unexpected event, plasma-derived product, and severe supply chain disruption.

A. Proposed Model Test Period

In proposed 42 CFR 513.1(c), we propose that the GLOBE Model would have a 7-year test period consisting of 5 performance years, beginning October 1, 2026 and ending September 30, 2031, during which the GLOBE Model beneficiary coinsurance and adjusted payments to providers and suppliers would apply (as applicable) and monitoring activities would occur, and 7 payment years during which CMS would calculate, invoice, collect, and reconcile the GLOBE Model rebates for a performance year, unless sooner terminated in accordance with proposed 42 CFR 513.100(d)). It is necessary to include 2 payment years after the end of the final performance year to allow for

⁷³ An international originator is an original biological product or drug approved or licensed in a non-U.S. country under that non U.S. country's regulatory framework under a pathway similar to 351(k) of the PHS Act or approved under a pathway similar to section 505(c) of the FD&A Act in the U.S. Individual countries differ in the regulatory processes and standards governing approval of drugs and biologics. Use of international drug pricing information in the proposed GLOBE Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved and non-U.S.-approved products.

⁷⁴ U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. (2020). *Medicare FFS Part B and International Drug Prices: A Comparison of the Top 50 Drugs*. Available at:

https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/197401/Part-B%20Drugs-International-Issue-Brief.pdf.

⁷⁵ These unadjusted price ratios of US to non-US OECD countries are taken from Table 4, Overall Ratios Spending for Matched Part B Drugs by Country, of this report: https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/197401/Part-B%20Drugs-International-Issue-Brief.pdf. The reported price ratio were converted to a percentage. The report also adjusts for purchasing power-adjusted GDP per capita. After adjusting for purchasing power-adjusted GDP per capita, the adjusted US to non-US OECD country price ratio decreases to 1.53 (153 percent). This price ratio is also volume weighted.

⁷⁶ These unadjusted price ratios of US to non-US OECD countries are taken from Table 4, Overall Ratios Spending for Matched Part B Drugs by Country, of this report: https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/197401/Part-B%20Drugs-International-Issue-Brief.pdf. The reported price ratios were converted to a percentage. The report also adjusts for purchasing power-adjusted GDP per capita. The adjusted price ratio changes to 1.06 (106 percent) for Japan and 1.66 (166 percent) for France. These price ratios are also volume weighted.

⁷⁷ Young, C.L., Frank, R.G., & Sachs, R. (2025). *International reference pricing for prescription drugs*. Brookings Institution. Available at: <https://www.brookings.edu/articles/international-reference-pricing-for-prescription-drugs/>.

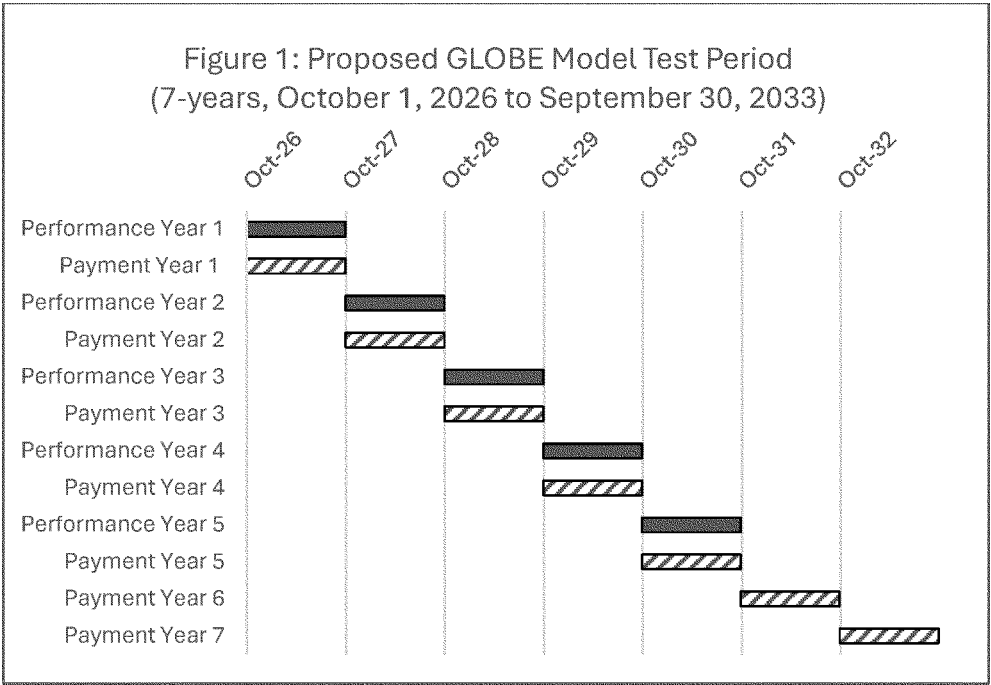
⁷⁸ U.S. originator drugs are the original biologics and drugs developed and licensed or approved via section 351(a) of the Public Health Services Act or submitted under section 505(b) and approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). U.S. originator drugs are also sometimes called brand name drugs, reference listed drug, or reference products.

rebate invoicing and reconciliation activities, as CMS delivers the information defined in 1847A(i)(1) of the Act no later than 6 months after the close of the calendar quarter, and, as codified in 42 CFR 427.501(d), CMS would perform reconciliation of the rebate amount in specified scenarios, including one regular reconciliation of the rebate amount within 12 months of the date of the receipt of the Rebate Report for each applicable calendar quarter. As such, CMS proposes a 7-year test period to include 7 payment years in order for rebate invoicing and reconciliation processes to take place for all of the applicable calendar quarters in the model performance period. The proposed model test period is illustrated in Figure 1.

In 42 CFR 513.20, we propose to define “*performance year*” (PY) as a 12-month period beginning on October 1 and ending on September 30 during the first 5 years of the GLOBE Model test period. As such, we propose to define “*GLOBE Model performance period*” as a 5-year period of time beginning on October 1, 2026, through September 30, 2031. We propose to define “*payment year*” as a 12-month period beginning on October 1 and ending on September 30 during the GLOBE Model test period. As such, we propose to define “*GLOBE Model payment period*” as the 7-year period of time beginning on October 1, 2026, through September 30, 2033. We propose to test the GLOBE Model to capture all applicable billing units (as discussed in section II.G.4. of this proposed rule) for all Medicare Part B

FFS claims for GLOBE Model drugs that are furnished to Medicare beneficiaries who are in the model cohort on the date of service during the model performance period and that are paid under the GLOBE Model. This means that, given the length of time during and after the end of an applicable calendar quarter that is necessary to conduct the proposed GLOBE Model processes for claims processing, data collection, rebate invoicing, manufacturer payment of GLOBE Model rebates, reconciliation, and model evaluation, model-related activities would continue into calendar year 2033, through September 30, 2033, as applicable, as codified in 42 CFR 513.1(c).

Figure 1: Illustration of the Proposed GLOBE Model Test Period⁷⁹



B. Proposed GLOBE Model Drugs

The proposed GLOBE Model would include, as GLOBE Model drugs, a set of Part B rebatable drugs (single source drugs and sole source biological products) that are used to treat beneficiaries with conditions where access barriers like high costs likely

contribute to deficits in care leading to poor clinical outcomes and high program expenditures which may be avoidable. Analysis of historical Medicare Part B FFS drug spending and non-U.S. OECD spending for similar drugs and biological products has highlighted U.S. originator drugs without generic⁸⁰ or biosimilar

biological product⁸¹ competition (called “*single source drug*” and “*sole source biological*” for purposes of this proposed rule and the GLOBE Model) as the main contributor to high drug spending within Medicare Part B FFS and globally.

⁷⁹ Payment Years 6 and 7 are for rebate invoicing and reconciliation for Performance Years 4 and 5.

⁸⁰ Part B drugs approved under an Abbreviated New Drug Application (ANDA) submitted under section 505(j) of the FD&C Act.

⁸¹ Biosimilar biological product is defined in section 1847A(c)(6)(H) of the Act as “biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for

another biological product licensed under section 351 of the Public Health Service Act.” See https://www.ssa.gov/OP_Home/ssact/title18/1847A.htm.

The majority of Medicare Part B FFS drug spending is also concentrated in a select number of drugs and biological products. For example, and as illustrated in Table 2, spending for the top 50 Medicare Part B FFS drugs and

biological products in 2024 was concentrated in the therapeutic areas of oncology (39 percent), immunology (19 percent), skin substitutes (13 percent), ophthalmology (12 percent), endocrinology (9 percent), and

rheumatology (5 percent). Per 42 CFR 427.101(b), skin substitutes are an excluded product category for Part B rebatable drugs.

TABLE 1: ILLUSTRATIVE PROPOSED KEY DATA TIMELINES FOR GLOBE PROVISIONS

	Reporting Window 1 Q3 2026	Reporting Window 2 Q4 2026	Reporting Window 3 Q1 2027	Reporting Window 4 Q2 2027
Applicable calendar quarter	Q4 2026	Q1 2027	Q2 2027	Q3 2027
Applicable ASP calendar quarter	Q2 2026	Q3 2026	Q4 2026	Q1 2027
Reduced coinsurance and rebate liability based on Method I or Method II benchmark effective	Q4 2026	Q1 2027	Q2 2027	Q3 2027
GLLOBE Model rebate payments associated with applicable calendar quarter due	Q3 2027	Q4 2027	Q1 2028	Q2 2028

In addition, studies have shown notable spending growth in cancer, endocrinology, immunology, rheumatology, and ophthalmology. Increased drug costs limits access to care and treatment for beneficiaries with conditions in these categories increasing their risk for deficits of care and worse health outcomes. According to an ASPE report, between 2008 and 2021, the average annual payment for Medicare Part B drugs grew by 8.8 percent.⁸² In contrast, Medicare Part B program

payments in the therapeutic areas of oncology, immunology, endocrinology, and rheumatology grew by an average of 10.8 percent annually,⁸³ suggesting that these therapeutic areas experienced faster spending growth. The same ASPE report also found that ophthalmologists⁸⁴ had the highest average annual Medicare Part B payment increase at 15 percent, 1.7 times higher than the overall average annual payment growth for all Medicare Part B drugs. These therapeutic types

and physician specialties use drugs and biological products to treat conditions related to cancer, endocrinology, immunology, rheumatology, and ophthalmology. CMS identified the categories for the top 50 Medicare Part B drugs using the standardized United States Pharmacopeia (USP) Drug Classification (DC) criteria paired with internal clinical knowledge and FDA label review. These therapeutic areas are associated with the following USP DC categories listed in Table 3.

TABLE 2. SUMMARY OF TOP 50 DRUGS AND BIOLOGICAL PRODUCTS BY SPENDING IN 2024 FOR MEDICARE PART B

Therapeutic Area	2024 Medicare Part B FFS Charges	Percent of Spend Among Top 50
Oncology	\$ 17,713,141,933	39%
Immunology	\$ 8,645,379,816	19%
Skin Substitutes	\$ 5,819,236,768	13%
Ophthalmology	\$ 5,475,187,474	12%
Endocrinology	\$ 4,152,351,517	9%
Rheumatology	\$ 2,295,127,222	5%
Skeletal Muscle Relaxants	\$ 502,254,588	1%
Diagnostic Agents	\$ 403,634,929	1%
Total	\$ 45,006,314,247	-

While higher drug costs are not the only contributor to Medicare Part B

spending growth, it may lead to increased financial burden for some

beneficiaries. Previous studies have found that high costs can increase the

⁸² Calculated from the "All" Category from Exhibit 5 of an ASPE 2023 Report (Nguyen, N., Olsen, A., Sheingold, S., and De Lew, N. Medicare Part B Drugs: Trends in Spending and Utilization, 2008–2021. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, June 2023. Available at: https://www.ncbi.nlm.nih.gov/books/NBK605978/pdf/Bookshelf_NBK605978.pdf).

⁸³ Calculated by combining therapeutic types of Cancer, Immunosuppressive, Intravenous Immunoglobulin (IVIG), Rheumatoid Arthritis, Oral Cancer, and Osteoporosis from Exhibit 5 of an ASPE 2023 Report (Nguyen, N., Olsen, A., Sheingold, S., and De Lew, N. Medicare Part B Drugs: Trends in Spending and Utilization, 2008–2021. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and

Human Services, June 2023. Available at: https://www.ncbi.nlm.nih.gov/books/NBK605978/pdf/Bookshelf_NBK605978.pdf).

⁸⁴ Ophthalmologists are more likely to have prescribed or used drugs in the ophthalmic agents category.

likelihood of nonadherence to medications leading to potentially worse health status.^{85 86 87} Thus, CMS is

proposing to scope the GLOBE Model to target potential deficits of care in

specific USP DC categories as shown in Table 3 and defined in 42 CFR 513.130.

TABLE 3: USP DC CATEGORIES AND RELATED THERAPEUTIC AREAS

USP DC Category	Associated Therapeutic Area(s)*
Antigout Agents	Rheumatology
Antineoplastics	Oncology
Blood Products and Modifiers	Immunology, Oncology
Central Nervous System Agents	Immunology
Immunological Agents	Immunology, Rheumatology, Oncology
Metabolic Bone Disease Agents	Endocrinology, Rheumatology
Ophthalmic Agents	Ophthalmology

*Note: This is not an exhaustive list of therapeutic areas that correspond to the USP DC categories but illustrates how the named USP DC categories are associated with the 5 therapeutic areas of oncology, endocrinology, immunology, rheumatology, and ophthalmology.

Previous analyses have also shown that U.S. originator drugs are, on average, about 422 percent more expensive in the U.S. than in non-U.S. OECD countries. Other studies indicate that growth in Medicare Part B drug spending has largely been driven by single source drugs and sole source biologics. As such, we propose to scope this model to focus on testing drugs and biological products where program expenditures are most likely to arise.

To meet this GLOBE Model intent, we also propose to identify the single source drugs and sole source biological products in the selected drug categories in Table 3 that would be GLOBE Model drugs for an applicable calendar quarter by applying a set of criteria (as further described in section II.B.1. of this proposed rule) in advance of the applicable calendar quarter using information available to CMS (as determined by CMS). By applying the proposed criteria to identify GLOBE Model drugs for an applicable calendar quarter, CMS would use a consistent methodology to identify a set of Part B rebatable drugs that are used to treat beneficiaries with conditions where deficits in care and high program expenditures are potentially avoidable and a representative subset of Part B rebatable drugs that account for a substantial portion of annual Medicare Part B FFS spending for Part B rebatable drugs. By excluding Part B rebatable drugs that are not sole source biological products, the GLOBE Model would also avoid including drugs with biosimilar biological product approvals in the U.S.

⁸⁵ Nekui F, Galbraith AA, Briesacher BA, Zhang F, Soumerai SB, Ross-Degnan D, Gurwitz JH, Madden JM. *Cost-related Medication Nonadherence and Its Risk Factors Among Medicare Beneficiaries*. Medical Care. 2021;59(1):13–21. <https://doi.org/10.1097/MLR.0000000000001458>.

which may be subject to unique market dynamics that would confound the model test. We note by definition that Part B rebatable drugs includes single source drugs and have chosen to reiterate the term “single source drugs” for clarity and completeness.

Using Part B rebatable drugs as the basis for identifying GLOBE Model drugs that are single source drugs and sole source biological products and meet the USP DC categories in Table 3 is necessary to allow CMS to test an alternative Part B inflation rebate amount calculation methodology. Limiting inclusion in the model test to a set of Part B rebatable drugs that meet the proposed inclusion criteria is necessary to focus the model test where model impacts related to expected high program expenditures may be observed within the study population over the course of the model evaluation (as described in section II.F. of this proposed rule). As further described in section II.B.1. of this proposed rule, CMS would identify GLOBE Model drugs and add them to the GLOBE Model Drug List that would be made available on the GLOBE Model web page at <https://www.cms.gov/priorities/innovation/innovation-models/globe>. The GLOBE Model Drug List would be maintained quarterly to add and remove drugs as appropriate in accordance with the inclusion criteria. We propose to identify a GLOBE Model drug using the same applicable billing and payment code (that is, Healthcare Common Procedure Coding System (HCPCS) Level II code) that is identified for the

⁸⁶ Arnold Ventures, Commonwealth Fund, and PerryUndem. *Drug Costs and Their Impact on Care*. February 10, 2025. Available at: <https://www.arnoldventures.org/stories/drug-costs-and-their-impact-on-care>.

Part B rebatable drug pursuant to 42 CFR 427.101(a)(1)(ii) for the Medicare Part B Drug Inflation Rebate Program.

Further, for the purposes of the GLOBE Model test, we propose to treat biosimilar biological products and their reference biological products as “multi-source” products instead of sole source biological products when certain conditions are met due to the unique market dynamics of these products within the U.S and because qualifying biosimilar biological products are not Part B rebatable drugs.

We note that qualifying biosimilar biological products (as defined under section 1847A(b)(8)(iii) of the Act) are not included in the Part B rebatable drug definition at 42 CFR 427.20 and therefore, would not be a GLOBE Model drug regardless of whether the criteria for exclusion in proposed 42 CFR 513.130(c) were met. We also note that the Medicare Part B Drug Inflation Rebate Program includes non-qualifying biosimilar biological products and their reference biological products.

We believe there are observable differences in pricing dynamics of sole source and multi-source biological products that lead to unique market dynamics. For example, when there is no competing biological product licensed under section 351(k) of the Public Health Service (PHS) Act to a U.S. originator drug, manufacturers are less likely to provide price concessions and rebates. Compared with sole source biological products, when reference biological products and their biosimilar biological products that are licensed

⁸⁷ Fusco, N., et al. (2023). “Cost-sharing and adherence, clinical outcomes, health care utilization, and costs: A systematic literature review.” *Journal of Managed Care & Specialty Pharmacy*.

under section 351(k) of the PHS Act are sold, manufacturers of multi-source biological products may provide higher price concessions and discounts to be competitive. These market differences result in varying manufacturer-to-provider incentives. In markets with competing biosimilar biological products, manufacturers may provide discounts to providers through price concessions and rebates that impact Medicare spending. Manufacturers may change these discount strategies depending on how many patients are within a GLOBE Model due to geographic location. As such, manufacturers may provide lower discounts to clinics with more patients in the GLOBE Model geographic region than to clinics with less patients. This difference in incentives may lead to providers switching between biosimilar biological products to their reference biological products, reference biological products to their biosimilar biological products, or from one biosimilar biological product to another.

We recognize that if the reference biological product for a biosimilar biological product that is licensed under 351(k) of the PHS Act were included in the GLOBE Model and the biosimilar biological product was not included, beneficiaries could face higher cost sharing amounts for biosimilar biological products than reference biological products. The discussion in section II.B.1. of this proposed rule further describes our proposed approach to exclude biosimilar biological products and their reference biological products.

1. Proposed GLOBE Model Drug Inclusion Criteria

We propose to apply the following criteria to identify GLOBE Model drugs for an applicable calendar quarter during the GLOBE Model performance period. In advance of each applicable calendar quarter, in 42 CFR 513.130, we propose that CMS would identify the GLOBE Model drugs for that applicable calendar quarter by applying these criteria to Part B rebatable drugs (as identified by CMS as set forth in 42 CFR 427.101): (1) are listed as antiout agents, antineoplastics, blood products and modifiers, central nervous system agents, immunological agents, metabolic bone disease agents, or ophthalmic agents as specified in the USP DC; (2) are single source drugs or sole source biological products as set forth in proposed 42 CFR 513.130; (3) have Medicare Part B FFS spending greater than \$100 million over a 12-month period (as further specified in proposed 42 CFR 513.130(d)); and (4) are drug or

biological products that are not excluded from the GLOBE Model under proposed 42 CFR 513.130(c). A Part B rebatable drug would have to meet all the four criteria to be included as a GLOBE Model drug.

To identify GLOBE Model drugs for the first criterion for the first applicable calendar quarter of the GLOBE Model performance period, we propose to use the USP Drug Classification 2025 (USP DC 2025)⁸⁸ to identify all Part B rebatable drugs that meet the categories listed in Table 3 using their scientific or nonproprietary name(s), brand name, and/or NDC. The publicly available USP DC system has four tiers, of which we propose to use the highest-level tier, USP DC category. CMS believes the drug category level is sufficient to identify therapeutic areas that may have deficits of care, while allowing for differences in mechanism of action and biological or molecular targets for products that treat the same therapeutic area. We recognize that a drug or biological product may be listed in more than one USP DC category. As such, as long as one of the categories listed in Table 3 applies to the drug or biological product, it would be considered to have met this criterion. We also recognize that drug and biological products may be added to the Part B rebatable drug list after the GLOBE Model's start and may not appear in USP DC 2025. As such, we propose that for Part B rebatable drugs that were not previously assigned a USP DC category, CMS would use the most recently published USP DC to identify the category for such Part B rebatable drug to determine whether it meets the first criterion. We also propose that once CMS has identified the USP DC category for a GLOBE Model drug or biological product, it would remain in that category for the entire model duration. Accordingly, drugs or biological products included in the initial GLOBE Model Drug List would retain their USP DC 2025 category, while newly added drugs and biological products to the GLOBE Model Drug List would retain the category assigned at the time of their identification, based on the most recently published USP DC available then. We also propose that, when posted on the GLOBE Model website, the GLOBE Model Drug List would include the USP DC category for each HCPCS Level II code. Table 4 shows the associated USP DC category for an illustrative list of HCPCS Level II codes. The USP DC 2025 has 50 categories of which Medicare Part B rebatable drugs

during 2024 are listed in at least 34 of them. Our proposal to include 7 categories represents 21 percent of the 34 possible Medicare Part B rebatable drug categories. Analysis of 2024 Medicare Part B FFS spending data indicates that these 7 USP DC categories were responsible for most Medicare Part B spending (91 percent), with antineoplastics having the highest proportion of any single category at approximately 47 percent.

We are also proposing that if USP creates a new drug category that stems from the drug categories set forth in 42 CFR 513.130(b)(1), then such newly created drug categories would be incorporated into the GLOBE Model drug inclusion criterion. We propose that CMS would make this determination based on a review of USP revision bulletins, revision histories, and corresponding change log information published by USP.

For the second criterion, CMS would focus the GLOBE Model test on a subset of Part B rebatable drugs that are single source drugs or sole source biological products. We recognize by definition, only single source drugs are Part B rebatable drugs and are proposing to use the same definition of single source drug as defined in section 1847A(c)(6)(D) of the Act, which is not a multiple source drug and which is produced or distributed under a new drug application approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application. A *multiple source drug*, as defined in section 1847A(c)(6)(C) of the Act, means, for a calendar quarter, a drug for which there are 2 or more drug products which: (1) are rated as therapeutically equivalent (under the FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations"); (2) except as provided in section 1847A(c)(6)(E) of the Act, are pharmaceutically equivalent and bioequivalent, as determined under section 1847A(c)(6)(F) of the Act and as determined by the FDA, and (3) are sold or marketed in the United States during the quarter.

We also propose to define "sole source biological" in 42 CFR 513.20 for the purposes of the GLOBE Model as a biological product licensed by the FDA in under a biologics license application (BLA) under section 351(a) of the PHS Act and that, at time of evaluating for inclusion into the GLOBE Model for each applicable ASP calendar quarter, is not the reference biological product, as defined in section 1847A(c)(6)(I) of the Act, for a biosimilar biological product

⁸⁸ The USP Drug Classification 2025 file can be found here: <https://www.usp.org/health-quality-safety/usp-drug-classification-system>.

licensed by the FDA in a BLA under section 351(k) of the PHS Act. The biosimilar biological product must be recognized in the FDA's Purple Book and be identified as sold or marketed in FDA's NDC Directory. We note that the proposed definition for sole source biological is different than the definition for *single source biological*, as defined in section 1847A(c)(6)(D) of the Act. As the proposed definition of a sole source biological is based on a 351(a) licensure and not being the reference biological product for a biosimilar biological product sold or marketed, any biological product that meets this definition—even if marketed by any cross-licensed producers or distributors operating under the BLA—qualifies as such sole source biological product. The counterpart to a sole source biological product is a multi-source biological product, and the difference is that they have a reference biological product and a biosimilar biological product that is recognized in the FDA's Purple Book and identified as sold or marketed.

We also propose to use the definition for “*sold or marketed*” established in 42 CFR 427.20 which would mean the marketing data as listed in either the ASP data reported to CMS by a manufacturer or an NDC directory list a start marketing date for the biosimilar biological product prior to the applicable calendar quarter and when one of the following criteria is met: (1) the NDC has units reported for the rebate quarter; (2) the end marketing date is during the rebate quarter; (3) the end marketing date is after the rebate quarter; or (4) the end marketing date is missing.

To apply this criterion, we propose, at the time of evaluating inclusion in the GLOBE Model for each applicable ASP calendar quarter, CMS would use the FDA's NDC Directory, including historical information from NDC Directory files such as discontinued, delisted, and expired listings, provided by the FDA or published on the FDA website to determine the marketing status of a biosimilar biological product. We propose that, if a biosimilar biological product is marketed, as determined by CMS for purposes of the GLOBE Model as of the beginning of an applicable calendar quarter, the biosimilar biological product, and reference biological product⁸⁹ for such biosimilar biological product would not

be included as a GLOBE Model drug for the applicable calendar quarter. We propose that for an applicable calendar quarter CMS would conduct this analysis as of the beginning of the applicable calendar quarter to update the GLOBE Model Drug List.

We recognize for the GLOBE Model that authorized generics and unbranded biological products share the same new drug application approved by the FDA or 351(a) licensure as the original drug and biological product and therefore meet the proposed definition of single source drug and sole source biologicals. As such, authorized generics and unbranded biological products could potentially be GLOBE Model drugs. Authorized generics are drugs sold without their brand name by the original manufacturer or a third party under the NDA of the original drug. Unbranded biological products are biological products sold without their brand name by the original manufacturer or a third party licensed by the BLA 351(a) of the original biological product. Since both authorized generics and unbranded biological products, are directly or indirectly, sponsored by the original pharmaceutical drug manufacturer, we believe that if an authorized generic or unbranded biological product is included in the Medicare Part B Drug Inflation Rebate Program, then, subject to the exclusions described in the next section of this proposed rule, it would be included in the GLOBE Model. In other words, an authorized generic or unbranded biological product could meet the definition of a single source drug or sole source biological product if approved under section 505(c) of the FD&C Act or licensed under section 351(a) of the PHS Act.

For the third criterion, we propose to identify the Part B rebatable drugs with total Medicare Part B FFS allowed charges greater than \$100 million over a 12-month period using separately payable final action claims (spend threshold). As specified in 42 CFR 513.130(d), we propose that CMS would identify Medicare Part B FFS final action claims with dates of service within the consecutive 12-month period ending 6 months prior to the start of the applicable calendar quarter that have separately payable allowed charges greater than \$0 for any billing and payment code used to describe the GLOBE Model drug, and sum the allowed charges. For example, if the applicable calendar quarter is Q1 2027, all separately payable final action claims with Medicare Part B FFS allowed charges greater than \$0 for any billing and payment code used to

describe the Part B rebatable drug with a date of service from July 1, 2025 to June 30, 2026 would be summed together to determine if the spend threshold is met. By applying a minimum total annual Medicare Part B FFS spend as an inclusion criteria, CMS intends that the GLOBE Model would be focused on Part B rebatable drugs that account for a significant portion of annual Medicare Part B FFS drug spending and on drugs that would be expected to account for approximately a minimum of \$8 million in allowed charges per month under the model. We also propose Part B rebatable drugs would need to meet the spend threshold at least one time during the duration of the GLOBE Model to meet this criterion for the applicable ASP calendar quarter and subsequent applicable ASP calendar quarters. For example, if Drug I meets the \$100 million threshold for performance year 1 over a 12-month period for Q3 2026 but not for Q4 2026, Drug I is still considered to have met this criterion for Q4 2026 and the subsequent GLOBE Model ASP calendar quarters and would retain inclusion in the GLOBE Model.

Historical analysis of Medicare Part B FFS drug spending has shown that the majority of spending is focused on a select number of drugs. A threshold of \$100 million in total annual Medicare Part B FFS spending applied to Part B rebatable drugs for the consecutive 12-month period ending on December 31, 2024 would encompass 90 percent of the total 2024 Medicare Part B FFS spending on Part B rebatable drugs and account for 21 percent of Part B rebatable drugs (by HCPCS Level II code). This analysis highlights that a small number of Part B rebatable drugs represent the majority of Medicare Part B FFS drug spending. A threshold of \$100 million would therefore focus the GLOBE Model on a majority of Medicare Part B drug spending to enable detection of expected savings for the GLOBE Model test while reducing the burden of studying the impacts of the GLOBE Model on all Part B rebatable drugs.

2. Proposed Exclusion of Certain Part B Rebatable Drugs

To avoid interactions with other initiatives and programs that focus on manufacturers of drugs payable under Medicare Part B, in 42 CFR 513.130(c)(1)(ii), we propose to exclude from the GLOBE Model a Part B rebatable drug from the GLOBE Model for which a maximum fair price (MFP) (as defined in section 1191(c)(3) of the Act) under the Medicare Drug Price Negotiation Program is in effect. This proposal would mean that drugs that

⁸⁹ Reference product is defined in section 1847A(c)(6)(I) of the Act as “biological product licensed under section 351 of the PHS Act that is referred to in application described in subparagraph (H) of the biosimilar biological product.” See https://www.ssa.gov/OP_Home/ssact/title18/1847A.htm.

have been selected for Medicare Drug Price Negotiation (under section 1192 of the Act), for which a MFP has been agreed upon, and for which the manufacturer of such drug is required to provide access to the MFP, would be excluded from the GLOBE Model for applicable calendar quarters in which the MFP is in effect.^{90 91} For example, if a GLOBE Model drug is selected for negotiation in 2027 for initial price applicability year 2029, the manufacturer and CMS agree upon a MFP for the drug during 2027, and the MFP would go into effect on January 1, 2029, the GLOBE Model drug would exit the GLOBE Model on December 31, 2028. We note that the earliest date for which a MFP would apply for a drug payable under Medicare Part B is January 1, 2028, per section 1192(a)(3) of the Act. Because we are proposing to begin the GLOBE Model on October 1, 2026, we note that there would be no Part B rebatable drugs that could be a GLOBE Model drug for which the manufacturer is required to provide access to the MFP at model start. We propose that this exclusion from the GLOBE Model would end when the Medicare Part B payment limit for a Part B rebatable drug that would otherwise be eligible to be a GLOBE Model drug is no longer based on the MFP. We believe that excluding drugs when the Medicare Part B payment limit is based on a MFP is appropriate because these drugs are subject to different market dynamics within the U.S., and we believe that including them could confound the model test and impact our ability to evaluate the impacts of the model.

In addition, we propose, in 42 CFR 513.130(c)(1)(i), that a Part B rebatable drug would not be a GLOBE Model drug for applicable calendar quarters prior to the first applicable calendar quarter for

which CMS identifies a specified amount pursuant to 42 CFR 427.302(b) for such drug. This proposal would ensure that the GLOBE Model and the Medicare Part B Drug Inflation Rebate Program would treat a subsequently approved drug (that is, a drug first approved or licensed by the FDA after December 1, 2020) in a similar manner. In other words, until a specified amount is established by CMS for a subsequently approved Part B rebatable drug, that drug would not be considered for the GLOBE Model. We note that, given the proposed GLOBE Model drug inclusion criteria in 42 CFR 513.130(b), this exclusion would only be applied to drugs that meet all the proposed inclusion criteria (that is, single source drugs or sole source biological products that are Part B rebatable drugs that are in the USP DC categories shown in Table 3 with total annual Medicare Part B FFS allowed charges greater than the \$100 million during the consecutive 12-month period that ends 6 months before the applicable calendar quarter).

We note that during the duration of the GLOBE Model, certain drugs or biological products may no longer be Part B rebatable drugs. As such, in 42 CFR 513.130(c)(1)(iii) we propose that if a GLOBE Model drug is no longer a Part B rebatable drug for an applicable calendar quarter, it would be excluded from the GLOBE Model for that applicable calendar quarter and any other subsequent quarters in which it is no longer rebatable.

3. Summary of GLOBE Model Drug Inclusion and Exclusion

To summarize, GLOBE Model drugs as defined in 42 CFR 513.130 would be a subset of Part B rebatable drugs that: (1) have the listed USP DC categories in Table 3; (2) are single source drugs or sole source biological products; (3) have a HCPCS Level II code with Medicare Part B FFS spending greater than \$100 million over a 12-month period; and (4) are not excluded from the GLOBE Model as proposed in 42 CFR 513.130(c).

In addition, once a drug or biological product has been identified as meeting the criterion for inclusion in the GLOBE Model, they would remain in the GLOBE Model unless the drug or biological product becomes multi-source (no longer a single source drug or sole source biological product) or meets the exclusions proposed in 42 CFR 513.130(c).

The drugs or biological products that meet the proposed definition of GLOBE Model drugs are frequently prescribed and administered by various providers in settings such as a physician's office

or hospital outpatient department to Medicare beneficiaries with various medical conditions and would have had a minimum of \$100 million in Medicare Part B FFS allowed charges over a 12-month period. Examples include drugs used to treat cancer and related conditions, rheumatoid arthritis and other immune mediated conditions, and macular degeneration and other serious eye conditions. Medicare Part B FFS beneficiaries who receive such drugs, often on a recurring basis, face substantial cost-sharing liability directly related to each drug administration in the form of monthly Medicare Part B premiums, the Medicare Part B annual deductible and coinsurance, and premiums and coinsurance through their supplemental insurance. The proposed approach for identifying GLOBE Model drugs could encompass approximately 55 percent⁹² of annual Medicare Part B FFS drug spending for separately payable Medicare Part B drugs based on an analysis of all 2024 Medicare Part B FFS claims. This proposed approach also focuses the model test on single source drugs and sole source biological products with high Medicare Part B program expenditures that could have beneficiaries with deficits of care due to high costs.

Table 4, Illustrative GLOBE Model Drug HCPCS Level II Code List, in section II.B.6. of this proposed rule shows an illustrative list of how the GLOBE Model could apply to Part B drugs by HCPCS Level II code using available claims information from calendar year (CY) 2024 after applying the proposed drug inclusion and exclusions as discussed in this section of this proposed rule. This illustrative list may not fully capture all relevant HCPCS Level II codes for potential GLOBE Model drugs and may include HCPCS Level II codes for drugs that may not meet the inclusion criteria and exclusion criteria that would be specified in a final rule establishing the GLOBE Model.

4. Alternatives Considered

We considered including all Part B rebatable drugs in the GLOBE Model. However, Medicare Part B FFS drug spending is concentrated among high expenditure drugs, with 50 drugs (by HCPCS Level II code) accounting for 64 percent of 2024 Medicare Part B FFS

⁹⁰ CMS, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of sections 1191 through 1198 of the Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028. September 30, 2025. Available at: <https://edit.cms.gov/files/document/ipay-2028-final-guidance.pdf>.

⁹¹ In accordance with the IRA, CMS engages in good-faith negotiations with participating companies and uses statutory factors listed at section 1194(e) of the Act as the basis for negotiation an MFP. A Primary Manufacturer with a selected drug is required to ensure that the negotiated price, the MFP, is made available to MFP-eligible individuals and to pharmacies, mail order services, and other dispensing entities with respect to such MFP-eligible individuals who are dispensed such drug, and to hospitals, physicians, and other providers of services and suppliers with respect to such MFP-eligible individuals to whom they furnish or administer such drug. The MFP applies to a selected drug during its price applicability period.

⁹² This statistic is based on an evaluation of all 2024 Medicare Part B FFS claims that would meet the GLOBE Model inclusion and exclusion criteria and does not account for any geography distinctions. Refer to section II.F. of this proposed rule for discussion on proposed GLOBE Model geographies.

drug spending. We also noted that many Medicare Part B rebatable drugs have average monthly total Medicare Part B FFS allowed charges of less than \$10 million. For example, using separately payable claims, 302 Medicare Part B rebatable drugs had less than \$100 million in total 2024 Medicare Part B FFS drug spending each, representing 7 percent of total 2024 Medicare Part B FFS drug spending. Similarly, 266 Medicare Part B rebatable drugs had less than \$50 million in total 2024 Medicare Part B FFS drug spending each, accounting for 3 percent of total 2024 Medicare Part B FFS drug spending. These lower spend drugs could have approximately \$8 million or less in allowed charges per month paid under the GLOBE Model, based on our proposed model design described in section II.B of this proposed rule. However, the approximately 80 Part B rebatable drugs with greater than \$100 million in 2024 Medicare Part B FFS allowed charges accounted for 61 percent of 2024 Medicare Part B FFS drug spending. As such, it may be too burdensome for the operational and administrative efforts to include Part B rebatable drugs with less than \$100 million in total Medicare Part B FFS allowed charges during a consecutive 12-month period in the model test at this time in order to detect potential changes in Medicare spending or beneficiaries' quality of care. We believe that the model test and evaluation could be efficiently focused on Medicare Part B rebatable drugs with over \$100 million in total annual Medicare Part B FFS spending without sacrificing the potential for meaningful model findings and learning. Therefore, we are not proposing to include all Part B rebatable drugs in the GLOBE Model and instead are proposing to focus the model on a subset of drugs that would be anticipated to have a meaningful amount of Medicare spending under the model test and address deficits of care for beneficiaries.

In addition, we considered the alternative of including all Part B rebatable drugs in the GLOBE Model, which would introduce multi-source biological products (biosimilar biological products and their reference biological products) into the model. Most of the biosimilar biological products that are available now and are separately payable under Medicare Part B are qualifying biosimilar biological products, which are excluded from the definition of Part B rebatable drugs, and as such could be excluded from being a Part B rebatable drug for some portion of the model performance period. We

recognize the list of qualifying biosimilar biological products may also change quarterly when the ASP of the biosimilar biological product exceeds the ASP of the reference biological product or when the applicable 5-year period for a temporary payment add-on has elapsed. Therefore, if biosimilar biological products that are not qualifying biosimilar biological products for an applicable calendar quarter were included as GLOBE Model drugs, there could be operational challenges related to monitoring, potential for beneficiary and healthcare provider confusion related to beneficiary coinsurance changes during the GLOBE Model performance years, and increased complexity and potential challenges in operating the model evaluation. As such and to meet our model intent, we propose to exclude biosimilar biological products licensed under 351(k) of the PHS Act and their reference biological products as proposed in 42 CFR 513.130(b).

We considered an alternate exclusion process for reference biological products by requiring the manufacturers of the reference biological product to submit an attestation of when a competing biosimilar biological product would be sold in the U.S. However, assessing whether market competition exists after a biosimilar biological product has been licensed by the FDA under section 351(k) of the PHS Act would likely require substantial investigation to verify a specific date of first sale. There would be insufficient time for CMS to review requests by a manufacturer of a reference biological product for GLOBE Model exclusion before the manufacturer submits ASP information for the applicable calendar quarter and prior to determination of the GLOBE Model beneficiary coinsurance for included drugs. Further, manufacturers of reference biological products may not have an accurate estimation of when sales of a biosimilar biological product would be first sold in the U.S.

Therefore, our proposed approach to use the sold or marketed definition established in 42 CFR 427.20 and FDA's NDC Directory to identify biosimilar biological products that are marketed would likely be a faster and more efficient way than verifying reference biological product manufacturer attestations to identify when a biosimilar biological product and its reference biological product would be excluded from the GLOBE Model drug list of an applicable calendar quarter to support our goal of focusing the model test on single source drugs and sole source biological products.

We also considered including additional USP DC categories such as antimyasthenic agents, cardiovascular agents, dermatological agents; genetic, enzyme, or protein disorder; replacement, modifiers, treatment; and respiratory tract/pulmonary agents, which are also categories represented in Part B rebatable drugs with Medicare Part B FFS spending over \$100 million in 2024. However, we believe starting the model with the high expenditure therapeutic areas and their USP DC categories shown in Table 3 would help focus the model test on patients with related conditions that are likely exposed to higher financial burden and greater deficits of care. We may explore a future expansion to other high spend USP DC categories outside of the therapeutic areas listed in Table 3 after we have made operational and administrative progress with respect to the model. We also considered reviewing the latest published USP DC at the beginning of each applicable calendar quarter to determine if a drug or biological product has changed categories. However, we believe using the 2025 USP DC for the GLOBE Model drug list, except in the case of drugs and biological products added after model start, would maintain data standardization. Similarly, we also believe keeping the same category for each drug and biological product once identified also maintains data standardization and allows CMS to test and evaluate an alternative Part B inflation rebate amount calculation. In addition, we considered categorizing the drugs or biological products by therapeutic areas such as endocrinology, immunology, rheumatology, oncology, or ophthalmology or for CMS to develop a classification method. However, we believe using a publicly available drug classification list such as the USP DC provides for a more transparent and straightforward method for identifying GLOBE Model drugs.

We considered other alternatives to the proposed subset of Part B rebatable drugs included as GLOBE Model Drugs such as including only a certain number of Part B rebatable drugs; only including drugs with high utilization among the Medicare population, for example, drugs furnished to more than 20,000 Medicare Part B FFS beneficiaries during a specified period;⁹³ and

⁹³ The minimum number of beneficiaries for a drug selected for the Medicare Drug Price Negotiation Program for the Initial Price Applicability Year 2026 is 20,000 (Imbruvica). Based on internal CMS analysis, if this was used as a threshold, then approximately 17 percent of all HCPCS Level II codes billed under Medicare Part B in 2024 would have met this criterion.

including drugs based on high annual per beneficiary coinsurance liability, for example, drugs with an average per beneficiary coinsurance amount greater than \$200 during a consecutive 12-month period (assuming a coinsurance percentage of 20 percent, this alternative would focus on drugs with approximately \$1,000 or more in average per beneficiary Medicare Part B allowed charges during a consecutive 12-month period). We also considered phasing in the inclusion of Part B rebatable drugs in the GLOBE Model over time, for example, starting the model with 50 drugs and adding drugs at the beginning of each performance year until all Part B rebatable drugs that would not be specifically excluded would be included in the model.

We are also considering if the spend threshold (total Medicare Part B FFS allowed charges greater than \$100 million over a 12-month period) would be adjusted for each subsequent performance year by the percentage increase or decrease in the CPI-U for the previous performance year. This would mean that for each subsequent performance year, the GLOBE Model spend threshold would adjust to account for inflation. We welcome comments on whether CMS should update the spend threshold based on inflation.

We considered these alternative approaches and believe that focusing the model on higher spend drugs that impact beneficiaries who likely have a deficit of care allows a transparent, consistent, and clear approach that would provide sufficient opportunity to observe the impacts of the model test on a sufficient number of Medicare FFS beneficiaries who may receive a Part B rebatable drug. Our proposed approach

would minimize complexity within the model implementation and evaluation and improve CMS' ability to understand the findings from model monitoring and evaluation activities by focusing on a subset of beneficiaries. We believe the benefits of including the higher spend drugs for specific USP DC categories of Part B rebatable drugs in the GLOBE Model with limited exclusions as discussed in this section of this proposed rule enable the model to encompass a large number of Part B rebatable drugs without increasing complexity and burden that may occur with a larger set of Part B rebatable drugs.

We welcome comments on our process for identifying the USP DC categories, our method for identifying and excluding certain drugs, and the alternatives we considered. We also welcome comments on CMS' proposed process for when a reference biological product would be excluded from the list of GLOBE Model drugs for an applicable calendar quarter. Specifically, we seek feedback on ways CMS could structure the exclusion process to minimize the potential for excluding a reference biological product for a biosimilar biological product that is marketed under a license under 351(k) of the PHS Act but not sold during an applicable calendar quarter.

5. Considerations Related to Cell and Gene Therapies and Plasma-Derived Products

We are also considering excluding cell and gene therapies (CGTs) from the GLOBE Model. CGTs include cellular immunotherapies, cancer vaccines and other products aimed to treat or prevent certain diseases including cancer, genetic diseases, and infectious diseases. We seek comments on the

merits of excluding CGTs based on supply chain criteria, or if there are other factors that warrant their inclusion or exclusion. We similarly welcome comments on whether the GLOBE Model would exclude plasma-derived products, particularly because these products may be more likely to experience shortages and the rebate amount for these products may be reduced as discussed in section II.G. of this proposed rule.

6. Illustrative List of Proposed Performance Year 1 GLOBE Model Drugs and Model Participants

To create an illustrative GLOBE Model Drug HCPCS Level II Code List, we identified the 2024 Part B rebatable drugs by HCPCS Level II code, applied the proposed GLOBE Model drug inclusion criteria and exclusions as discussed in sections II.B.1. and II.B.2. of this proposed rule. Using this approach, an illustrative GLOBE Model Drug HCPCS Level II Code List is shown in Table 4 and includes drugs and biological products that met the proposed criteria for at least one applicable calendar quarter in 2024. Table 4 is an illustrative list of how the GLOBE Model might apply to Part B rebatable drugs and is not intended as a list of GLOBE Model drugs or Part B rebatable drugs that would be applicable for a quarter in a performance year. Further, this illustrative list is based on CMS' initial analyses and proposals discussed in this proposed rule and is provided for informational purposes only. Readers should note that the illustrative list may not reflect the final model design and does not indicate that these drugs or biological products would owe a GLOBE Model rebate.

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TABLE 4: ILLUSTRATIVE GLOBE MODEL DRUG HCPCS LEVEL II CODE LIST*

HCPCS Level II Code	Short Description	USP DC Category
J0129	Abatacept injection	Immunological Agents
J0178	Aflibercept injection	Ophthalmic Agents
J0485	Belatacept injection	Immunological Agents
J0490	Belimumab injection	Immunological Agents
J0717	Certolizumab pegol inj 1mg	Immunological Agents
J0881	Darbepoetin alfa, non-esrd	Blood Products and Modifiers
J0896	Inj luspaterecept-aamt 0.25mg	Blood Products and Modifiers
J0897	Denosumab injection	Antineoplastics/Metabolic Bone Disease Agents
J1300	Eculizumab injection	Immunological Agents
J1303	Inj., ravulizumab-cwvz 10 mg	Immunological Agents
J1459	Inj ivig priven 500 mg	Immunological Agents
J1555	Inj cuvitru, 100 mg	Immunological Agents
J1559	Hizentra injection	Immunological Agents
J1561	Gamunex-c/gammaked	Immunological Agents
J1568	Octagam injection	Immunological Agents
J1569	Gammagard liquid injection	Immunological Agents
J1602	Golimumab for iv use 1mg	Immunological Agents
J1930	Lanreotide injection	Antineoplastics
J2323	Natalizumab injection	Central Nervous System Agents
J2350	Injection, ocrelizumab, 1 mg	Central Nervous System Agents
J2353	Octreotide injection, depot	Antineoplastics
J2357	Omalizumab injection	Immunological Agents
J2507	Pegloticase injection	Antigout Agents
J2777	Inj, faricimab-svoa, 0.1mg	Ophthalmic Agents
J2781	Inj, pegcetacoplan, 1mg	Immunological Agents
J2796	Romiplostim injection	Blood Products and Modifiers
J3111	Inj. romosozumab-aqqg 1 mg	Metabolic Bone Disease Agents
J3241	Inj. teprotumumab-trbw 10 mg	Ophthalmic Agents
J3245	Inj., tildrakizumab, 1 mg	Immunological Agents
J3262	Tocilizumab injection	Immunological Agents
J3380	Inj vedolizumab iv 1 mg	Immunological Agents
J7170	Inj., emicizumab-kxwh 0.5 mg	Blood Products and Modifiers
J7503	Tacrol envarsus ex rel oral	Immunological Agents
J9022	Inj, atezolizumab,10 mg	Antineoplastics
J9023	Injection, avelumab, 10 mg	Antineoplastics
J9042	Brentuximab vedotin inj	Antineoplastics
J9043	Cabazitaxel injection	Antineoplastics
J9047	Injection, carfilzomib, 1 mg	Antineoplastics
J9055	Cetuximab injection	Antineoplastics
J9063	Inj, elahere, 1 mg	Antineoplastics
J9119	Inj., cemiplimab-rwlc, 1 mg	Antineoplastics
J9144	Daratumumab, hyaluronidase	Antineoplastics
J9145	Injection, daratumumab 10 mg	Antineoplastics
J9173	Inj., durvalumab, 10 mg	Antineoplastics
J9177	Inj enfort vedo-ejfv 0.25mg	Antineoplastics
J9223	Inj. lurbinectedin, 0.1 mg	Antineoplastics
J9228	Ipilimumab injection	Antineoplastics
J9271	Inj pembrolizumab	Antineoplastics
J9272	Inj, dostarlimab-gxly, 10 mg	Antineoplastics
J9298	Inj nivolumab 3mg/1mg	Antineoplastics
J9299	Injection, nivolumab	Antineoplastics
J9301	Obinutuzumab inj	Antineoplastics

HCPCS Level II Code	Short Description	USP DC Category
J9303	Panitumumab injection	Antineoplastics
J9306	Injection, pertuzumab, 1 mg	Antineoplastics
J9308	Injection, ramucirumab	Antineoplastics
J9309	lnj, polatuzumab vedotin 1mg	Antineoplastics
J9316	Pertuzu, trastuzu, 10 mg	Antineoplastics
J9317	Sacituzumab govitecan-hziy	Antineoplastics
J9354	lnj, ado-trastuzumab emt 1mg	Antineoplastics
J9358	lnj fam-trastu deru-nxki 1mg	Antineoplastics
Q2043	Sipuleucel-t auto cd54+	Antineoplastics
Q2056	Ciltacabtagene car-pos t	Antineoplastics

*Note: The scientific or nonproprietary name was used to identify the 2025 USP DC category. A HCPCS Level II code may belong in more than one USP DC Category.

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C. Proposed Defined Population

For the GLOBE Model design, we considered ways to identify the Medicare beneficiaries who would be eligible for inclusion in either the intervention or comparison groups. After considering a number of factors, we propose to use a geographically randomized design such that the defined population for the GLOBE Model would be a set of CMS-selected Medicare Part B FFS beneficiaries who are identified as eligible for inclusion in the model cohort as set forth in 42 CFR 513.120 and receive a GLOBE Model drug (as set forth in 42 CFR 513.130) during the model performance period for which separate Medicare Part B payment is made under the GLOBE Model. The Medicare Part B FFS beneficiaries who are identified as eligible for inclusion in the model cohort would be included in the model cohort as a GLOBE Model beneficiary as of the date they are furnished a GLOBE Model drug for which separate Medicare Part B payment is made during the model performance period. GLOBE Model beneficiaries would be eligible for the GLOBE Model adjusted beneficiary coinsurance for GLOBE Model drugs, if applicable, and would remain in the model cohort unless they no longer meet the criteria for inclusion. A GLOBE Model beneficiary may receive one or more GLOBE Model drugs.

Specifically, we propose that, prior to the model start, CMS would randomly identify the model geographic areas (based on ZIP Code Tabulation Areas as discussed in section II.F.2. of this proposed rule). We also propose that, prior to model start and periodically thereafter, but no more frequently than weekly, CMS would identify eligible Medicare FFS beneficiaries (as set forth in 42 CFR 513.120) and update the *GLOBE Model Eligible Beneficiary List*, which would be effective when the

Medicare claims processing system are updated with the *GLOBE Model Eligible Beneficiary List* information. We propose that the identification of eligible beneficiaries and the timing of such identification and updating of the *GLOBE Model Eligible Beneficiary List* and the Medicare claims processing systems, as well as the identification of Medicare FFS beneficiaries who are eligible for inclusion in the comparison group, would be performed by CMS and would not be subject to review. In 42 CFR 513.120, we propose how CMS would identify the Medicare beneficiaries who would be eligible for inclusion in the model cohort and comparison group. In 42 CFR 513.20, we propose to define the term “GLOBE Model eligible beneficiary” as a Medicare beneficiary who has been identified by CMS for potential inclusion in the model and added to the *GLOBE Model Eligible Beneficiary List* for some or a portion of the GLOBE Model performance period as set forth in 42 CFR 513.120. Specifically, in 42 CFR 513.120(b), we propose that, approximately 30 days prior to model start using available Medicare program administrative information as determined by CMS, CMS would identify Medicare beneficiaries who are enrolled in Medicare Part B, have Traditional Medicare Part B as their primary payer, and have an address of record within the GLOBE Model geographic areas selected for inclusion in the model at model start (as identified by CMS under 42 CFR 513.110(c)), as determined by CMS. These beneficiaries would encompass the Medicare FFS beneficiaries who would be eligible for inclusion in the GLOBE Model at model start. CMS would add such beneficiaries to the *GLOBE Model Eligible Beneficiary List* and update the Medicare claims processing systems with such list for the first applicable calendar quarter of performance year one.

Similarly, in 42 CFR 513.120(b)(2), we propose that, approximately 30 days prior to model start using available Medicare program administrative information as determined by CMS, we would identify Medicare beneficiaries who are enrolled in Medicare Part B, have Traditional Medicare Part B as their primary payer, and do not have an address of record within the GLOBE Model geographic areas selected for inclusion in the model at model start (as identified by CMS under 42 CFR 513.110(c)), as determined by CMS. These beneficiaries would be assigned as being eligible for inclusion in the comparison group. For a discussion on the evaluation, see section II.P. of this proposed rule.

To maintain a clear record of which beneficiaries are eligible for inclusion in the model cohort, in 42 CFR 513.120(c), we propose that, CMS would update the *GLOBE Model Eligible Beneficiary List* periodically, but not more frequently than weekly, using available Medicare program administrative information as determined by CMS, to: (1) identify the Medicare beneficiaries who are enrolled in Medicare Part B, have Traditional Medicare Part B as their primary payer, and have an address of record within the GLOBE Model geographic areas selected for inclusion (as identified by CMS under 42 CFR 513.110(c)), are not yet included on the *GLOBE Model Eligible Beneficiary List*, are not assigned as eligible for the comparison group, and adds such beneficiaries to the *GLOBE Model Eligible Beneficiary List* at the next update; and (2) identify beneficiaries on the *GLOBE Model Eligible Beneficiary List* that no longer meet the criteria for a GLOBE Model eligible beneficiary and removes such beneficiaries from the *GLOBE Model Eligible Beneficiary List* at the next update. CMS would not routinely reevaluate the eligibility of beneficiaries who were identified as eligible for the comparison group. That is, beneficiaries

who are identified as eligible for inclusion in the comparison group prior to model start would remain eligible for inclusion in the comparison group and model monitoring and analyses as determined by CMS.

In 42 CFR 513.120(d), we propose beneficiary exclusions for clarity regarding the beneficiaries who would not be eligible for assignment to the *GLOBE Model Eligible Beneficiary List* or comparison group, as applicable: beneficiaries who do not have Medicare Part B FFS as their primary payer, and beneficiaries who are enrolled in a Medicare Advantage plan, section 1876 of the Act cost plan, section 1833 of the Act healthcare prepayment plans, or who have other group health coverage that is a primary payer (such as employer-sponsored health insurance). In addition, 42 CFR 513.120(d)(3) clarifies that beneficiaries who are identified by CMS as eligible for inclusion in the comparison group prior to model start remain eligible for the comparison group as determined by CMS.

We propose that, for purposes of identifying a beneficiary's address and determining if the beneficiary's address is within the *GLOBE Model* geographic areas, we would use the beneficiary's address as recorded in CMS' Medicare Beneficiary Database (MBD), System No. 09–70–0536, at the time CMS identifies beneficiaries for inclusion in the model. We also propose to define in 42 CFR 513.20 the term “*GLOBE Model* geographic areas” as the set of ZIP Codes in the U.S., excluding U.S. territories identified as set forth in 42 CFR 513.110 (as discussed in section II.F. of this proposed rule).

Under our proposed approach for identifying the defined population, beneficiaries who are identified by CMS as a *GLOBE Model* eligible beneficiary, at the start of the model or subsequently, would be added to the *GLOBE Model Eligible Beneficiary List* and remain on the list until the model ends or the beneficiary is no longer enrolled in Medicare FFS or is otherwise ineligible for inclusion. For example, if a beneficiary is identified for inclusion on the *GLOBE Model Eligible Beneficiary List* based on the beneficiary's address as recorded in CMS' Medicare Beneficiary Database (MBD) being within the selected model geographic areas and then subsequently the beneficiary's address recorded in CMS' MBD changes such that the beneficiary no longer has an address within the *GLOBE Model* geographic areas, the beneficiary would continue to be assigned as a *GLOBE Model* eligible beneficiary unless the beneficiary is no

longer enrolled in Medicare FFS or is otherwise ineligible for inclusion. Beneficiaries who become newly enrolled in Medicare FFS due to becoming newly eligible for Medicare FFS after the model begins and are identified by CMS as a *GLOBE Model* eligible beneficiary (because all criteria are met) would be added to the *GLOBE Model Eligible Beneficiary List* from the time CMS next updates the list and remain on the list unless the beneficiary is no longer enrolled in Medicare FFS or is ineligible for inclusion. Beneficiaries for whom Medicare Part B FFS switches from being a secondary payer to being the primary payer and who are identified by CMS as a *GLOBE Model* eligible beneficiary (because all criteria are met) would be added to the *GLOBE Model Eligible Beneficiary List* when CMS next updates the list and remain on the list unless the beneficiary is no longer enrolled in Medicare FFS or is ineligible for inclusion. No other beneficiaries would be added to the *GLOBE Model Eligible Beneficiary List*. For example, the following changes would not enable beneficiary inclusion on the *GLOBE Model Eligible Beneficiary List* after the model starts: (1) beneficiaries who were enrolled in Medicare Part B at the time CMS creates the initial *GLOBE Model Eligible Beneficiary List* prior to the start of the model and had an address within CMS' MBD that was not selected as a *GLOBE Model* geographic area then had an address change to a *GLOBE Model* geographic area; and (2) newly enrolled Medicare Part B FFS beneficiaries with an address with a new ZIP Code that did not exist at the time that the *GLOBE Model* geographic areas were identified. In addition, beneficiaries who were identified by CMS as being eligible for the comparison group would not be eligible for the model cohort.

Testing the *GLOBE Model* in this population would allow the *GLOBE Model* alternative rebate test to apply to a broad set of conditions, clinical settings, localities, and manufacturers rather than having the model test focus on a limited set of conditions, drugs (for example, only including drugs approved under section 505 of the FD&C Act) or a single type of clinical setting (for example, only including *GLOBE Model* drugs that are furnished in a physician's office). Defining the population broadly and in a manner that fosters a stable and consistent model cohort and comparison group would allow CMS to observe the implications of an alternative approach to determining the net Medicare payment for *GLOBE Model* drugs across a broad set of

providers and suppliers and beneficiaries, as well as a large set of manufacturers.

D. Proposed Scale for Inclusion of GLOBE Model Beneficiaries

Section 1115A(b) of the Act gives the Secretary discretion in the design of models, including the geographic reach of models. Section 1115A(a)(5) of the Act states that the Secretary may elect to limit testing of a model to certain geographic areas. Testing a model in randomly selected geographic areas facilitates identification of the intervention and comparison groups for model implementation. We have considered the variation in cost and use in the Medicare population of proposed *GLOBE Model* drugs along with other aspects of the proposed model design and determined that a sufficient allocation between intervention and comparison groups for achieving precise estimates in tests is approximately 25 percent of Medicare FFS beneficiaries. To determine the geographic areas that CMS would use to identify approximately 25 percent of Medicare FFS beneficiaries as *GLOBE Model* eligible beneficiaries, we propose that CMS would select geographic regions to represent 25 percent of Medicare FFS beneficiaries (as described in section II.F.2. of this proposed rule).

E. Proposed Model Participants

1. Proposed Mandatory Participation of Manufacturers of GLOBE Model Drugs

We propose that model participation would be mandatory for all manufacturers of *GLOBE Model* drugs (as described in section II.B. of this proposed rule) that are furnished to a *GLOBE Model* beneficiary during the *GLOBE Model* performance period. We propose that, for purposes of the *GLOBE Model*, “manufacturer” would have the same meaning as that term is defined and used in section 1847A(c)(6)(A) of the Act and 42 CFR 427.20. We note that this is consistent with how CMS defines “manufacturer” for purposes of the Medicare Part B Drug Inflation Rebate Program. We also note that the proposed *GLOBE Model* drugs, as single source drugs and sole source biological products, usually have one manufacturer. However, there could be *GLOBE Model* drugs for which multiple manufacturers report ASP data to CMS, for example, when there is a repackager or relabeler or when more than one manufacturer markets a single source drug or sole source biological product within the U.S. In such cases, we propose that all manufacturers of a *GLOBE Model* drug would each be

required to participate in the GLOBE Model.

We propose to define “GLOBE Model participant” as a manufacturer of a GLOBE Model drug that is required to participate in the GLOBE Model in accordance with proposed 42 CFR 513.100. We propose that there would be no specific enrollment activities for GLOBE Model participants; rather, their participation would be effectuated by the requirements under the Medicare Part B Drug Inflation Rebate Program, and where applicable, the application of the proposed GLOBE Model calculation for the GLOBE Model rebate amount. Mandatory participation can enhance the generalizability of model results, as mandatory model participants may be more broadly representative of all entity types that could be affected by a model. Requiring manufacturer participation in the GLOBE Model would allow us to observe the experiences of manufacturers of drugs with diverse characteristics. Further, we believe mandatory participation in the GLOBE Model would be essential to the model test because we believe that, despite the potential for the GLOBE Model to lower beneficiaries’ financial liability for a manufacturer’s Part B rebatable drug and reduce financial barriers to access such drugs which could increase utilization of such drugs, manufacturers of proposed GLOBE Model drugs would likely not volunteer to participate in this model.

In the proposed 42 CFR 513.100(a), we propose to codify that model participation would be mandatory for all manufacturers of GLOBE Model drugs.

We considered excluding manufacturers where the U.S. manufacturer may not be the same entity that is responsible for sales in other countries. Another option we considered was to except manufacturers that had existing sales or licensing agreements with other entities outside of the U.S. to sell GLOBE Model drugs prior to the publication of this NPRM. However, we were concerned about the possibility of manufacturers transferring responsibilities to other entities to avoid model participation. We also considered an application process through which a manufacturer could qualify for a model exemption given their lack of responsibility for sales of drugs outside of the U.S. However, given the complex nature of manufacturer relationships outside of the U.S., such an exclusion might potentially being too broad, diluting CMS’ ability to rigorously evaluate the model’s impact on costs and quality. Having considered these alternatives, CMS is not proposing such

exclusions. We also seek comment on other factors, for example, manufacturer size, that CMS could consider exempting certain manufacturers while maintaining sufficient model participation and a robust model test.

We seek comments on our proposal for mandatory participation in the GLOBE Model by all manufacturers that may be subject to the model (that is, manufacturers of Part B rebatable drugs that could be designated as GLOBE Model drugs pursuant to the criteria in proposed 42 CFR 513.130). We also seek feedback on whether manufacturers of proposed GLOBE Model drugs would voluntarily participate in the proposed GLOBE Model absent a mandatory participation requirement and feedback on evidence that could support a voluntary participation approach which would ensure sufficient model participation for a robust model test and evaluation during performance year 1 and thereafter.

2. Proposed Model Participation Requirements

In 42 CFR 513.100, we propose to codify GLOBE Model participant requirements during the GLOBE Model test period. During the GLOBE Model test period described in proposed 42 CFR 513.100(b), we propose that GLOBE Model participants must—

- Adhere to the proposed GLOBE Model rebate payment instructions as proposed in 42 CFR 513.740 and established by CMS and its contractors responsible for providing rebate reports containing GLOBE Model rebate amounts and processing payments, including without limitation those described in proposed 42 CFR 513.500, to ensure appropriate and accurate GLOBE Model rebate payments; and
- Participate in GLOBE Model monitoring and evaluation activities in accordance with 42 CFR 403.1110(b), including collecting and reporting of information as the Secretary determines is necessary to monitor and evaluate the GLOBE Model.

- If electing to submit international drug net pricing data, adhere to the requirements set forth in proposed 42 CFR 513.610 and the GLOBE Model data agreement.

In addition, for GLOBE Model participants that elect to submit international drug net pricing data for the applicable ASP calendar quarter beginning April 1, 2025, we propose that such GLOBE Model participants would be required to adhere to the requirements set forth in proposed 42 CFR 513.620 and the GLOBE Model data agreement prior to the start of performance year 1.

We seek comments on our proposal for model participation requirements from potential GLOBE Model participants.

We refer readers to section II.G.6. of this proposed rule for a discussion of the option for eligible manufacturers of separately payable Part B single source drugs and sole source biological products determined to be GLOBE Model drugs to voluntarily submit manufacturer international net drug pricing information to CMS for purposes of identifying a per unit Method II GLOBE Model benchmark which could potentially lower the total GLOBE Model rebate amount that a GLOBE Model participant would be responsible for. If electing to submit international drug net pricing data, we propose that the manufacturer must adhere to the requirements set forth in proposed 42 CFR 513.610 and in the proposed GLOBE Model data agreement as described in proposed 42 CFR 513.620.

3. Standard Provisions

We propose that the Standard Provisions for Innovation Center Models, originally established in 42 CFR part 512, subpart A and applicable to certain Innovation Center models, would not apply to the GLOBE Model. Given the unique characteristics and operational framework of the GLOBE Model, we believe it differs substantially from most mandatory Innovation Center models. Therefore, rather than applying the Standard Provisions, we propose implementing GLOBE-specific requirements that would provide the necessary regulatory specificity and flexibility to effectively test and evaluate the GLOBE Model’s innovative approach.

We propose specific audit, record access, and retention requirements for manufacturers participating in the GLOBE Model. These provisions are essential to ensure program integrity, enable proper oversight of the model’s implementation, and protect the interests of Medicare beneficiaries and the Federal government. Given the unique structure and operational characteristics of the GLOBE Model, we believe it is necessary to establish clear audit rights, record access requirements, and retention standards that are specifically tailored to this model’s framework.

We propose at § 513.100(d)(1) to establish explicit Federal audit rights to ensure that CMS, HHS, the Comptroller General, and their designees maintain comprehensive oversight authority over GLOBE Model implementation. This provision is necessary to verify compliance with model requirements,

assess program effectiveness, and identify potential areas for improvement or corrective action.

We propose at § 513.100(d)(2) record access requirements would ensure that manufacturers maintain and provide access to all documentation necessary for effective oversight. This includes, but is not limited to, records supporting the accuracy of voluntarily-submitted data and documentation related to CMS identified program integrity issues. Such access is critical for validating manufacturer-reported information and ensuring the model operates as intended.

We propose at § 513.100(d)(3) a six-year retention period for GLOBE Model-related records, with extensions under specific circumstances. This timeframe aligns with standard Federal audit and investigation cycles while providing flexibility for situations involving disputes, fraud allegations, or special retention needs identified by CMS. The proposed retention requirements balance the need for thorough oversight with reasonable administrative burden on participating manufacturers.

We propose at § 513.100(d)(4) that in the event we terminate the GLOBE Model, we would provide written notice to GLOBE Model participants specifying the grounds for termination and the effective date of such termination. As provided by section 1115A(d)(2) of the Act termination of the model under section 1115A(b)(3)(B) of the Act would not be subject to administrative or judicial review.

We seek comment on our proposed requirements for audit, record access, and record retention, and model termination parameters for GLOBE Model manufacturers.

F. Proposed GLOBE Model Test Design and Geographic Areas

1. Proposed Model Test Design

In 42 CFR 513.110, for the model test design, we propose a randomized design in which the GLOBE Model geographic reach would be determined by selection of geographic areas where approximately 25 percent of Medicare Part B FFS beneficiaries have an address of record within CMS' MBD (as determined by CMS as set forth in 42 CFR 513.120) and CMS would identify the selected geographic areas for the model start. Model test geographic areas would be randomly selected to balance the Medicare beneficiary population and Medicare expenditures nationwide. We also propose that after CMS finalizes a rule establishing the GLOBE Model, no later than 30 calendar days in advance of model start, CMS would

provide a table on the GLOBE Model website that lists the GLOBE Model geographic areas by ZIP Code. CMS may include other information such as total Medicare beneficiary statistics and total Medicare Part A and Medicare Part B FFS expenditures. This table would identify the GLOBE Model geographic areas for model start. CMS would not change the list of GLOBE Model geographic areas by ZIP Code after the initial random selection of the model geographic areas. For example, during the model performance period, if a ZIP Code that is within the GLOBE Model geographic areas is split or redesignated, that ZIP Code would not get reassigned to a GLOBE Model geographic area.

2. Proposed Unit of Analysis

In developing the proposed GLOBE Model, CMS determined that conducting the proposed GLOBE Model test in the population of Medicare FFS beneficiaries who may receive Part B rebatable drugs that are included in the model (as discussed in section II.C. of this proposed rule) would provide the best means for testing an innovative payment model using the alternative rebate calculation. Defining the population in this manner would allow CMS to assess if the GLOBE Model payment test reduced Medicare costs while preserving or enhancing quality of care, in line with section 1115A(b)(2) of the Act across a broad set of providers and suppliers and beneficiaries, as well as a broad set of manufacturers. Learnings from the GLOBE Model would inform CMS and other interested parties about the effect of applying the proposed innovative rebate approach to a broad set of drugs on a diverse set of beneficiaries and to the Medicare program.

3. Proposed Method for Identification of GLOBE Model Geographic Areas

a. Proposed Geographic Unit of Randomization

We considered establishing the unit of geography CMS would use for randomization and for evaluation of model impacts based on existing well-defined geographic units that were sufficiently numerous to support statistical analysis. Based on CMS' review of existing defined geographic units that are suitable for statistical purposes, CMS, after consideration of alternatives, identified that ZIP Code Tabulation Areas (ZCTAs) would be an appropriate geographic unit for a limited scope model and for the proposed GLOBE Model specifically. ZIP Code Tabulation Areas (ZCTAs) are approximate area representations of

USPS five-digit ZIP Code service routes that the Census Bureau creates using whole blocks to present statistical data from censuses and surveys. A change in site of service due to a difference in incentives between the intervention and comparison group could bias statistical analyses. Given that beneficiary address would be the basis for their geographic assignment as eligible for the model test or comparison group, the site of service for the administration of a GLOBE Model drug would not bias statistical analyses. As a result, the smallest practical geographic area is preferred to allow for a simpler randomized design, that would involve fewer strata or weights. A simple random selection of small geographic units would achieve the desired balance for both observable and unobservable characteristics between the model test and comparison groups. In particular, it would allow us to achieve our intended geographic scope in terms of approximate share of beneficiaries and Medicare spending.

Therefore, we are proposing to identify the GLOBE Model geographic areas through a simple random selection of 25 percent of all ZIP Code Tabulation Areas (ZCTAs) in the U.S., excluding the U.S. territories. Specifically, in 42 CFR 513.110(a), we propose that the GLOBE Model geographic areas would be identified by ZIP Codes that are aligned with ZCTAs that are randomly selected by CMS no later than 60 calendar days prior to the start of the model performance period. During the model performance period, if a ZIP Code that is within the GLOBE Model geographic areas is split or redesignated, that ZIP Code is not reassigned to a GLOBE Model geographic area.

b. Alternatives Considered

We also considered the suitability of the following as the geographic unit from which the GLOBE Model geographic areas would be identified: (1) ZIP Codes; (2) counties; (3) states; (4) Census-defined Core Based Statistical Areas (CBSAs) or Combined Statistical Areas (CSAs); and (5) Medicare Administrative Contractor (MAC) regions. ZIP Codes were considered because they are part of the beneficiary data that is maintained in Medicare beneficiary records and are the proposed basis for identifying GLOBE Model beneficiaries. However, ZIP Codes, unlike ZCTAs are not technically geographic areas, but represent U.S. postal delivery routes. ZIP Codes are useful identifiers to link a beneficiary record to a specific geographic area but are not geographic areas. Counties, states and CBSAs were determined to be too heterogeneous in their size and

population to achieve balance between selected and not selected regions for measured and unmeasured factors that may be linked to the outcomes for the proposed model design. The Medicare Administrative Contractor (MAC) regions were considered to reduce operational complexity but also were determined to be too large in size and heterogeneous.⁹⁴

We also considered selecting the entire country as the model geographic area. However, we concluded that limiting geographies would facilitate the identification of a representative comparison group, which would improve CMS' ability to identify a suitable counterfactual for evaluating the impact of the GLOBE Model test.

We also considered starting the model with a greater number of geographic areas to include up to approximately 50 percent of Medicare Part B FFS beneficiaries in the model eligible beneficiary cohort instead of our proposal to test the model in geographic areas with approximately 25 percent of Medicare Part B FFS beneficiaries. We also considered an approach of initially testing the model in geographic areas with approximately 25 percent of Medicare Part B FFS beneficiaries and then, after initial monitoring observations were assessed, increasing the model beneficiary cohort to include up to approximately 50 percent of Medicare Part B FFS beneficiaries by including additional geographic areas. Under an approach where the number of included geographic areas would increase during the model performance period, we considered that CMS could update the table provided on the GLOBE Model website to include the complete list of GLOBE Model geographic areas by ZIP Code over time. We note that these alternatives would likely necessitate selection of the initial and potentially additional geographic areas at the same point, prior to model start and processes for including additional geographic areas. These approaches would have the benefit of enhancing the model evaluation as a random selection of approximately 50 percent of the Medicare FFS population would enable a 1:1 allocation of the treatment to comparison group.

We considered including the ZCTAs of U.S. territories among the geographic regions from which the randomly selected model geographic area would be selected.

We welcome comment on our proposal to use ZCTAs as the basis for the model geographic areas, exclude U.S. territories, and select the geographic area. We welcome comment on our proposal to test the model with geographic areas that would include approximately 25 percent of Medicare Part B FFS beneficiaries in the model beneficiary cohort and on whether CMS should test the model with an alternative approach that would include additional geographic areas and beneficiaries in the model as well as the processes that CMS should consider for such an approach.

G. Proposed Model Payment Test for GLOBE Model Drugs

In accordance with section 1847A(i) of the Act as codified in 42 CFR 427, CMS determines the rebate amount that manufacturers of Part B rebatable drugs owe to the Federal Supplementary Medical Insurance Trust Fund and computes adjusted beneficiary coinsurance and adjusted Medicare payment for Part B rebatable drugs as applicable. Under the GLOBE Model, we propose to test an alternative rebate calculation and an alternative calculation to adjust the beneficiary coinsurance and Medicare Part B payment for GLOBE Model drugs that are furnished to GLOBE Model beneficiaries. The alternative calculation would expand upon the current methodology by incorporating additional drug pricing information while ensuring that beneficiary coinsurance and net Medicare payment for a service would not exceed what they would be absent the model test.

We propose to base the alternative calculation on a per unit GLOBE Model benchmark that is described in section II.G.2. of this proposed rule. To test two methods for identifying a per unit GLOBE Model benchmark using different data sources, we propose that the per unit GLOBE Model benchmark for a GLOBE Model drug would be, subject to available information as determined by CMS (as described in section II.G.1. of this proposed rule), based on the greater of a per unit Method I GLOBE Model benchmark that reflects the lowest country-level price among a set of reference countries,⁹⁵ (as discussed in section II.G.2.a. of this proposed rule) or a per unit Method II

GLOBE Model benchmark that reflects the volume-weighted average of the manufacturer's net pricing for sales within a set of reference countries based on data voluntarily reported by the manufacturer (as discussed in section II.G.2.b. of this proposed rule), after applying an economic adjustment under each method.⁹⁶ In section II.G.1.e. of this proposed rule, we propose the criteria that would be applied to identify the set of reference countries for purposes of identifying the information that would be used, as available, by CMS to determine the per unit Method I GLOBE Model benchmark and the per unit Method II GLOBE Model benchmark. To the benchmark that is greater, in section II.G.3.a. and II.G.3.b. of this proposed rule, we propose to apply an “*applicable threshold percentage*” and an amount, “*add-on percentage amount*”, that would, in general, equal any add-on percentage included in the Medicare Part B payment limit under section 1847A(b) of the Act (which would, in general, be the same as the “*specified amount*” (as determined under 42 CFR 427.302(b))) to calculate a per unit GLOBE Model benchmark amount and then determine if a GLOBE Model rebate amount would apply. The alternative calculation would be structured such that the GLOBE Model rebate amount would not be less than the rebate amount (if any) determined under the Medicare Part B Drug Inflation Rebate Program as codified in 42 CFR part 427.

As discussed in section II.G.4.a. of this proposed rule, we propose that the per unit GLOBE Model rebate amount for an applicable calendar quarter would reflect the result of the alternative rebate calculation. That is, for a GLOBE Model drug, for an applicable calendar quarter, we propose that the per unit GLOBE model rebate amount would be the greater of: (1) the difference between the specified amount, as determined under 42 CFR 427.302(b), and the per unit GLOBE Model benchmark amount, as determined under 42 CFR 513.400(c); or (2) the difference between the specified amount determined under 42 CFR 427.302(b), and the inflation-adjusted payment amount determined under 42 CFR 427.302(g). In section II.G.4.b. of this proposed rule, we propose a methodology for identifying the included billing units of a GLOBE Model drug in the total GLOBE Model rebate amount calculation. In section

⁹⁴ Centers for Medicare & Medicaid Services. What's a MAC. Available at: <https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs/whats-mac>.

⁹⁵ Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug pricing information in the proposed GLOBE Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved and non-U.S.-approved products.

⁹⁶ The economic adjustment would be based on differences in gross domestic product and purchasing power between the U.S. and reference countries.

II.G.4.c. of this proposed rule, we propose that the total GLOBE Model rebate amount for a GLOBE Model drug during an applicable calendar quarter would be the product of the per unit GLOBE Model rebate amount of such drug, as determined under 42 CFR 513.510(a), and the total number of GLOBE Model billing units, as identified by CMS as set forth in 42 CFR 513.520. To facilitate the model test, we propose that the incremental GLOBE Model rebate amount for a GLOBE Model drug for an applicable calendar quarter would be the product of the incremental per unit GLOBE Model rebate amount of such drug, as determined under 42 CFR 513.510(b), and the total number of GLOBE Model billing units, as identified by CMS as set forth in 42 CFR 513.520. The incremental per unit GLOBE Model rebate amount would be the amount in excess of the per unit rebate amount calculated as set forth in 42 CFR 427.302. That is, as determined in 42 CFR 513.510(b) and discussed in section II.G.4.c. of this proposed rule, the incremental per unit GLOBE Model rebate amount would be an 'incremental amount' that taken together with the per unit rebate amount calculated as set forth in 42 CFR 427.302 would represent the per unit GLOBE Model rebate amount. To determine GLOBE Model billing units, in 42 CFR 513.520, CMS proposes to identify the number of billing units in accordance with 42 CFR 427.303(b) where, on the date of service, the beneficiary was identified by CMS as a GLOBE Model eligible beneficiary and for which Medicare Part B FFS made separate payment. We also propose, in section II.G.4.d. of this proposed rule, that the incremental GLOBE Model rebate amount may be reduced or adjusted in the same manner as described in 42 CFR 427 subparts E and F, if applicable, when a drug is currently in shortage or when there is a severe supply chain disruption, and/or through the reconciliation or suggestion of error process.

In section II.G.8. of this proposed rule, we present two alternative proposals, a combined approach and an incremental approach, for how CMS would provide rebate reports and reconciliation rebate reports to GLOBE Model participants, and a process for suggestion of error when GLOBE Model rebates are owed. Under the combined approach, CMS would delay Medicare Part B Drug Inflation Rebate Program invoicing for all manufacturers by up to two months and would provide a combined report (invoice) to all manufacturers of Part B rebatable drugs for both the Medicare

Part B Drug Inflation Rebate Program and the GLOBE Model. Under the incremental approach, CMS would use a separate invoicing process that would run approximately a month after the Medicare Part B Drug Inflation Rebate Program reports and would invoice manufacturers of GLOBE Model drugs for the total GLOBE Model rebate amount using the *incremental GLOBE Model rebate amount* and reconciling the portion of the total GLOBE Model rebate amount invoiced through the Medicare Part B Drug Inflation Rebate Program processes. We seek comment on these alternative approaches for reporting, invoicing, and reconciliation and intend to adopt only one approach for the model. CMS' intent is to establish an efficient approach that closely aligns with processes currently used by the Medicare Part B Drug Inflation Rebate Program and would be familiar to manufacturers of Part B rebatable drugs. Under these alternative approaches, we propose that GLOBE Model participants would have access to reports, submit a Suggestion of Error to CMS, and pay GLOBE Model rebate amounts based on the GLOBE Model's alternative calculation in the same manner, or substantially similar manner, as set forth in 42 CFR 427.504 with respect to the Medicare Part B Drug Inflation Rebate Program. In addition, in 42 CFR 513.740, we propose that the provisions for the deadline and process for payment of the rebate amount in 42 CFR 427.505 would apply to GLOBE Model rebate amounts in the same manner as they do to Part B drug rebate amounts that are calculated under 42 CFR 427.301. However, to align GLOBE Model rebate processes closely with the Medicare Part B Drug Inflation Rebate Program, we have identified the need to adjust the timing for providing reports and are proposing to use the Innovation Center's waiver authority to do so as discussed in section II.G.8. of this proposed rule.

We also propose that, in addition to other applicable authorities, the provisions for enforcement of manufacturer payment of rebate amounts of the Medicare Part B Drug Inflation Rebate Program and the implementing regulations at 42 CFR 427.600, regarding civil money penalties would apply to manufacturers of GLOBE Model drugs with respect to GLOBE Model rebate amounts.

The proposed GLOBE Model would also test alternative calculations to adjust the beneficiary coinsurance and Medicare Part B payment for separately payable units of GLOBE Model drugs that are furnished to GLOBE Model beneficiaries (that is, beneficiaries who

are on the GLOBE Model Eligible Beneficiary List as discussed in section II.C. of this proposed rule). As discussed in section II.G.7. of this proposed rule, we propose to use the alternative calculation for identifying the per unit GLOBE Model benchmark amount to identify the GLOBE Model beneficiary coinsurance that would be applied as a percent to the payment amount for a GLOBE Model drug for an applicable calendar quarter. To ensure that beneficiary financial liability for coinsurance amounts for GLOBE Model drugs under the GLOBE Model would not be more than it would be absent the model test, for a calendar quarter, we propose that CMS would compare a per unit GLOBE Model benchmark amount (that would be calculated in advance of the calendar quarter, with limited exceptions in cases of error, as determined by CMS, to the applicable inflation-adjusted payment amount as determined under 42 CFR 427.302(g) and the lesser of those amounts would be used in the computation of the GLOBE Model beneficiary coinsurance percentage and the GLOBE Model Medicare Part B FFS payment amount for separately payable units of the GLOBE Model drug furnished to GLOBE Model beneficiaries during the applicable calendar quarter. The GLOBE Model beneficiary coinsurance would only be applicable to separately payable units of GLOBE Model drugs that are furnished to the Medicare Part B FFS beneficiaries who are, for the date of service, on the GLOBE Model Eligible Beneficiary List in use by the Medicare claims processing systems on the date a claim was processed, as determined by CMS. When the GLOBE Model reduced beneficiary coinsurance applies to units of GLOBE Model drugs furnished to Medicare Part B FFS beneficiaries who are included in the GLOBE Model beneficiary cohort, the provider or supplier would reduce the amount of coinsurance charged to the beneficiary and the portion of the Medicare Part B allowed amount that would be payable by Medicare Part B would be adjusted upwards.

For a discussion on the proposed approach for the GLOBE Model monitoring and evaluation, we refer readers to sections II.L. and II.P. of this proposed rule, respectively.

1. Proposed International Drug Pricing Information Data Sources

This section of this proposed rule discusses the proposed international drug pricing information data sources and the international drug pricing information that CMS proposes to use, if available, to identify the per unit

Method I GLOBE Model benchmark, based on available data from existing data sources (as described in section II.G.2.a. of this proposed rule). This section of this proposed rule also discusses the proposed data and information that eligible manufacturers would have the option to voluntarily submit to CMS, which would, if submitted and determined to meet completeness criteria, be used to identify the per unit Method II GLOBE Model benchmark (as described in section II.G.2.b. of this proposed rule). We propose that the availability of data and information, its completeness, and use for purposes of the GLOBE Model would be determined solely by CMS. In section II.G.2.e. we discuss the proposed criteria and process CMS would use to identify the non-U.S. countries that would be included in the set of reference countries for the GLOBE Model for purposes of identifying international drug pricing information available in existing data sources and calculating the per unit Method I GLOBE Model benchmark (as described in section II.G.2.a. of this proposed rule) and the per unit Method II GLOBE Model benchmark (as described in section II.G.2.b. of this proposed rule).

a. Existing Data Sources for International Drug Pricing Information

To identify the per unit Method I GLOBE Model benchmark (as described in section II.G.2.a. of this proposed rule), we propose to rely on existing data sources available to CMS that contain international drug pricing information, including pricing information, sales, and/or volume data (for example, package size, and number of items or packages sold), as available, in order to optimize operational efficiency and inform the identification of the per unit GLOBE Model benchmark amount including in the absence of voluntarily submitted manufacturer net pricing data and information (which we propose to use to inform the identification of the per unit Method II GLOBE Model benchmark as described in section II.G.2.b. of this proposed rule). Within available data sources, sales and list prices may be based on ex-manufacturer prices (sometimes referred to as ex-factory price), that represent actual or calculated prices paid to the manufacturer by wholesalers and other distributors, retail prices, prices for other distribution channels, or a combination thereof. Data sources have proprietary collection, and projection methodologies to harmonize data across countries. For example, data sources may use proprietary adjustment factors

to facilitate comparison of different pricing level information or apply proprietary projection methodology to estimate data available for a sample of distribution channels to obtain a projected value for the entire country. Confidential manufacturer rebates would not likely be accounted for within these available data sources; therefore, existing sources for international drug sales data may overstate actual prices realized by manufacturers. On balance, we believe existing data sources are adequate for purposes of identifying country-level prices and a per unit Method I GLOBE Model benchmark (as described in section II.G.2.a. of this proposed rule), particularly because we are proposing that eligible manufacturers would have the option to voluntarily submit international drug net pricing data to CMS that could potentially be used instead to identify the per unit GLOBE Model benchmark.

We have assessed several existing data sources to determine the availability and sufficiency of international drug pricing information. These data sources include those made available by private companies, which may include data reported by manufacturers or data obtained through a review of publicly filed material by manufacturers in other countries or in the U.S. Specifically, we reviewed proprietary global pharmaceutical pricing data sources that include drug pricing data for a large diverse set of pharmaceutical products (that are the types of pharmaceutical products that could be covered under Medicare Part B) for more than 30 countries. These data sources vary with respect to the scope (such as products, manufacturer level, market level data, countries), and periodicity of updates (such as daily, monthly, quarterly). For example, IQVIA MIDAS⁹⁷ is an IQVIA proprietary information service which integrates IQVIA's national audits into a globally consistent view of the pharmaceutical market, and provides estimated product volumes of registered medicines, trends and market share through retail and non-retail channels. IQVIA MIDAS⁹⁸ includes detailed drug product information, such as drug

name, molecule, strength, dosage form, pack size, manufacturer, generic product classification (such as non-generic or generic), biologic classification (such as biosimilar or reference biological products), market information (such as country, distribution channel, the Anatomical Therapeutic Chemical (ATC) classification,⁹⁹ sales data, standard units, extended units, number of packs), pricing information (such as price per pack, price per unit, derived average list price), temporal information (such as month, quarter, year of sale), and other information.¹⁰⁰ IQVIA MIDAS is updated monthly and retains extensive historical data for 33 countries.

Another potential data source we assessed is GlobalData Pharmaceutical Prices (POLI)¹⁰¹ which includes three price levels (ex-manufacturer, wholesalers, and retail) for at least 80 countries at the pack level (pharmaceutical name, generic name, dosage form, strength and number of units). POLI includes drug product information (such as drug descriptor, molecule type, dosage form, strength, classification as brand or generic), and market information (such as ATC classification, therapy area, and geography). POLI is updated monthly and provides historic data since 2016. Eversana NAVLIN's Price & Access database,¹⁰² includes pricing data for more than 100 countries, as well as tools to compare international pricing information (specifically, pricing across

⁹⁹ For information about The World Health Organization's Anatomical Therapeutic Chemical classification see: <https://www.who.int/tools/atc-ddd-toolkit/atc-classification#~:text=In%20the%20Anatomical%20Therapeutic%20Chemical,groups%20at%20five%20different%20levels.>

¹⁰⁰ IQVIA national audits and IQVIA MIDAS reflect local industry standard source of pack prices, which may be list price or average invoice price, depending upon the country and the available information; they do not take into account rebates or clawbacks, details of which are normally confidential, and therefore these estimated prices do not reflect net prices realized by the manufacturers. Sales values reflected in these IQVIA audits are calculated by applying such relevant pricing to the product volume data collected for, and reflected in, such audits. In addition, to allow the national audit sales values to be viewed at a common sales level, MIDAS applies a single average industry margin to the locally reported values. Prices derived from MIDAS data are therefore estimates, and IQVIA cautions against using prices in MIDAS data as metrics in their own right.

¹⁰¹ GlobalData. Data Lake-Pharmaceutical Prices (POLI) Available at: <https://marketaccess.globaldata.com/product-solutions/data-lake-pharmaceutical-prices-poli/>.

¹⁰² NAVLIN by Eversana. Available at: <https://www.navlin.com/products/navlin-price-access-data.>

⁹⁷ The statements, findings, conclusions, views, and opinions contained and expressed in this proposed rule are based in part on data obtained under license from the following IQVIA information service(s): IQVIA MIDAS®. Copyright IQVIA. All Rights Reserved. The statements, findings, conclusions, views and opinions contained and expressed herein are not necessarily those of IQVIA or any of its affiliated or subsidiary entities.

⁹⁸ IQVIA MIDAS Overview. Available at: <https://www.iqvia.com/solutions/commercialization/data-and-information-management/midas.>

countries), and is another potential data source.

These data sources, if available, would likely provide adequate information to inform CMS' identification of a Method I GLOBE Model benchmark for the vast majority of proposed GLOBE Model drugs (as discussed in section II.G.2.a. of this proposed rule).

Another data source option we considered would be for CMS to construct price comparisons from public sources of each country. However, we believe this would be cumbersome and we may not have all the information necessary for CMS to routinely identify a Method I GLOBE Model benchmark for a broad set of proposed GLOBE Model drugs.

In 42 CFR 513.310(c), we propose to use one or more existing data sources for international drug pricing available to CMS to identify the per unit Method I GLOBE Model benchmark for a GLOBE Model drug. Specifically, we propose to use one or more data sources available to CMS at least 60 business days prior to the start of the first applicable calendar quarter for which the drug is a GLOBE Model drug to identify if the per unit Method I GLOBE Model benchmark is available. As proposed in 42 CFR 513.310(c)(1)(ii), such data sources would utilize a standardized method for identifying drugs across countries within the data source, such as using an internationally recognized method for identifying scientific and nonproprietary product names and a standard method for identifying dosage form, route of administration such as using an internationally recognized nomenclature for pharmaceutical forms like the New Form Code classification (that, at a minimum, distinguishes among injectable, oral, and other forms of a drug), and strength. For example, the data source might use the International Nonproprietary Names (INN), as applicable.¹⁰³ We are proposing that the data source must use a standardized method for identifying drug names, dosage forms, and route of administration because the process that CMS proposes to use to identify the country-level prices to identify the per unit Method I GLOBE Model benchmark requires mapping between the data source's method for identifying drug names, dosage forms and route of administration to the HCPCS Level II codes that are associated with GLOBE

Model drugs. We are proposing that the data source must use a standardized method for identifying strength because this could be used to identify the quantity of drug and the billing units. Further, we propose that the one or more data sources that we would use would contain international drug pricing information and the corresponding volume data (for example, number of items, packages, or units sold) or data sources with only pricing information, where applicable. We propose that the pricing information in the data sources would include sales data (which may be based on ex-manufacturer prices, sometimes referred to as ex-factory prices) that represent actual or calculated prices paid to the manufacturer by wholesalers and other distributors, or retail prices that represent actual or calculated sales for retail purchasers, or prices paid by other purchasers in the distribution channels (such pricing information must be expressed in U.S. currency. We also propose the data source would use a standard method based on regulatory approval pathways to identify U.S. originator drugs and international originator drugs (such as brand name products, reference listed drug, or reference products), and U.S. non-originator drugs and international non-originator drugs¹⁰⁴ (such as generics, biosimilars, biocomparable products, reference product equivalents, or off-patent products). In addition, we propose that the one or more data sources we would use must have mechanisms in place to maintain, update, and correct, if necessary, the data source on at least a quarterly basis. Further, we propose that the data sources we would use must be maintained by organizations that seek to limit the lag inherent in data to no more than 90 days from the end of the calendar quarter for which drug pricing information is compiled to the time that the organization makes such updates available to users of the data source. Based on CMS assessment of the available data sources, the current lag may be up to 90 days. We believe the limit of no more than 90 days provides sufficient time for organizations to collect data, perform data checks, and update their data sources, and for CMS to obtain and use the most current,

timely available data for the purposes of the GLOBE Model.

Whenever possible, to identify the per unit Method I GLOBE Model benchmark for a GLOBE Model drug, we propose to use international drug pricing information from two calendar quarters prior to the first applicable calendar quarter to which the total GLOBE Model rebate amount would apply since the ASP payment limits that apply to that calendar quarter (and are generally the basis for the specified amount set forth in 42 CFR 427.302(b)) are based on manufacturers' U.S. sales from two calendar quarters prior. For GLOBE Model drugs to be included on the GLOBE Model drug list for the first calendar quarter of performance year 1 (that is, the calendar quarter beginning October 1, 2026), as proposed in 42 CFR 513.130, CMS would use international drug pricing information from the second calendar quarter of 2026 (that is, the ASP calendar quarter beginning on April 1, 2026). In addition, except for extracted data used by CMS to identify the most recent per unit Method GLOBE Model benchmark from January 1, 2024 to December 31, 2024, we propose to use international drug pricing information from no earlier than the second calendar quarter of 2025 (that is, the ASP calendar quarter beginning on April 1, 2025) to minimize the possibility of having no international drug pricing information to calculate the per unit Method I GLOBE Model benchmark while limiting the possibility that historical data would not reasonably approximate international drug pricing information for the applicable ASP calendar quarter and mitigating the potential effect of manufacturers' limiting the availability of international drug pricing information during the GLOBE Model performance period. If international drug pricing information from two calendar quarters prior to the first applicable calendar quarter to which the total GLOBE Model rebate amount would apply are not used, we propose that CMS would use international drug pricing information from the most recent ASP calendar quarter for which data are available.

b. Proposed Hierarchy for Using Existing Data Sources

To identify available data sources for purposes of identifying the per unit Method I GLOBE Model benchmark for each GLOBE Model drug, we propose that CMS would use the following hierarchy that we propose to codify in 42 CFR 513.310(c)(2):

- A data source with drug specific sales and volume data for the applicable

¹⁰³ World Health Organization. International Nonproprietary Names Programme and Classification of Medical Products. International Nonproprietary Names (INN). Available at: <https://www.who.int/teams/health-product-and-policy-standards/inn>.

¹⁰⁴ Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug pricing information in the proposed GLOBE Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved and non-U.S.-approved products.

ASP calendar quarter from at least one country that is included in the set of reference countries identified by CMS in accordance with 42 CFR 513.310(b).

- Except for extracted data used by CMS to identify the most recent per unit Method GLOBE Model benchmark from January 1, 2024 to December 31, 2024, a data source with drug specific sales and volume data for any prior ASP calendar quarter beginning on or after April 1, 2025 from at least one country that is included in the set of reference countries identified by CMS in accordance with 42 CFR 513.310(b) when drug specific sales and volume data are not available for the applicable ASP calendar quarter from at least one country that is included in the set of reference countries identified by CMS in accordance with 42 CFR 513.310(b).

- The extracted data used by CMS to identify the most recent per unit Method I GLOBE Model benchmark available in a document posted on the GLOBE Model website. We note that could include a data source with drug specific sales and volume data from January 1, 2024, to December 31, 2024, from at least one country that is included in the set of reference countries identified by CMS in accordance with 42 CFR 513.310(b).

- A data source with drug specific ex-manufacturer price (sometimes referred to as ex-factory price) data for the applicable ASP calendar quarter from at least one country that is included in the set of reference countries identified by CMS in accordance with 42 CFR 513.310(b).

- A data source with drug specific list price data (for example, the price made available to wholesalers) for the applicable ASP calendar quarter from at least one country that is included in the set of reference countries identified by CMS in accordance with 42 CFR 513.310(b).

In cases when there is more than one data source meeting the requirements in 42 CFR 513.310(c)(2) for a GLOBE Model drug for a reference country, we propose to use the data source at the highest level of the hierarchy that contains information from the highest number of countries, and, if available, incorporates discounts, rebates, or other price concessions into its drug pricing information. Our proposed approach for using existing data sources would allow CMS to use different data sources for different GLOBE Model drugs over different quarters. We propose that CMS would select a data source and extract the data as available from that data source, and we would not make adjustments to account for differences between the data source selected and

other available data sources. For example, for GLOBE Model drug X, suppose we identify Data Source 1 that meets the requirements of 42 CFR 513.310(c)(2) where Data Source 1 contains sales and volume data for GLOBE Model drug X for the applicable ASP calendar quarter from 7 out of a total of 19 reference countries, Data Source 2 contains sales and volume data for GLOBE Model drug X for the applicable ASP calendar quarter from 8 reference countries, Data Source 3 contains sales and volume data from one quarter prior to the applicable ASP calendar quarter for GLOBE Model drug X from 9 reference countries, and Data Source 4 contains list price information for the applicable ASP calendar quarter from all included countries. In this scenario, in accordance with our proposed approach, we would use information solely from Data Source 2, and we would not use Data Sources 1, 3, or 4 for that applicable calendar quarter.

We note that in that scenario, if CMS were unable to identify a data source for international drug pricing information for GLOBE Model drug X for a reference country, the lowest per unit country-level price would be identified using the information available. That is, a country-level price for each of the reference countries would not be required and CMS would solely use the available information for as many reference countries as possible. Further, we would not combine data from different data sources to identify international drug pricing information for GLOBE Model drug X across countries.

c. Alternatives Considered for Using Existing Data Sources

In cases when there is more than one data source meeting the requirements in proposed 42 CFR 513.310(c)(3) for a GLOBE Model drug, or in cases when there is more than one data source meeting the requirements in proposed 42 CFR 513.310(c)(3) for a GLOBE Model drug and for the same number of countries, we considered two alternatives. Under one alternative, we would first identify the data source at the highest level of the data source hierarchy that has the most pricing information available and use the lowest value of the pricing information available within that data source even if international drug pricing information is available from other reference countries within another data source. We also considered using all the available data sources for a drug and calculating the average of the pricing information available across all the data sources.

Because these alternative approaches could result in cases where available international drug pricing information for a drug from a reference country would not be used or cases where different types of pricing information for a drug from a reference country would be combined, we are not proposing them at this time and may reconsider the potential value of these approaches based on feedback from interested parties and further information gathering. We also seek comments on these alternatives and how CMS could use the most comprehensive international pricing information available.

We are interested in better understanding the existing data sources for international drug pricing information that may be available to CMS and steps we could follow to best use such data sources for the GLOBE Model payment test. We welcome comments on the methods or processes CMS could consider when more than one existing data source is available at the highest level of the hierarchy to determine which data source is more comprehensive, as well as on how CMS might refine the hierarchy for potential use of more than one data source for a GLOBE Model drug or to incorporate new data sources that may become available during the GLOBE Model performance period.

d. Proposed Voluntary Submission of International Drug Net Pricing Data

Under the GLOBE Model, if a manufacturer elects to submit international drug net pricing data for a GLOBE Model drug, to be considered by CMS for identifying the *per unit Method II GLOBE benchmark*, we propose that the manufacturer would be required to execute a data agreement that must be effective prior to the manufacturer's first submission of voluntary international drug net pricing data. The data agreement would establish terms, conditions, and requirements, including data completeness and validity requirements, and compliance responsibilities. In 42 CFR 513.620(b), we propose that, once the data agreement is effective, it would remain applicable for the duration of the GLOBE Model unless either the manufacturer or CMS terminates the agreement. We considered having data agreements that were effective for a shorter duration such as one performance year or for one quarter of a performance year. However, we were concerned that allowing manufacturers to opt in and out of reporting for each quarter would potentially result in manufacturers choosing to report only if

the Method II benchmark would be higher than the Method I benchmark. Additionally, given the operational complexity associated with conducting reporting on a quarterly basis, CMS believes it would be less burdensome for CMS and manufacturers to enter one data agreement for the duration of the GLOBE model. Under the data agreement, manufacturers may make submissions for one or more GLOBE Model drugs for any applicable ASP calendar quarter. For each submission, we propose that the manufacturer must include “*applicable international analog*”, defined in 42 CFR 513.600 as a non-US analog whose scientific or nonproprietary name, dosage form, and route of administration (if applicable) align with a GLOBE Model drug and that are sold in one or more reference countries identified in 42 CFR 513.310(b) during the applicable ASP calendar quarter, excluding those identified in their respective country as a generic or biosimilar biological product according to the country’s own regulations.¹⁰⁵ We propose that manufacturers would use data that (1) represents the price of the international originator drugs; (2) have complete package size information; (3) have a strength; and (4) represents a dosage form that could be described by the GLOBE Model drug’s HCPCS Level II code descriptor, including route of administration (if applicable). For example, if the HCPCS Level II code descriptor includes the word injection, manufacturers would provide applicable international analog net pricing data for products that are administered by injection (for example, data for liquid and dry powder for injection products would be submitted whereas data for tablets that are administered orally would not be submitted). Further information on the manufacturer voluntary submission is described in section II.G.6. of this proposed rule. We also propose that manufacturers who elect the option to submit international drug net pricing data for an applicable calendar quarter during the GLOBE Model performance period would submit data that corresponds to the applicable ASP calendar quarter for that applicable calendar quarter. The applicable ASP calendar quarter is the calendar quarter two quarters prior to the applicable

calendar quarter. For example, for the proposed first applicable calendar quarter of model performance year 1 that would begin on October 1, 2026, the applicable ASP calendar quarter would be April 1, 2026, to June 30, 2026. We propose that submission of the data must occur no later than 30 days after the end of the applicable ASP calendar quarter. For example, for the proposed first applicable calendar quarter of performance year 1, manufacturers would have to submit data to CMS no later than July 30, 2026, for it to be considered submitted timely and, if determined to be acceptable by CMS, be considered by CMS for purposes of identifying the per unit Method II GLOBE Model benchmark. The manufacturer submitted data would include data for the entire applicable ASP calendar quarter (April 1, 2026 to June 30, 2026). This would mean manufacturers would have to establish an effective data agreement no later than July 30, 2026.

We propose that CMS would conduct a verification review for validity to determine whether the manufacturer’s submission meets the submission requirements as proposed in 42 CFR 513.610, which is necessary for CMS to determine whether the submission represents an “applicable submission” to identify a per unit Method II GLOBE Model benchmark. To conduct the verification review, CMS would—(1) review the data for completeness to ensure all required data elements are present; (2) verify the validity of the data, including verifying that the submitted sales and volume data and calculated international net pricing values are greater than zero and adhere to data format requirements (for example, values are numeric and are rounded at the third decimal place); and (3) as part of verifying the validity of the data, CMS will assess the extent to which the submission reflects international drug net pricing in the reference countries using all available data sources and information, including data sources used to identify the per unit Method I GLOBE Model benchmark and previous submissions by the manufacturer for the same GLOBE Model drug (as determined by CMS). For example, existing data shows U.S. ex-manufacturer prices are, on average, 278 percent higher than prices in other OECD countries, with U.S. originator drugs exhibiting an even greater difference of 422 percent. Therefore, we expect, on average, that reported international net prices for applicable international analogs would be, in general, on average, less than the

average sales price that is reported to CMS and below or similar to prices contained within existing international drug pricing information data sources. We also expect that manufacturer submitted international drug net pricing data for the applicable ASP calendar quarter would be within a reasonable margin of previous submissions by the manufacturer for the same set of applicable international analogs (if data exists), meaning we do not expect manufacturer submitted international drug net pricing data to increase beyond pricing in existing international data pricing information data sources. We welcome comments on other methods CMS could consider for verification. The proposed process for how manufacturers would submit international drug net pricing data to CMS is discussed in section II.G.6. of this proposed rule.

e. Proposed Criteria and Process for Identifying the Set of Reference Countries

In this section, we propose the criteria and process CMS would use to identify the non-U.S. countries that would be included in the set of reference countries for the GLOBE Model for purposes of identifying international drug pricing information available in existing data sources and calculating the per unit Method I GLOBE Model benchmark as described in section II.G.2.a. of this proposed rule and the per unit Method II GLOBE Model benchmark as described in section II.G.2.b. of this proposed rule.

Our proposed approach aims to select a large set of reference countries that are economically similar to the U.S., and have reasonably comparable purchasing power to the U.S. Specifically, we propose that CMS would identify a set of reference countries that are non-U.S. Organization for Economic Co-operation and Development members (that is, non-U.S. OECD-member countries)¹⁰⁶ as of October 1, 2025 with: (1) a real GDP per capita that is at least 60 percent of the U.S. real GDP per capita, as estimated and available in the Central Intelligence Agency (CIA) World Factbook;¹⁰⁷ and (2) an annual real GDP that is at least \$400 billion (as measured in U.S. dollars) as estimated and available in

¹⁰⁵ Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug pricing information in the proposed GLOBE Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved and non-U.S.-approved products.

¹⁰⁶ OECD. Members and Partners, available at: <https://www.oecd.org/en/about/members-partners.html>.

¹⁰⁷ The United States Central Intelligence Agency (CIA). The World Factbook, Country Comparisons—Real GDP per Capita. Available at: <https://www.cia.gov/the-world-factbook/field/real-gdp-per-capita/country-comparison/>.

the CIA World Factbook,¹⁰⁸ as determined by CMS. For each country, at 42 CFR 513.310(b) we propose to use the real GDP per capita and the annual real GDP based on purchasing power parity (PPP), as estimated and available in the CIA World Factbook for the year 2024 and available as of October 1, 2025. Further, while the CIA online World Factbook is updated daily, the underlying data such as GDP and PPP are reported no more frequently than annually, based on a July 1 mid-point. Therefore, our proposal to identify the set of reference countries using data available as of October 1, 2025, in the CIA World Factbook would mean that the set of reference countries would be identified using real GDP information from 2024. There are other existing sources for GDP per capita data besides the CIA World Factbook, including the World Bank,¹⁰⁹ and the International

Monetary Fund.¹¹⁰ Upon examining these sources, we noted that the GDP data across these sources are highly associated with one another. We propose using the CIA World Factbook as our source for real GDP per capita and real GDP data as it is issued by a U.S. government agency and includes data for countries that are economically comparable to the U.S. CMS seeks comments on the proposed data sources as well as other data sources considered.

Given that the identified set of countries are economically comparable to the U.S. based on real GDP per capita in 2024 and aggregate real GDP in 2024, we propose that the identified set of reference countries would remain the same throughout the 5-year GLOBE Model performance period, even if the CIA World Factbook shows that, based on more recent information, a country would no longer meet the criteria for the set of reference countries during any performance year of the model. We propose to codify the criteria that CMS would use once to identify the set of

reference countries for purposes of the GLOBE Model in 42 CFR 513.310(b).

To illustrate the potential set of reference countries that would result if the proposed criteria for identifying the set of reference countries are adopted in a final rule establishing the GLOBE Model, we applied the proposed criteria (as set forth in 42 CFR 513.310(b)) using CIA World Factbook data that were available on October 1, 2025 and identified the following potential set of reference countries: Australia, Austria, Belgium, Canada, Czechia, Denmark, France, Germany, Ireland, Israel, Italy, Japan, Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom (see Table 5). All 19 countries are economically comparable to the U.S. with real GDP per capita in 2024 (the most recent data available) falling between 63 and 170 percent of U.S. real GDP per capita in 2024 and aggregate real GDP in 2024 exceeding \$400 billion and are non-U.S. OECD member countries.

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¹⁰⁸ The United States Central Intelligence Agency (CIA). The World Factbook, Country Comparisons—Real GDP (Purchasing Power Parity). Available at: <https://www.cia.gov/the-world-factbook/field/real-gdp-purchasing-power-parity/country-comparison/>.

¹⁰⁹ The World Bank Group. Data. GDP per capita (current US\$). Available at: <https://data.worldbank.org/indicator/NY.GDP.PCAP.CD>.

¹¹⁰ International Monetary Fund. Datasets. Available at: <https://www.imf.org/external/datamapper/datasets/WEO>.

TABLE 5: ILLUSTRATIVE LIST OF US AND REFERENCE COUNTRIES GDP PER CAPITA AND ECONOMY SIZE

Countries	Annual Real GDP (\$billion)	Real GDP per Capita	Percent of U.S. Real GDP per Capita	GDP (PPP) Adjuster*
United States	\$25,676	\$75,500	100%	1.000
Canada	\$2,341	\$56,700	75%	1.332
France	\$3,732	\$54,500	72%	1.385
Germany	\$5,247	\$62,800	83%	1.202
Italy	\$3,133	\$53,100	70%	1.422
Japan	\$5,715	\$46,100	61%	1.638
United Kingdom	\$3,636	\$52,500	70%	1.438
Australia	\$1,635	\$60,100	80%	1.256
Korea, South	\$2,607	\$50,400	67%	1.498
Netherlands	\$1,276	\$70,900	94%	1.065
Spain	\$2,361	\$48,400	64%	1.560
Austria	\$581	\$63,300	84%	1.193
Belgium	\$749	\$63,100	84%	1.197
Czechia	\$522	\$48,000	64%	1.573
Ireland	\$621	\$115,300	153%	1.000*
Norway	\$508	\$91,100	121%	1.000*
Sweden	\$669	\$63,300	84%	1.193
Switzerland	\$741	\$82,000	109%	1.000*
Denmark	\$441	\$73,700	98%	1.024
Israel	\$472	\$47,300	63%	1.596

*Notes: Annual real GDP and real GDP per capita are based on PPP. The GDP (PPP) adjuster is calculated by dividing the U.S. real GDP per capita by the reference country's real GDP per capita for the same year; the GDP (PPP) adjuster is capped at 1 in cases where the ratio is below 1.0 (see section II.G.1.f. of this proposed rule for additional details). The GDP (PPP) adjuster is used to calculate the per unit Method I GLOBE Model benchmark and per unit Method II GLOBE Model benchmark (see section II.G.2. of this proposed rule).

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We believe that applying a minimum of 60 percent of the U.S. real GDP per capita and \$400 billion aggregate real GDP strikes a balance between having too low a real GDP per capita threshold and including data from countries with economies that are substantially different from the U.S. while also not having such a high real GDP per capita threshold that the set of reference countries would be very small. For example, a real GDP per capita threshold of 80 percent of the U.S. real GDP per capita could result in the set of reference countries only including 9 countries (Austria, Belgium, Denmark, Germany, Ireland, Netherlands, Norway, Sweden, and Switzerland). By contrast, a real GDP per capita threshold of 40 percent of the U.S. real GDP per capita

could result in a set of 23 reference countries including the 19 countries noted above as well as Chile, Poland, Portugal, and Turkey. We believe that our proposed approach would result in a set of reference countries that are economically similar, have reasonably comparable purchasing power to the U.S., and generally have existing international drug pricing information that is available.

We considered different criteria to identify economy size, including aggregate nominal and real GDP below \$400 billion, between \$400 billion and \$1 trillion, between \$1 and \$2 trillion, and greater than \$2 trillion. Lower aggregate real GDP thresholds would include more countries, while a threshold above real GDP \$2 trillion would result in a small number of

countries. For example, using the CIA World Factbook data for 2024 that were available on October 1, 2025, only eight non-U.S. OECD member countries—Canada, France, Germany, Italy, Japan, Spain, South Korea, and the United Kingdom—have economies larger than \$2 trillion in real terms. We also considered criteria based on intergovernmental political and economic forums like the Group of Seven (G7) countries that include Canada, France, Germany, Italy, Japan, and the United Kingdom, or the Group of 20 (G20).¹¹¹

¹¹¹ Non-US members of the G20 are Argentina, Australia, Brazil, Canada, China, France, Germany, India, Indonesia, Italy, Japan, Mexico, Russia, Saudi Arabia, South Africa, South Korea, Turkey, and the United Kingdom.

We also considered alternative approaches to our proposed criteria for identifying the set of reference countries. Specifically, we considered including all non-U.S. OECD member countries or including countries based on factors such as the World Health Organization (WHO) recognition as a Stringent Regulatory Authority (to be replaced by the WHO-listed authority or WLA) and intellectual property protections.^{112 113} We also considered including only countries that may represent large markets for drug manufacturers such as all countries in the European Union, Canada, Japan, and United Kingdom. However, we do not believe that these approaches would be as objective and predictable for purposes of identifying the GLOBE Model benchmark amount.

We also considered alternatives that would phase-in countries or would adjust the set of reference countries over time based on a defined set of characteristics, such as real GDP per capita or average drug prices. However, at this time, we believe that phasing in countries over time or adjusting the set of reference countries periodically would create instability within the model test and could cause potential negative impacts on GLOBE Model participants (for example, creating confusion regarding voluntary data submission), GLOBE Model beneficiaries (for example, greater variation in coinsurance from calendar quarter to calendar quarter) and the Medicare Part B program (for example, additional administrative costs that would reduce potential model savings).

Despite our concerns about potential negative impacts that could occur if the set of reference countries is not held constant during the 5-year GLOBE Model performance period as stated in this section of this proposed rule, we welcome comment on the potential benefits and drawbacks of establishing a threshold for removing a country from the set of reference countries (that CMS would identify using CIA World Factbook data available as of October 1, 2025 for the year 2024) at certain points during the model performance period. Specifically, we seek comment on the proposed criteria to select the list of reference countries and whether or not to revise the list of reference countries. We also welcome comments on the processes and timing that would be necessary to operationalize a change to

the set of reference countries that would minimize impacts on the model test.

f. Proposed Data and Methodology for Identifying the GDP (PPP) Adjuster

In this section we discuss the proposed data sources and calculation to identify the GDP (PPP) adjuster, which CMS proposes to codify at 42 CFR 513.430. Sections II.G.2. and II.G.6. of this proposed rule discuss the application of the GDP (PPP) adjuster in calculating the per unit GLOBE Model benchmark.

For each country in the set of reference countries identified as determined in 42 CFR 513.310(b) and discussed in section II.G.1.e. of this proposed rule, CMS proposes to use the most recent data on real GDP per capita based on purchasing power parity for a country available in the CIA World Factbook at the start of the applicable ASP calendar quarter (as defined in 42 CFR 513.20) as determined by CMS. CMS proposes to use the following calculation to determine the GDP (PPP) adjuster: divide the U.S. real GDP per capita by the country's real GDP per capita and round the result to the third decimal place. In calculating the GDP (PPP) adjuster CMS proposes to apply the following limitations: (1) the country's real GDP per capita and U.S. real GDP per capita data from the same year; and (2) the real GDP per capita used must be for the same year as the data used to calculate the per unit country-level price (as defined in 42 CFR 513.410), or the most recent earlier year available; and (3) in cases where the resulting ratio is less than 1.000, the GDP (PPP) adjuster is set to 1.000.

Table 5 presents an illustrative GDP (PPP) adjuster using 2024 data from the CIA World Factbook. As noted in section II.G.6. of this proposed rule, CMS intends to publish a supplemental document on the GLOBE Model website with details on which GDP (PPP) adjuster would be used for each applicable ASP calendar quarter. To establish the GDP (PPP) adjuster for each ASP calendar quarter, CMS would use the most recently available information from the CIA World Factbook for each reference country. CMS would publish this GDP (PPP)-adjuster at the beginning of each applicable calendar quarter.

2. Proposed Methodology To Identify the Per Unit GLOBE Model Benchmark

The proposed GLOBE Model would test alternative calculations to those used by CMS to determine the Part B inflation rebate amount that manufacturers of Part B rebatable drugs owe to the Medicare Supplementary Medical Insurance Trust Fund, adjusted beneficiary coinsurance, and the

adjusted Medicare payment for Part B rebatable drugs, as applicable, pursuant to section 1847A(i) of the Act as codified in 42 CFR 427. Under the GLOBE Model, these alternative calculations would expand upon the current methodology by incorporating additional drug pricing information (as described in section II.G.1. of this proposed rule) while ensuring that beneficiary coinsurance and net Medicare Part B payment would not exceed what they would be absent the model test. In this section of this proposed rule, we propose to test two alternative calculation approaches using different data sources for international drug pricing information and methods to identify the per unit GLOBE Model benchmark. Specifically, we propose that, subject to available information as determined by CMS, the per unit GLOBE Model benchmark for a GLOBE Model drug for an applicable quarter during the model performance period would be based on the greater of—(1) a “*per unit Method I GLOBE Model benchmark*” that would reflect the GDP (PPP) adjusted¹¹⁴ lowest country-level price among a set of reference countries at a baseline using existing data sources for international drug pricing information for the applicable ASP calendar quarter as available to and calculated by CMS (this benchmark would be identified by CMS for the first applicable calendar quarter for the GLOBE Model drug and remains in place for each applicable calendar quarter thereafter until the end of the model performance period, as proposed in section II.G.2.a. of this proposed rule; or (2) a “*per unit Method II GLOBE Model benchmark*” that would reflect the volume-weighted average of the GDP (PPP) adjusted manufacturer's international drug net pricing for sales among a set of reference countries for the applicable ASP calendar quarter based on data calculated and voluntarily reported by eligible manufacturers to CMS on a quarterly basis (this benchmark would only be available and identified by CMS if acceptable data was submitted by all manufacturers of the GLOBE Model drug, as determined by CMS), as proposed in section II.G.2.b. of this proposed rule.

As further described in section II.G.2.a. of this proposed rule, to identify the *per unit Method I GLOBE Model benchmark* and determine if such benchmark is available for purposes of identifying the *per unit GLOBE Model benchmark* for a GLOBE Model drug, we

¹¹² World Health Organization. WHO-Listed Authority (WLA). Available at: <https://www.who.int/initiatives/who-listed-authority-reg-authorities>.

¹¹³ World Health Organization. Intellectual Property and Trade. WHO Response. Available at: https://www.who.int/health-topics/intellectual-property#tab=tab_2.

¹¹⁴ GDP (PPP) means purchasing power parity (PPP)-adjusted per capita gross domestic product (GDP).

propose that, in general, CMS would follow these steps (subject to data availability): identify available international drug pricing information for the set of reference countries for the first applicable ASP calendar quarter (or prior calendar quarter, if necessary) for which the drug is a GLOBE Model drug; apply data checks; convert the available international drug pricing information to align with the HCPCS Level II code long descriptor associated with the GLOBE Model drug; identify per unit GDP (PPP) adjusted country-level prices using the applicable methodology for the available international drug pricing information for a country (for example, calculating a volume-weighted average per unit price when pricing and volume data are available or calculating an average per unit price when pricing data are available but volume data are not available in the selected data source); and identify the lowest per unit GDP (PPP) adjusted country-level price as the *per unit Method I GLOBE Model benchmark*. The results of the interim calculation steps would be rounded to the fifth decimal place and the last step would be rounded to the third decimal place.

As further described in section II.G.2.b. of this proposed rule, to identify the *per unit Method II GLOBE Model benchmark* and determine if such benchmark is available for purposes of identifying the *per unit GLOBE Model benchmark*, we propose that, in general, CMS would follow these steps for a GLOBE Model drug for each applicable calendar quarter (subject to data availability): identify voluntary manufacturer-submitted international drug net pricing data that was timely submitted and meets requirements for completeness and validity (as set forth in 42 CFR 513.610 and described in section II.G.6. of this proposed rule); identify the volume-weighted average per unit price as the *per unit Method II GLOBE Model benchmark*. As set forth in 42 CFR 513.420, the manufacturer across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit data element (further discussed in section II.G.6. of this proposed rule) would be calculated by the manufacturer and would be rounded to the third decimal place prior to being submitted to CMS.¹¹⁵ As discussed in section II.G.6. of this

proposed rule, CMS is proposing that manufacturers would have two data submission options—streamlined and limited—for the international drug net pricing data that would be voluntarily submitted. Refer to section II.G.6. of this proposed rule for additional details on the two manufacturer data submission options.

In 42 CFR 513.410, we propose that, prior to model start in accordance with proposed 42 CFR 513.410, CMS would identify the per unit Method I GLOBE Model benchmark for each GLOBE Model drug for the first applicable calendar quarter of performance year 1. These benchmarks would remain in place until the end of the model performance period. Similarly, subsequently, for each Part B rebatable drug that becomes a GLOBE Model drug during the performance period, CMS would identify the per unit Method I GLOBE Model benchmark for the first applicable calendar quarter for which the drug is a GLOBE Model drug and that benchmark would remain in place for the remaining applicable calendar quarters until the end of the model. Thus, quarterly for each GLOBE Model drug, after CMS would identify the *per unit Method I GLOBE Model benchmark* (as previously calculated at baseline, if available) and the *per unit Method II GLOBE Model benchmark* (as most recently calculated, if available), CMS would compare the *per unit Method I GLOBE Model benchmark* and the *per unit Method II GLOBE Model benchmark* to identify which is greater; the greater of the two would be identified as the *per unit GLOBE Model benchmark* for the GLOBE Model drug for the applicable calendar quarter. If only the *per unit Method I GLOBE Model benchmark* is available for the GLOBE Model drug (manufacturer has not submitted international drug net pricing data), then the *per unit Method I GLOBE Model benchmark* becomes the *per unit GLOBE Model benchmark* for the GLOBE Model drug for the applicable calendar quarter.

As discussed in section II.G.3. of this proposed rule, we propose how CMS would use the identified *per unit GLOBE Model benchmark* to calculate the *per unit GLOBE Model benchmark amount* for the GLOBE Model drug for that applicable calendar quarter which would be used to calculate the alternative rebate amounts, coinsurance adjustments, and adjusted Medicare payments to providers.

We believe that our proposed approach to identify the *per unit Method I GLOBE Model benchmark* for a GLOBE Model drug once, based on available international drug pricing

information, is necessary to protect the integrity of the model test and minimize corresponding impacts if the international drug pricing information in available data sources become artificially inflated by shifts in manufacturers' pricing and rebate practices, such as a shift to higher prices along with greater rebates that do not change the net pricing realized by manufacturers. Given the potential ease with which available international drug pricing information could be potentially manipulated by manufacturers by changing their pricing and rebate strategies and/or by taking actions that would restrict data sources' ability to source or update international drug pricing information in a manner that represents actual prices and given that such behavioral change would impede CMS' ability to test the model, we believe it is essential to establish the *per unit Method I GLOBE Model benchmark* once at a baseline (at the time the drug enters the model) and use that benchmark for the duration of the GLOBE Model.

Therefore, under our proposal, prior to model start in accordance with proposed 42 CFR 513.410, CMS would identify the *per unit Method I GLOBE Model benchmark* for each GLOBE Model drug for the first applicable calendar quarter of performance year 1. These benchmarks would remain in place for the duration of the model. Similarly, subsequently, for each Part B rebatable drug that becomes a GLOBE Model drug during the performance period, CMS would identify the *per unit Method I GLOBE Model benchmark* for the first applicable calendar quarter for which the drug is a GLOBE Model drug and that benchmark would remain in place for the remaining applicable calendar quarters until the end of the model.

a. Proposed Methodology To Identify the Per Unit Method I GLOBE Model Benchmark Using Existing Data Sources

In this section of this proposed rule, we propose a methodology that CMS would use to identify the *per unit Method I GLOBE Model benchmark* for a GLOBE Model drug for the first applicable calendar quarter that the Part B rebatable drug is a GLOBE Model drug using existing data sources that are described in section II.G.1. of this proposed rule. As proposed in section II.G.1.b. of this proposed rule, CMS would use available international drug pricing information data sources in accordance with the proposed hierarchy to select the data source used to identify a per unit country-level price for each country that is included in the set of

¹¹⁵ When there is more than one manufacturer submission for a GLOBE Model drug for an applicable calendar quarter, CMS proposes to calculate a volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit using data across all of the applicable submissions using the steps described in section II.G.2.b. of this proposed rule.

reference countries (as specified in 42 CFR 513.310(b)).

Specifically, we propose that CMS would first identify available data sources, available to CMS at least 60 business days prior to the start of the applicable calendar quarter, meeting the requirements in proposed 42 CFR 513.310(c), that have international drug pricing information for the scientific or nonproprietary name for the GLOBE Model drug for the applicable ASP calendar quarter for any country that is included in the set of reference countries identified in proposed 42 CFR 513.310(b). Then for each country that is included in the set of reference countries, CMS would select a data source at the highest level of the hierarchy as available, extract international drug pricing information for the scientific or nonproprietary name for the GLOBE Model drug, and using available data identify a per unit country-level price or determine that a per unit country-level price was unavailable for that reference country.

To select a data source at the highest level of the hierarchy as available and identify available international drug pricing data for the GLOBE Model drug, we propose that CMS would align the GLOBE Model drug's HCPCS Level II code long description (including dosage form and if applicable, route of administration) with the data sources' standardized method for identifying scientific names or nonproprietary names and dosage forms, as applicable. CMS would then extract available drug pricing information for that country from the selected international drug pricing information data source. We propose that CMS would extract and use data that, as determined by CMS, (1) represent the price of a U.S. originator drug or international originator drug (as applicable for data for a country); (2) have complete package size information; (3) represent scientific or nonproprietary name and dosage form that could be described by the GLOBE Model drug's HCPCS Level II code descriptor, including route of administration (if applicable); and (4) have strength data.¹¹⁶ We propose to only extract and use data for dosage form that could be described by the GLOBE Model drug's HCPCS Level II code long descriptor (as determined by CMS) because a HCPCS Level II code

may only describe drug products that are a certain type of formulation, such as short-acting intravenously administered drug products, and a data source's standardized method for drug names could apply more broadly such that a different formulation, such as a long-acting suspension for intramuscular injection, might be extracted if our proposed limitation was not adopted. For example, we would examine the data source's methods for describing dosage form and only extract data where the description is complete and clear, as determined by CMS. We would also examine the data source's methods for describing products in terms of being sold as a U.S. originator drug, international originator drug, or other indicator that would allow CMS to not extract and use pricing information for products that are identified as generic or biosimilar biological products.

To avoid unintentionally using extracted pricing information for drug products that do not align with the GLOBE Model drug's HCPCS Level II code descriptor, we would apply data checks to ensure that the extracted data aligns with the HCPCS Level II code descriptor for the GLOBE Model drug and information about formulations and package sizes sold. Based on our experience using existing international drug pricing information data sources, we propose to perform additional data checks to identify and discard extracted data when the sales or volume data are not greater than zero or the product information (for example, product strength or package size) is inconsistent or not verifiable with available product labeling or product approval information for the GLOBE Model drug. CMS proposes to exclude these records because these records could inappropriately contribute to the calculation of country-level prices.

In addition, we propose to make adjustments to align volume data with the HCPCS Level II code dosage descriptor, when necessary, as determined by CMS. For example, if we find that a data source from which we obtain international drug pricing information makes adjustments for overfill, we would make adjustments to the data that we extract from such source so that the extracted data would be used in a manner that is comparable to how CMS uses ASP data to calculate payment limits. In these cases, we propose to identify the quantity of drug without counting overfill based on the package labeling or other documentation related to product licensing within a country. There could be other cases where we may find it

necessary to make adjustments to align the extracted data with a HCPCS Level II code descriptor for a GLOBE Model drug. For example, there may be cases where a selected data source shows package size information that is standardized (for example, "per each" which may not clearly distinguish the quantity of drug) or inconsistent with a manufacturer's publicly available information that describes their drug product or the amount of active drug in a presentation level. In such cases where we confirm a difference and an appropriate conversion method, we would make adjustments in how the pricing, sales and volume data are associated with the HCPCS Level II code descriptor, as necessary, before calculating the country-level price, such as limiting the number of HCPCS billing units assigned. HCPCS billing units, as defined in 42 CFR 513.20, are the standardized measurement quantities (such as milligrams, milliliters, or individual items) used to determine how medical services, procedures, supplies, and drugs are quantified and billed for reimbursement under the Healthcare Common Procedure Coding System, where the billing quantity is calculated by dividing the total amount administered or provided by the unit of measurement defined for that specific HCPCS Level II code. For the purposes of the GLOBE Model, this can be determined by dividing the quantity of drug in the package by the HCPCS dosage (quantity of drug represented in one HCPCS billing unit, which is the identifiable quantity of a drug or biological product associated with a billing and payment code (for example, a HCPCS Level II code), as established by CMS). Based on our experience, we believe that such cases would be uncommon, and, in most cases, the appropriate conversion would be straightforward. We note that there could be additional cases when adjustments would be necessary if international drug pricing data sources that are available show prices, sales or volume data that are inconsistent with other reliable data sources (for example, product information available on manufacturers' websites), include multiple ingredients for a single drug product and the data source presents information in a different manner from the HCPCS Level II code descriptor, or are in error (for example, the package size represents the maximum volume of a vial instead of the volume or quantity of drug in a package as indicated in product labeling).

In addition, to carefully align extracted data with the HCPCS Level II

¹¹⁶ Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug pricing information in the proposed GLOBE Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved and non-U.S.-approved products.

code for a GLOBE Model drug, CMS would assess whether there are differences in the international pricing information attributed to data source coding or country-specific considerations to determine whether the available international pricing information consistently and accurately aligns with the HCPCS Level II code long descriptor. An example of a data coding difference that CMS would consider equivalent is if some available international pricing information records describe the packaging as a disposable vial in some countries but in others, the packaging is described as a single-dose vial in other records. Because disposable vials are single-dose vials, in this case, CMS would determine that disposable vials and single-dose vials are equivalent packaging and would not consider such variations to be inconsistent with product information. An example of country-specific considerations that CMS would take into account is differences in drug naming standards across countries. For example, although not a GLOBE Model drug, in the U.S. and Japan, acetaminophen is the scientific or nonproprietary name while in most other countries, instead of being called acetaminophen, it is referred to as paracetamol. In this type of case, CMS would consider acetaminophen and paracetamol equivalent drugs when a data source's standardized method for identifying scientific names or nonproprietary names treats them as equivalent or alternative names.

To further avoid the potential that some international drug pricing information available in existing data sources may not represent actual prices and, if included in the calculation of country-level prices, could result in a per unit country-level price that would not be a reasonable benchmark, at 42 CFR 513.410(a)(4)(i)(A) we propose to remove pricing information at the dosage form and strength level for a country that falls below 5 percent of the average price in the U.S. Specifically, prior to calculating the per unit country-level price, CMS would calculate an average price for a reference country only using pricing information for the same scientific or nonproprietary name, dosage form, and strength using extracted international drug pricing information (that was not discarded due to data checks). If the resulting average price for a country for a dosage form and strength falls below 5 percent of the average U.S. price for the scientific or nonproprietary name (across all dosage forms and strength), CMS would remove the pricing information for that dosage

form and strength and would not use such data to calculate the per unit country-level price.

For purposes of this step, which would compare and then remove certain pricing information from the calculation of per unit country-level prices for the Method I alternative calculation approach, CMS proposes to identify an "average U.S. price" using pricing information from the selected data source used for the reference country for the applicable ASP calendar quarter, if available, otherwise CMS would use the most recently published Medicare Part B payment limit (minus the add-on amount, that is, in general 100 percent ASP) for the HCPCS Level II code for the GLOBE Model drug for the calendar quarter *before* the applicable ASP calendar quarter. Because existing data sources for international drug pricing information have a unique approach for presenting drug pricing information and for making data within the data source useful for cross-country comparison, we believe that, if available, using drug pricing information for the applicable ASP calendar quarter that would be extracted from the same data source for both the reference country and the U.S. would be a more consistent and appropriate approach for this proposed purpose than using available ASP-based Medicare payment limit information, which, given time limitations, would be for a prior calendar quarter. Nevertheless, if the selected data source for the reference country did not contain available U.S. pricing information for the GLOBE Model drug, we believe that using available ASP data would be a reasonable alternative and would be suitable for purposes of removing pricing information that is low and may not reflect actual prices for a dosage form and strength.

We considered several alternatives, including not proposing to remove potentially inappropriately low pricing information, only using U.S. pricing information from external data sources, and applying a higher threshold (for example, removing pricing information that would fall below 10 percent of the average price in the U.S.). Using available international drug pricing information, we estimate that a 5 percent threshold, on average, could raise the benchmark about 1 percent overall. For a few potential GLOBE Model drugs, the impact would raise the benchmark to a more reasonable level and would still likely result in a country-level price for a reference country being available. At a 10 percent threshold level, we observed that reference country pricing information

that appears consistent with U.S. pricing information would be removed which suggests that a lower threshold would be more appropriate. We also considered whether to compare reference country pricing information at the country level across all products regardless of dosage forms and strengths. This approach was more likely to result in a country-level price being unavailable, due to data for one dosage form and strength impacting the overall average price for all dosage forms and strengths when the data were combined.

For a GLOBE Model drug where CMS has selected a data source and extracted available international drug pricing information for an international drug for a country that is included in the set of reference countries, we propose that CMS would use the following steps to identify a per unit country-level price by country, apply the GDP (PPP) adjuster (as determined pursuant to 43 CFR 513.430) and identify the lowest per unit GDP (PPP) adjusted country-level price as the *per unit Method I GLOBE Model benchmark*:

Step 1: Apply data checks (as described above and in proposed 42 CFR 513.410(a)(2)) and discard or adjust data as applicable as determined by CMS.

Step 2: Convert the volume data to the unit of measurement delineated in the HCPCS Level II code descriptor (for example, mg, ml, mcg, etc.), as applicable, using volume and strength information as proposed in 42 CFR 513.410(a)(3). Note that volume data includes both information about the quantity of drug in the product packaging and, when available, the amount of sales.

Step 3: Adjust the volume data (as proposed in 42 CFR 513.410(a)(3)(i)), as applicable, before converting the volume data to the unit of measurement delineated in the GLOBE Model drug's HCPCS Level II code descriptor when the data source shows the package size for a presentation level that is inconsistent with the manufacturer's information about that product, as determined by CMS.

Step 4: Limit the number of HCPCS billing units (as proposed in 42 CFR 513.410(a)(3)(ii)) when—

- The available information (such as package labeling) indicates a limited quantity of drug to be used from the presentation level; and
- Depending on the HCPCS Level II code description, the HCPCS dosage is per therapeutic dose, per dose, or per treatment.

Step 5: By country, identify the per unit country-level price using the calculation that is applicable.

a. If an international drug pricing information data source with sales and volume data is used, the applicable calculation is as follows (as proposed in 42 CFR 513.410(a)(4)(i)):

(1) CMS removes pricing information at the dosage form and strength level for a country that falls below 5 percent of the average price in the U.S. as set forth in 42 CFR 513.410(d).

(2) Using remaining data, CMS sums the adjusted volume data for the presentation levels for the applicable international analog (as specified in 42 CFR 513.600).

(3) Using remaining data, CMS sums the total sales for the presentation levels for the applicable international analog (as specified in 42 CFR 513.600) (that remain after performing the data checks).

(4) CMS divides the sum determined in Step 5a.(3) by the sum determined in Step 5a.(2), resulting in an average country-level price per unit, where the unit is the same unit delineated in the HCPCS Level II code descriptor.

b. If an international drug pricing information data source with ex-manufacturer or list prices is used (that is, the data source does not contain available volume data and the pricing data is a positive value (note that data that have missing, negative, or zero values would be discarded by data checks)), the applicable calculation is as follows (as proposed in 42 CFR 513.410(a)(4)(ii)):

(1) For each extracted ex-manufacturer or list price, CMS calculates the number of HCPCS billing units in the presentation level by dividing the quantity of drug in the presentation level by the quantity of drug represented in the HCPCS dosage form from the HCPCS Level II code descriptor.

(2) CMS divides the ex-manufacturer or list price, as applicable, by the number of HCPCS billing units in the presentation level, resulting in a price per unit where the unit is the same unit delineated in the HCPCS Level II code descriptor.

(3) CMS removes pricing information at the dosage form and strength level for a country that falls below 5 percent of the average price in the U.S. as set forth in 42 CFR 513.410(d)(2).

(4) CMS calculates the sum of the price per unit calculated in Step 5b.(2) for each ex-manufacturer or list price that was identified as available and not removed in step 5b.(3).

(5) CMS divides the sum calculated in Step 5b.(4) by the number of ex-

manufacturer or list prices that were summed in Step 5b.(4), resulting in an average country-level price per unit where the unit is the same unit delineated in the HCPCS Level II code descriptor.

Step 6: Calculate the per unit GDP (PPP) adjusted country-level price by multiplying the average per unit country-level price calculated in Step 5 by the applicable GDP (PPP) adjuster for such country as set forth in 43 CFR 513.430 (and illustrated in Table 5) and round the result at the fifth decimal place.

Step 7: After identifying the available per unit GDP (PPP) adjusted country-level price by country, we propose that CMS would identify the lowest per unit GDP (PPP) adjusted country-level price, round that amount at the third decimal place, and identify the result as the per unit Method I GLOBE Model benchmark.

In developing our proposal to base the per unit Method I GLOBE Model benchmark on the identified lowest per unit GDP (PPP) adjusted country-level price we considered that a 2024 analysis comparing drug prices in the U.S. and other countries concluded that U.S. prices for brand drugs were at least 3.22 times as high as prices in OECD countries. This study did not account for economic differences across markets. We believe that testing this model by selecting the lowest per unit GDP (PPP) adjusted country-level price would more reasonably align the per unit Method I GLOBE Model benchmark with both the sum of beneficiary coinsurance amounts and net Medicare spending amounts for GLOBE Model drugs under the model and international prices for GLOBE Model drugs, which would represent an alternative Part B inflation rebate amount calculation that could reduce access barriers to GLOBE Model drugs and improve quality of care for beneficiaries with deficits in care and generate potential savings for the Medicare program and such beneficiaries. As such, we believe that the proposed GLOBE Model fits within the statutory authority under section 1115A of the Act which authorized the Secretary to test models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare beneficiaries.

CMS believes that using the lowest GDP (PPP) adjusted country-level price after applying data checks that would remove pricing information at the dosage form and strength level for a country that falls below at least 5 percent of prices in the U.S. would more closely represent the actual net prices for the drug when available existing

international drug pricing information data sources are used because these data sources may not include pricing information that reflects all price concessions. Further, the lowest country-level price, when volume data is available from existing international drug pricing information data sources, corresponds to how much of that country's sales volume is sold at that price. CMS considered using an across country average instead of the lowest country-level price. However, calculating an across country average of prices that does not represent actual prices paid for a GLOBE Model drug in the reference countries would not closely reflect the typical price in a country, particularly considering a result that would include data that was GDP (PPP) adjusted.

CMS also considered using the *n* lowest country-level price or the average of the *n* lowest GDP (PPP) adjusted country-level prices. As noted above, these methods do not closely represent the actual price of the drug and the corresponding volume. We also considered an alternative approach to identify the per unit Method I GLOBE Model benchmark that would involve applying a gross to net sales estimate in aggregate to available international drug pricing information. However, gross to net sales data is generally not publicly available at the drug level making this approach impractical for CMS to test and would not yield a transparent benchmark metric.

In our proposed methodology to determine the per unit Method I GLOBE Model benchmark amount, we opted to adjust the country-level prices to account for economic differences among countries, such as GDP per capita, prior to the comparison of the available country-level prices to identify the lowest country-level price for a GLOBE Model drug. We believe that adjusting a single country-level price using a GDP (PPP) adjuster is reasonable. Specifically, given that the reference countries are economically comparable to the U.S., we would expect that adjusting for country wealth differences based on PPP adjusted GDP would more likely result in appropriate international pricing information that align with other country-specific dynamics.

We seek comment on our proposed approach and steps to identify the per unit Method I GLOBE Model benchmark once in advance of the first applicable calendar quarter for the GLOBE Model drug and potential alternative approaches, including available data sources, methods for identifying an international pricing benchmark using existing international drug pricing

information, and ways to use such information to closely represent actual prices of a drug in reference countries. We also seek comment on whether we should consider data sources that report only in local currency, which could require CMS to perform a currency conversion in addition to a GDP (PPP) adjustment. We also seek comment on our proposal to apply a GDP (PPP) adjustment, including the extent to which it may be appropriate to make any adjustments based on other factors not considered in this proposed rule.

b. Proposed Methodology for Identifying the Per Unit Method II GLOBE Model Benchmark Using Manufacturer Submitted Data

In this section of this proposed rule, we propose a methodology that CMS would use to identify the *per unit Method II GLOBE Model benchmark* for a GLOBE Model drug for an applicable calendar quarter using voluntarily manufacturer-submitted international drug net pricing data (as described in section II.G.2.b. of this proposed rule) when such data is available and meets acceptance criteria (as described in section II.G.6. of this proposed rule), as determined by CMS.

To identify available manufacturer-submitted international drug net pricing data for a GLOBE Model drug, we propose that CMS would use accepted manufacturer-submitted international drug net pricing data (that is, an “*applicable submission*” for a GLOBE Model drug as set forth in 42 CFR 513.610) for an applicable ASP calendar quarter that aligns with the applicable calendar quarter and the GLOBE Model drug’s HCPCS Level II code long description (including scientific or nonproprietary name, dosage form, and route of administration (if applicable)).

We propose to only use data for dosage forms that can be described by the GLOBE Model drug’s HCPCS Level II code long descriptor (as determined by CMS) because a HCPCS Level II code may only describe drug products that are a certain type of formulation, such as short-acting intravenously administered drug products, and manufacturer-submitted international drug net pricing data for an international drug could apply more broadly such that information for a different formulation, such as a long-acting suspension for intramuscular injection, might be available and used if our proposed limitation was not adopted. To avoid unintentionally using data for formulations that do not align with the GLOBE Model drug’s HCPCS Level II code descriptor, we would apply data checks to ensure that the

accepted manufacturer-submitted international drug net pricing data aligns with the HCPCS Level II code descriptor for the GLOBE Model drug.

Because manufacturers would submit net pricing data at the HCPCS Level II code billing unit level and would not include overfill in the net pricing data and because applicable submissions would meet a completeness and validity check, we do not foresee the need to make adjustments to the manufacturer-submitted international drug net pricing data for a GLOBE Model drug.

Because we are proposing that manufacturers have the option to submit international drug net pricing data for a GLOBE Model drug and we anticipate the potential situation where CMS would not identify available data, in such cases, we propose that, in the absence of available manufacturer-submitted net pricing information for a GLOBE Model drug for an applicable ASP calendar quarter, CMS would identify that the *per unit Method II GLOBE Model benchmark* was unavailable for an applicable calendar quarter.

Therefore, when there is one manufacturer submission of international drug net pricing data for a GLOBE Model drug for an applicable calendar quarter, we propose that the *across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit* data element (as defined in 42 CFR 513.20 and further discussed in section II.G.6. of this proposed rule), submitted by the manufacturer and accepted by CMS according to subpart G, would be identified as the *per unit Method II GLOBE Model benchmark*. Further, we propose that, when there is more than one manufacturer submission of international drug net pricing data for a GLOBE Model drug for an applicable calendar quarter, we propose to calculate a volume-weighted average using data across all of the applicable submissions. For example, when a manufacturer and a repackager submit international drug net pricing data and CMS accepts both manufacturer submissions, CMS would calculate a volume-weighted average using the *across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit* data elements and the volume data element (that is submitted in HCPCS billing units). Specifically, we propose that CMS would apply the following steps:

Step 1: Separately, for each applicable submission, CMS multiplies the *across country volume-weighted average GDP (PPP) adjusted net price per HCPCS*

billing unit by the sum of the *volume in billing units*.

Step 2: CMS sums the amounts calculated in Step 1.

Step 3: CMS calculates the total volume by summing the billing units across all applicable submissions.

Step 4: CMS divides the sum calculated in Step 2 by the total volume calculated in Step 3. The resulting volume-weighted average would be rounded at the third decimal place and would be identified as the *per unit Method II GLOBE Model benchmark*.

However, we also propose that when a manufacturer submission for an applicable calendar quarter as set forth in 42 CFR 513.20 is either not accepted by CMS as set forth in 42 CFR 513.610 or was not submitted by all manufacturers of the GLOBE Model drug, CMS would identify that the *per unit Method II GLOBE Model benchmark* is unavailable for such applicable calendar quarter. That is, when there is more than one manufacturer of a GLOBE Model drug, all manufacturers of such GLOBE Model drug would have to voluntarily submit net pricing data for the applicable ASP calendar quarter and each of such data submissions would have to be acceptable (as per 42 CFR 513.400(b)(3)) in order for CMS to identify a *per unit Method II GLOBE Model benchmark*.

In cases where CMS does not identify a *per unit Method II GLOBE Model benchmark*, the *per unit GLOBE Model benchmark* would only be available if a *per unit Method I GLOBE Model benchmark* was available.

In our proposed methodology to determine the *per unit Method II GLOBE Model benchmark*, we opted to allow manufacturer-submitted international drug net pricing data to be adjusted using a GDP (PPP) adjuster, as specified by CMS. We believe, based on our proposed criteria for the set of reference countries, that all of the countries included in the set of reference countries would be economically comparable with the U.S. and each other reference country (that is, each reference country’s GDP per capita would be no less than 60 percent of U.S. GDP per capita) and would have a comparable economy size (real GDP greater than \$400 billion). Previous research comparing international prices of U.S. originator drugs and international originator drugs show that prices can vary widely across countries. For example, among the countries listed in Table 5, the U.S. originator prices are between 339 and 703 percent higher

than international originator drugs.¹¹⁷ We expect that the *per unit Method II GLOBE Model benchmark* would tend to be higher than the *per unit* lowest country-level price identified under our proposed methodology for the *per unit Method I GLOBE Model benchmark*—before CMS would apply the proposed GDP (PPP) adjuster—because it reflects the price variations in reference countries and accounts for them through a volume-weighted price. As such, we believe this approach would be a strong incentive for manufacturers to conduct data gathering, analyses, and reporting activities related to voluntary manufacturer submission of international drug net pricing data as discussed in section II.G.6. of this proposed rule. Our goal is to encourage manufacturers to report international drug net pricing data (that is reflective of the actual transaction prices internationally) for GLOBE Model drugs to CMS for purposes of the GLOBE Model to enhance the model test and inform CMS' model monitoring and evaluation activities. We welcome comments or data on the extent to which the *per unit Method II GLOBE Model benchmark* would tend to be higher than the *per unit Method I GLOBE Model benchmark*, as well as comments on situations when the *per unit Method II GLOBE Model benchmark* may be lower than the *per unit Method I GLOBE Model benchmark*.

We welcome comment on our proposed methodology to identify the *per unit Method II GLOBE Model benchmark* for a GLOBE Model drug for an applicable calendar quarter.

c. Alternatives Considered

Instead of proposing that, for a GLOBE Model drug, CMS would identify the *per unit Method I GLOBE Model benchmark* once for the first applicable calendar quarter for such GLOBE Model drug and CMS would not reassess that benchmark, we considered an alternative that would allow CMS to revise the benchmark prospectively, no more frequently than quarterly, only if such benchmark would be lower than the currently applicable *per unit Method I GLOBE Model benchmark*. For example, prior to model start in accordance with proposed 42 CFR 513.410, CMS would identify the *per unit Method I GLOBE Model benchmark* for each GLOBE Model drug for the first

applicable calendar quarter of performance year 1. These benchmarks would remain in place for the duration of the model performance period unless CMS identifies a lower GDP (PPP) adjusted country-level price for the GLOBE Model drug using available data sources that meet the requirements in proposed 42 CFR 513.310. Similarly, for drugs that become GLOBE Model drugs during the performance period, CMS would identify the *per unit Method I GLOBE Model benchmark* for the first applicable calendar quarter for which the drug is a GLOBE Model drug and that benchmark would remain in place for the remaining applicable calendar quarters until the end of the model performance period unless CMS identifies a lower GDP (PPP) adjusted country-level price for the GLOBE Model drug. Under this alternative, if a *per unit Method I GLOBE Model benchmark* was prospectively revised, the revised benchmark would remain in place for the remaining applicable calendar quarters until the end of the model performance period unless CMS identifies a lower GDP (PPP) country-level price for the GLOBE Model drug that would be used beginning with the next applicable calendar quarter. We note this approach would allow CMS to consider international drug pricing information that becomes available over time, for example, after a *per unit Method I GLOBE Model benchmark* is identified by CMS for a GLOBE Model drug, a new data source may become available, a data source may add data for additional countries to its offering, data for sales for certain countries in the set of reference countries might become available within an existing data source, or international sales pricing and volume data may reflect lower prices related to market changes in reference countries. A lower benchmark could result in a lower *per unit GLOBE Model benchmark amount* and greater total GLOBE Model rebate amount as well as lower GLOBE Model beneficiary coinsurance. Allowing for a potential lower *per unit* country-level price could potentially positively impact model beneficiaries' access to GLOBE Model drugs and lower beneficiary financial liability. However, doing so would increase operational complexity for the model and could impact manufacturers' decisions to voluntarily submit international drug net pricing data, which would interfere with the model test of implementing and testing an alternative rebate calculation using Method II and collecting such data. Therefore, to avoid unnecessary complexity in the model design and to

reduce the potential for confounding events during the GLOBE Model test related to changes to the *per unit Method I GLOBE Model benchmark*, CMS has opted to not revise the *per unit Method I GLOBE Model benchmark* for a GLOBE Model drug once it has been identified by CMS.

Similarly, CMS considered identifying the lowest country-level GDP (PPP) adjusted net price per HCPCS billing unit reported by a manufacturer as the Method II benchmark. This also could result in a lower benchmark, lower *per unit GLOBE Model benchmark amount*, and likely greater total GLOBE Model rebate amount as well as lower GLOBE Model beneficiary coinsurance. However, CMS is concerned this could also impact manufacturers' decision to voluntarily submit international drug net pricing data, which could prevent CMS from being able to test the alternative rebate calculation using Method II.

We considered not adjusting the country-level prices for differences in economy size and purchasing power. That is, we considered not applying a GDP (PPP) adjustment within the calculations for the Method I and Method II benchmarks, which would result in lower benchmarks, and applying a GDP (PPP) adjustment to the Method II benchmark only, because there is some uncertainty in our belief that existing international drug pricing information closely reflects actual prices paid as those data may not include lagged price concessions and therefore may not closely represent actual prices. Using available 2024 international drug pricing information, we estimate that not applying a GDP (PPP) adjustment would result in lower benchmarks and greater anticipated model savings and beneficiary coinsurance reductions for GLOBE Model beneficiaries. Relatedly, manufacturers would also be more likely to owe total GLOBE Model rebates. Our analysis showed that including the GDP (PPP) adjustment, using illustrative 2024 data, could result in up to 28 percent less potential model performance year 1 savings, given that the reference countries are economically comparable to the U.S., we would expect that adjusting for country wealth differences based on PPP adjusted GDP would more likely result in appropriate international pricing information that align with other country-specific dynamics. We also considered that there are a range of alternative rebate calculations that could be appropriate for testing under the GLOBE Model and that it may be feasible to test other alternative approaches (or calculation steps) than the two methods we propose

¹¹⁷ Andrew W. Mulcahy, Daniel Schwam, Susan L. Lovejoy. *International Prescription Drug Price Comparisons: Estimates Using 2022 Data*, RAND Corporation. RR-2956-ASPEC, 2021b. Available at: <https://aspe.hhs.gov/reports/comparing-prescription-drugs>.

to test. For example, a benchmark could be identified by using a formula that calculates an average “lowest” country-level price by calculating an average country-level price across the countries with the two lowest country-level prices. To test a limited model design, we have opted to propose a test for two alternative rebate calculations that each use unique calculations and different international drug pricing information data sources. Although there could be other appropriate alternative calculations for a model test, we opted to test alternatives that would have distinct features related to data sources and benchmark calculations to enhance the potential to understand the impact of each alternative and the overall model test.

In addition, we considered testing an alternative rebate calculation using the proposed Method I and Method II approaches in different subsets of the GLOBE Model beneficiary cohort, such as creating two separate model beneficiary groups using different model geographic areas (that is, after selecting the model geographic areas, about half would be aligned with testing each benchmark approach). We opted not to pursue this alternative because the proposed model test calculations are specific to a GLOBE Model drug and manufacturer submission of international net pricing information would be voluntary making separate test areas not necessary and potentially insufficient. For example, a separate population subset for testing each benchmark methodology could result in weaker incentives for manufacturers to voluntarily submit data necessary for CMS to test identifying a benchmark based on the proposed Method II approach. Further, we believe that, if the GLOBE Model were to test our proposed Method II approach, or any alternative rebate calculation, using a benchmark based on voluntary manufacturer reporting of international net pricing information in a distinct model beneficiary cohort, a default benchmark would still be necessary in cases when manufacturer net pricing information would not be available. As such, we believe our proposed approach of testing a Method I benchmark alongside a test of a Method II benchmark is essential for a feasible model design that would test an alternative rebate calculation that is based on manufacturer submitted net pricing information. Therefore, we opted to pursue the approach of a single model beneficiary cohort for testing both alternative rebate calculations.

We welcome comments on the alternative we considered and our

proposed approach for identifying a *per unit GLOBE Model benchmark* using two alternative calculations.

3. Proposed Methodology for Identifying the Per Unit GLOBE Model Benchmark Amount for an Applicable Calendar Quarter

In this section of this proposed rule, we propose the methodology CMS would use to determine the *per unit GLOBE Model benchmark amount* for a GLOBE Model drug for an applicable calendar quarter.

In 42 CFR 513.400, we propose that, quarterly for each GLOBE Model drug, after CMS identifies the *per unit Method I GLOBE Model benchmark* as set forth in 42 CFR 513.410, as available, and the *per unit Method II GLOBE Model benchmark* as set for the in 42 CFR 513.420, as available, CMS would compare the identified *per unit Method I GLOBE Model benchmark* (if available) and the identified *per unit Method II GLOBE Model benchmark* (if available) to identify which benchmark is greater and would be identified as the *per unit GLOBE Model benchmark* for the GLOBE Model drug for the applicable calendar quarter. In 42 CFR 513.400(b)(3), we propose that if CMS determines that neither of these benchmarks is available, CMS would determine that the *per unit GLOBE Model benchmark* for the GLOBE Model drug for the applicable calendar quarter is “not available”.

In addition, we propose that CMS would apply an adjustment to the identified *per unit GLOBE Model benchmark* to calculate the *per unit GLOBE Model benchmark amount*, which would include: (1) a modest increase to account for potential differences between the U.S. market and markets in the reference countries that may remain after allowing for economic and purchasing power differences (called the “*applicable threshold percentage*” as set forth in 42 CFR 513.400 and discussed in section II.G.3.a. of this proposed rule); and (2) an amount that would equal the dollar value of the “*add-on percentage*” included in the Medicare Part B drug payment limit for the GLOBE Model drug for the applicable calendar quarter (as set forth in 42 CFR 513.400 and discussed in section II.G.3.b. of this proposed rule) which would be called the “*add-on percentage amount*”. The *add-on percentage* would be the percentage above 100 percent that is specified under section 1847A(b)(1)(B) of the Act. In general, the Medicare Part B payment limit would be equal to the “specified amount” (as defined at 42 CFR 427.20). As noted previously, for

most HCPCS Level II codes, the add-on percentage is 6 percent in most cases, but it may be 3 percent or 8 percent (when ASP is not yet available during the initial sales period, for certain qualifying biosimilar biological products, and in certain circumstances specified within section 1847A(d)(3)(C) of the Act).

The *per unit GLOBE Model benchmark amount* would be used in the calculation of the *per unit GLOBE Model rebate amount* for a GLOBE Model drug for an applicable calendar quarter as discussed in section II.G.4.a. of this proposed rule.

As discussed in section II.G.2. and proposed in 42 CFR 513.400(b)(3) of this proposed rule, for a GLOBE Model drug for an applicable period, if neither a *per unit Method I GLOBE Model benchmark* nor a *per unit Method II GLOBE Model benchmark* is available, CMS would identify that the *per unit GLOBE Model benchmark* for such GLOBE Model drug for such applicable calendar quarter as “not available”. In such cases, we propose that CMS would determine that the *per unit GLOBE Model benchmark amount* was not available for purposes of calculating the *per unit GLOBE Model rebate amount* in proposed 42 CFR 513.400, as discussed in section II.G.4. of this proposed rule. We note that this scenario would be possible in cases where a GLOBE Model drug is sold in the U.S. and international drug pricing information for applicable international analog for that GLOBE Model drug is not available through at least one international drug pricing information data source, including voluntary manufacturer submission of international drug net pricing data, and in cases where such GLOBE Model drug is sold in the U.S. but is not sold in any of the reference countries. We also note that in such cases (as proposed in section II.G.4. of this proposed rule), the *per unit GLOBE Model rebate amount*, as proposed in 42 CFR 513.510, would be based on the difference between the *specified amount* (as determined under 42 CFR 427.302(b)) and the *inflation-adjusted payment amount* (as determined under 42 CFR 427.302(g)). This means that, in cases where CMS has not identified a *per unit GLOBE Model benchmark amount*, the *per unit GLOBE Model rebate amount* would equal the *per unit rebate amount* that CMS determines in accordance with the Medicare Part B Drug Inflation Rebate Program under 42 CFR 427.302, as applicable.

a. Proposed Applicable Threshold Percentage

In 42 CFR 513.400(c)(1), we propose to increase the *per unit GLOBE Model benchmark* by an *applicable threshold percentage* which would allow for a modest increase over the international benchmark to account for potential differences between the U.S. market and markets in the set of reference countries for which international drug pricing information was available for identifying the benchmark. Although the proposed calculation for the *per unit GLOBE Model benchmark* includes adjustments for economic and purchasing power parity differences, further adjustment for some potential remaining differences by applying a minimal threshold adjustment could be warranted.

Because the reference countries for which international drug pricing information would be available for identifying either the Method I or Method II benchmark (as described in sections II.G.2.a. and II.G.2.b. of this proposed rule, respectively) could vary by GLOBE Model drug, by applicable calendar quarter, and by the alternative calculation approach used (that is, Method I or Method II), we considered whether a consistent or variable approach for selecting the applicable threshold percentage would be appropriate for the model test. We considered that there could be many factors that could be included in the development of a threshold that would suit our aim of allowing for a modest margin over the identified *per unit GLOBE Model benchmark* that would be connected meaningfully to the different methods and data sources for an alternative rebate calculation that would be tested and would not be overly complex such that the calculation would be as transparent and easily implemented as practical. We also believe that applying a consistent threshold to the benchmarks that were identified using the same method and data sources is appropriate for the model test. That is, we believe that the threshold, if adopted for the model test, should be determined consistently for both methods, but that the magnitude of the threshold could be different for Method I and Method II to account for potential remaining differences for each method between the U.S. market and markets in the reference countries. We believe that this straightforward approach would avoid unnecessary variation in the model test and would increase the learning potential for the model.

Under our proposed approach for identifying the *per unit Method I GLOBE Model benchmark*, the benchmark would be based on available existing international drug pricing information data sources that contain prices that could represent list prices, ex-manufacturer prices (sometimes called ex-factory prices) that represent actual or calculated prices paid to the manufacturer by wholesalers and other distributors, retail prices that represent actual or calculated sales for retail purchasers, and/or prices paid by other purchasers in the distribution (as discussed in section II.G.1. of this proposed rule). Such pricing information may not include all applicable discounts such that net pricing would be lower than the identified benchmark particularly after the proposed GDP (PPP) adjustment, even though we propose to base the benchmark on the lowest country-level price. Further, existing data sources capture drug pricing information that is made available from various sources and, by its nature, does not likely reflect the full range of confidential discounts and net pricing. In addition, because drug pricing information that is made available to existing data sources becomes accessible to drug purchasers, the variation among such prices for a given drug would be expected to lessen over time. Thus, we believe a reasonable margin necessary for purposes of the model test above a benchmark that would be based on international drug pricing information from existing data sources would be minimal, perhaps a de minimis amount of up to 2 percent, to account for potential differences between the U.S. market and markets in the reference countries that would not be addressed by other proposed aspects of the alternative calculation that is based on the lowest-country-level price.

Under the proposed approach for identifying the *per unit Method II GLOBE Model benchmark*, the benchmark would be based on voluntary manufacturer-submitted international drug net pricing information which is intended to reflect the full range of discounts and net pricing. To account for the likelihood of larger price variations across countries that may occur in actual transaction prices abroad, CMS proposes to use a higher applicable threshold percentage of 5 percent. A lower applicable threshold is appropriate for the Method I benchmark since it relies on the lowest country level prices, which do not reflect the full range of discounts and net pricing. These variations in the applicable threshold percentage

advance the testing of two alternative rebate calculations for the model, one that uses aggregate net pricing benchmarks while the other uses the lowest country level price that lacks net pricing information. In 42 CFR 513.400(d), we propose that, when the per unit GLOBE Model benchmark is based on the *per unit Method I GLOBE Model benchmark*, the applicable threshold percentage would be 102 percent. When the per unit GLOBE Model benchmark is based on the *per unit Method II GLOBE Model benchmark*, the applicable threshold percentage would be 105 percent.

In developing our proposal, we considered two options for structuring the threshold: (1) apply a fixed adjustment (such as a percentage amount) for all GLOBE Model drugs regardless of the benchmark method; or (2) apply a variable adjustment that reflects one or more characteristics of the GLOBE Model drug, the alternative rebate calculations, or reference countries. We also considered that no adjustment would be necessary. As noted above, we opted to prioritize a straightforward approach that would be connected to the alternative benchmark calculation methodologies.

In developing this proposal, we also considered that, although our proposal for how CMS would identify the *per unit GLOBE Model benchmark amount* would allow a modest threshold above the *per unit GLOBE Model benchmark* to account for potential remaining differences between the U.S. market and markets in the reference countries, the difference between the proposed adjustment, which is 102 percent of the per unit Method I GLOBE Model benchmark (that is, the lowest per unit GDP (PPP) adjusted country-level price) and the 105 percent of the per unit Method II GLOBE Model benchmark, might not provide sufficient incentive for manufacturers to voluntarily submit international drug pricing information for testing the Method II alternative rebate calculation. Without a sufficient incentive, the model test of the Method II benchmark could be limited or unsuccessfully implemented.

We welcome comments on our proposal for the applicable threshold percentage and alternatives that may help advance the aims of the model test.

b. Proposed Add-On Percentage Amount

In 42 CFR 513.400(c)(2), we propose to increase the *per unit GLOBE Model benchmark* by the *add-on percentage amount* (that is, the dollar value of the *add-on percentage*) that is included in the *specified amount* (as determined under 42 CFR 427.302(b)) when

calculating the *per unit GLOBE Model benchmark amount*. Specifically, CMS would identify the dollar amount of the statutory add-on amount, typically 6 percent of the Medicare Part B payment amount as calculated under section 1847A(b) of the Act (which is typically based on the volume-weighted average sales price). For example, if the *per unit volume-weighted average sales price* for a drug for an applicable calendar quarter is \$100 and the 6 percent add-on applies, the statutory add-on amount *per unit* would be \$6 and CMS would add \$6 in the calculation of the *per unit GLOBE Model benchmark amount*. This proposed approach is intended to avoid including an amount equal to the add-on within the GLOBE Model rebate amounts that manufacturers would owe. We note that under the Medicare Part B Drug Inflation Rebate Program, when the specified amount (as determined under 42 CFR 427.302(b)) and the inflation-adjusted payment amount (as determined under 42 CFR 427.302(g)) are compared, each of these amounts could include an amount related to an add-on percentage. Our proposed approach would be consistent with the treatment of add-on amounts under the Medicare Part B Drug Inflation Rebate Program.

We considered an alternative of not increasing the *per unit GLOBE Model benchmark* to account for an add-on that would be included in the *specified amount* (as determined under 42 CFR 427.302(b)) but we decided to propose this increase because we believe that increasing the *per unit GLOBE Model benchmark* by the dollar value of the add-on included in the *specified amount* (as determined under 42 CFR 427.302(b)) would likely increase the rebate amounts manufacturers could owe simply due to one part of the rebate calculation including an add-on amount while the other part in the comparison would not.

We welcome comments on our proposed methodology for identifying the *per unit GLOBE Model benchmark amount* and our rationale for this approach. We also welcome comment on potential alternative approaches that would closely align the *per unit GLOBE Model benchmark amount* with the net pricing in various international markets. For the *per unit Method I GLOBE Model benchmark*, we also considered the possibility of adjusting annually for inflation. However, it is not clear how best to do that given differences across reference countries that exist and because each drug may have a different reference country that is used to identify the *per unit Method I GLOBE Model benchmark*. Therefore, we are soliciting

comments on this potential policy to inflation adjust the default international benchmark and the best ways to implement this while maintaining the goals of the model test.

4. Proposed Methodology for Calculating the GLOBE Model Rebate Amount

In this section of the proposed rule, we propose how CMS would calculate the *per unit GLOBE Model rebate amount* and the *incremental per unit GLOBE Model rebate amount* due. We also propose a methodology to identify the *total number of GLOBE Model billing units* in order to calculate the *total GLOBE Model rebate amount* and the *incremental GLOBE Model rebate amount* due. Finally, we propose a methodology to reduce the *incremental GLOBE Model rebate amount* for GLOBE Model drugs in shortage and when there is a severe supply chain disruption.

a. Proposed Methodology for Calculation of the Per Unit GLOBE Model Rebate Amount and the Incremental Per Unit GLOBE Model Rebate Amount

In this section of this proposed rule, we propose how CMS would identify the *per unit GLOBE Model rebate amount* and the *incremental per unit GLOBE Model rebate amount* for a GLOBE Model drug for an applicable calendar quarter. The *per unit GLOBE Model rebate amount* would reflect the result of the alternative rebate calculation and the *incremental per unit GLOBE Model rebate amount* would be the amount in excess of the rebate amount calculated as set forth in 42 CFR 427.301. Thus, the *incremental per unit GLOBE Model rebate amount* would be an “incremental amount” in addition to the Medicare Part B drug inflation rebate amount to avoid complex operational overlap with the Medicare Part B Drug Inflation Rebate Program activities and potential confusion for GLOBE Model participants.

To test the program impact of the alternative rebate calculation, for a GLOBE Model drug for an applicable calendar quarter, we propose that the *per unit GLOBE Model rebate amount* would be the greater of: (1) the difference between the *specified amount* (as determined under 42 CFR 427.302(b)) and the *per unit GLOBE Model benchmark amount* (as described in section II.G.3. of this proposed rule), if available; or (2) the difference between the *specified amount* (as determined under 42 CFR 427.302(b)) and the *inflation-adjusted payment amount* (as determined under 42 CFR 427.302(g)). If the result is an amount

less than \$0, we propose that the *per unit GLOBE Model rebate amount* would be set at \$0.

We intend to design the GLOBE Model in a manner that ensures Medicare FFS beneficiaries who are GLOBE Model eligible beneficiaries would not face greater financial liability when they receive a GLOBE Model drug for which Medicare Part B allows separate payment and the Medicare program would not also pay more in such cases. Therefore, we are proposing that the *per unit GLOBE Model rebate amount* would not be lower than the difference between the specified amount (as determined under 42 CFR 427.302(b)) and the inflation-adjusted payment amount (as determined under 42 CFR 427.302(g)). That is, our proposed approach would ensure that the *per unit GLOBE Model rebate amount* would not be less than the Part B inflation rebate amount, if any, for the applicable calendar quarter.

We are also proposing to calculate an *incremental per unit GLOBE Model rebate amount* for a GLOBE Model drug for an applicable calendar quarter which would represent the amount in excess of the *per unit Part B rebate amount* calculated as set forth in 42 CFR 427.302. We believe that calculating the *incremental per unit GLOBE Model rebate amount* for a GLOBE Model drug for an applicable calendar quarter is necessary for purposes of the GLOBE Model test to provide transparency to manufacturers with respect to how GLOBE Model rebate amounts would be invoiced, due, and paid—that is, the follow-on model operational activities that are inherent components of the model test but that, given the proposed limited geographic scope of the model, must coincide with Medicare Part B Drug Inflation Rebate Program operational activities for a Part B rebatable drug. We believe that calculating incremental distinct amounts for purposes of GLOBE Model follow-on activities would provide clarity, reduce potential confusion, and facilitate accurate invoices and rebate payment for both the GLOBE Model and the Medicare Part B Drug Inflation Rebate Program as further discussed in section II.G.8. of this proposed rule.

We propose to codify these calculations in 42 CFR 513.510, including that the results would be rounded to the second decimal place.

We note that in cases where CMS determines that the *per unit GLOBE Model benchmark amount* is not available, our proposal means that the *per unit GLOBE Model rebate amount* for an applicable calendar quarter would be the difference between the

specified amount (as determined under 42 CFR 427.302(b)) and the inflation-adjusted payment amount (as determined under 42 CFR 427.302(g)). We also note that, in these cases, the *incremental per unit GLOBE Model rebate amount* would be zero because there would be no amount in excess of the per unit Part B rebate amount calculated as set forth in 42 CFR 427.302.

We welcome comment on our proposed methodology for determining the *per unit GLOBE Model rebate amount* and calculating the *incremental per unit GLOBE Model rebate amount* for a GLOBE Model drug for an applicable calendar quarter.

b. Proposal for Identification of the Total Number of GLOBE Model Billing Units

In this section of this proposed rule, we discuss how the *total number of GLOBE Model billing units* for a GLOBE Model drug for an applicable calendar quarter would be identified for purpose of thereafter being used to calculate the *total GLOBE Model rebate amount* and the *incremental GLOBE Model rebate amount*.

For purposes of the Medicare Part B Drug Inflation Rebate Program, CMS identifies the total number of billing units as set forth in 42 CFR 427.303. We propose, in 42 CFR 513.520, that, to identify the *total number of GLOBE Model billing units*, CMS would identify the total number of billing units from the total number of billing units that CMS identified in accordance with 42 CFR 427.303(b) where, on the date of service, the Medicare beneficiary was identified by CMS as a GLOBE Model eligible beneficiary and for which Medicare Part B FFS made separate payment. We propose that the resulting sum of the identified billing units would be identified as the *total number of GLOBE Model billing units* that CMS would use to calculate the *total GLOBE Model rebate amount* and the *incremental GLOBE Model rebate amount* for a GLOBE Model drug for an applicable calendar quarter. This approach would ensure that units that are not included in the total number of billing units determined under 42 CFR 427.303, such as 340B units and units of discarded drugs, would also not be included in the *total number of GLOBE Model billing units*.

We note that, because the *total number of GLOBE Model billing units* would be determined from the total number of billing units that CMS identified in accordance with 42 CFR 427.303(b), the *total number of GLOBE Model billing units* would always be

equal to or less than the total number of billing units identified for the Medicare Part B Drug Inflation Rebate Program and most likely substantially less given our proposal to limit the model scope to approximately 25 percent of Medicare Part B FFS beneficiaries. We also note that this method of identification of the *total number of GLOBE Model billing units* prevents any potential discrepancies related to the number of billing units used to calculate GLOBE Model rebate amounts because the total number of billing units as determined under 42 CFR 427.303 would be the starting point and the GLOBE Model Eligible Beneficiary List and Medicare claims would clearly facilitate CMS' identification of the subset of those billing units where, on the date of service, the Medicare beneficiary was identified by CMS as a GLOBE Model eligible beneficiary and for which Medicare Part B FFS made separate payment.

c. Proposal for the Calculation of the Total GLOBE Model Rebate Amount and Incremental GLOBE Model Rebate Amount Due for a GLOBE Model Drug for an Applicable Calendar Quarter

In this section of this proposed rule and in 42 CFR 513.500, we propose how the *total GLOBE Model rebate amount* and the *incremental GLOBE Model rebate amount* for a GLOBE Model drug for an applicable calendar quarter would be calculated. To clearly identify the alternative rebate under the GLOBE Model test, CMS would calculate the *total GLOBE Model rebate amount* that manufacturers would be accountable for. To avoid potential duplication across activities under the Medicare Part B Drug Inflation Rebate Program, a per unit incremental amount would be used to identify the *incremental GLOBE Model rebate amount* which manufacturers would owe to CMS in addition to any amount invoiced under the Medicare Part B Drug Inflation Rebate Program. Both of these amounts would be used for follow-on steps for GLOBE Model reporting, invoicing, and rebate payment as discussed in section II.G.8. of this proposed rule. The *incremental GLOBE Model rebate amount* would be adjusted prior to these follow-on steps, when applicable, for GLOBE Model Drugs in shortage and when there is a severe supply chain disruption as discussed in section II.G.4.d. of this proposed rule.

We propose that the *total GLOBE Model rebate amount* for a GLOBE Model Drug for an applicable calendar quarter owed by a manufacturer of the GLOBE Model drug to the Federal Supplementary Medical Insurance Trust

Fund would be the amount calculated as the product of the *per unit GLOBE Model rebate amount* as calculated pursuant to 42 CFR 513.510(a) and the *total number of GLOBE Model billing units* (as identified as set forth in 42 CFR 513.520(c)). We note that when the *per unit GLOBE Model rebate amount* is zero, the *total GLOBE Model rebate amount* would also be zero. To simplify operations while clearly invoicing manufacturers for this amount, we propose to calculate an *incremental GLOBE Model rebate amount* that would represent the amount of the *total GLOBE Model rebate amount* that is in excess of the rebate amount for the Medicare Part B Drug Inflation Rebate Program that applies to the *total number of GLOBE Model billing units*.

In 42 CFR 513.500(b), we propose that the *incremental GLOBE Model rebate amount* would be the amount calculated as the product of the *incremental per unit GLOBE Model rebate amount* as set forth in 42 CFR 513.510(b) and the *total number of GLOBE Model billing units* (as identified as set forth in 42 CFR 513.520).

Table 6 presents illustrative incremental per unit GLOBE Model rebate amounts for an illustrative Part B rebatable drug that could potentially be a GLOBE Model drug for an illustrative quarter based on average estimates of a per unit Method I and Method II GLOBE Model benchmarks¹¹⁸ using international drug pricing information that was available to CMS for purposes of this proposed rule. The illustrative specified amount, illustrative add-on percentage amount, estimated per unit inflation-adjusted payment amount, and estimated per unit Part B inflation rebate amount are based on CMS claims data for 2024 and represent averages for an illustrative GLOBE Model drug. The illustrative per unit GLOBE Model benchmark for Method I and Method II

¹¹⁸ This estimate is not based on international net pricing information, but it is calculated based on the volume-weighted average across countries using a GDP (PPP) adjuster as described in this proposed rule, IQVIA national audits and IQVIA MIDAS® reflect local industry standard source of pack prices, which may be list price or average invoice price, depending upon the country and the available information; they do not take into account rebates or clawbacks, details of which are normally confidential, and therefore these estimated prices do not reflect net prices realized by the manufacturers. Sales values reflected in these IQVIA audits are calculated by applying such relevant pricing to the product volume data collected for, and reflected in, such audits. In addition, to allow the national audit sales values to be viewed at a common sales level, MIDAS applies a single average industry margin to the locally reported values. The drug price provided is an estimated price and its intended function is to convert volumes to sales—this estimated price is not intended to be used as a metric in its own right.

is based on international pricing information available to CMS following the process described in sections II.G.1. and II.G.3. of this proposed rule. The illustrative per unit Method I GLOBE Model benchmark represents the lowest per unit GDP (PPP) adjusted country-level price. To provide an illustrative per unit Method II GLOBE Model benchmark, CMS used international pricing data available as a proxy for an across country volume-weighted average GDP (PPP) adjusted net price. For example, for Method I the illustrative per unit benchmark amount (\$16.16) is

calculated by taking the sum of the product of the illustrative per unit Method I benchmark and a threshold percentage of 102 percent and the dollar value of the illustrative add-on percentage of the Medicare Part B payment limit ($\$13.378 * (1.02) + \$2.514$). The illustrative per unit GLOBE Model rebate amount for Method I is the greater of \$28.26 or \$0.59, where \$28.26 is the difference between the illustrative specified amount and the illustrative per unit GLOBE Model benchmark amount ($\$44.416 - \$16.16$) and \$0.59 is the difference between the illustrative

specified amount and the estimated per unit Inflation-Adjusted rebate amount ($\$44.416 - \$43.830$). The illustrative incremental per unit GLOBE Model rebate amount is then calculated as the difference between the illustrative per unit GLOBE Model rebate amount and the estimated per unit Part B rebate amount ($\$28.26 - \$0.59$). We follow a similar process to calculate the illustrative Method II per unit GLOBE Model rebate amount using 105 percent as the threshold percentage. CMS welcomes comments on this proposal.

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TABLE 6: ILLUSTRATIVE INCREMENTAL PER UNIT GLOBE MODEL REBATE AMOUNT AND COINSURANCE REDUCTION FOR AN ILLUSTRATIVE HCPCS LEVEL II CODE UNIT: METHOD I AND METHOD II BENCHMARKS

Method	Illustrative Specified Amount ^a	Illustrative Add-on Percentage Amount of the Medicare Part B Payment Limit ^a	Estimated Per Unit Inflation-Adjusted Payment Amount ^a	Estimated Per Unit Part B Drug Rebate Amount ^a	Illustrative Per Unit GLOBE Model Benchmark ^a	Illustrative Per Unit GLOBE Model Benchmark Amount ^a	Illustrative Per Unit GLOBE Model Rebate Amount ^a	Illustrative Incremental Per Unit GLOBE Model Rebate Amount ^a	Illustrative Coinsurance Percentage ^b	Illustrative Adjusted Coinsurance Reduction Amount ^b
Method I	\$44.416	\$2.51	\$43.83	\$0.59	\$13.38	\$16.16	\$28.26	\$27.67	7.2%	\$3.18
Method II	\$44.416	\$2.51	\$43.83	\$0.59	\$20.97	\$24.53	\$19.89	\$19.30	10.6%	\$4.70

Notes: ^a This table provides highly simplified estimates for an illustrative HCPCS Level II code meeting the selection criteria for a GLOBE Model drug for an illustrative applicable quarter using data from 2024 for Method I and Method II. The illustrative per unit benchmarks are based on IQVIA MIDAS® annual sales and volume data for period January 2024 to December 2024. Copyright IQVIA. All rights reserved. ^b The illustrative coinsurance percentage is calculated as the product of 20 percent and the sum of the per unit GLOBE Model benchmark and the illustrative add-on percentage amount divided by the specified amount. For example for Method I, the illustrative coinsurance percentage of 7.16 percent is calculated as: $0.20 * (\$16.16) / (\$44.42)$. The illustrative adjusted coinsurance reduction amount is the product of the illustrative coinsurance percentage and the specified amount. For example, the illustrative adjusted coinsurance reduction amount for Method I of \$3.178 is the result of multiplying 0.0716 by \$44.416.

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d. Proposal for Reducing the Incremental GLOBE Model Rebate Amount for GLOBE Model Drugs in Shortage and When There Is a Severe Supply Chain Disruption

(1) Reducing the Incremental GLOBE Model Rebate Amount for GLOBE Model Drugs in Shortage

In accordance with section 1847A(i)(3)(G)(i) of the Act as codified in 42 CFR 427.401, CMS reduces the total rebate amount determined under 42 CFR 427.301(a), if any is owed, for a Part B rebatable drug that is currently in shortage, as set forth in 42 CFR 427.400. For purposes of the Medicare Part B Drug Inflation Program, to calculate the reduction in the total rebate amount for a Part B rebatable drug that is currently in shortage, CMS calculates the number of days such drug is described as “currently in shortage” on an FDA shortage list in a calendar quarter, divides by the number of days in the calendar quarter, and then multiplies that amount by the applicable percentage as specified in 42 CFR 427.401(b)(2).

For purposes of the GLOBE Model, CMS proposes at 42 CFR 513.500(d) to reduce the *incremental GLOBE Model rebate amount* using in the methodology specified in 42 CFR 427.401(b)(1). Specifically, to closely align with the Medicare Part B Drug Inflation Rebate Program, for any GLOBE Model drug currently in shortage during an applicable calendar quarter during the model performance period, CMS proposes to use the applicable percent reduction and percentage of time the drug was currently in shortage during the applicable quarter as set forth in 42 CFR 427.401(b). In proposed 42 CFR 513.500(d), CMS would reduce the *incremental GLOBE Model rebate amount*, if any, for such GLOBE Model drug for such applicable calendar quarter. The “applicable percent reduction” in the formula would be determined as set forth in 42 CFR 427.401(b)(2) as applicable, including to account for whether the GLOBE Model drug is a plasma-derived product and the number of consecutive applicable calendar quarters such drug is currently in shortage. We note that this approach would maintain the meaning and use of the terms “applicable percent reduction” and “time drug was currently in shortage” as those terms are used in 42 CFR 427.401(b). Specifically, we are proposing that the equation would be—

Reduced incremental GLOBE Model rebate amount = the incremental GLOBE

Model rebate amount multiplied by (1 *minus* “applicable percent reduction” determined under 42 CFR 427.401(b)(2) multiplied by (“percentage of time drug was currently in shortage during the applicable calendar quarter” as determined in accordance with 42 CFR 427.401(b)(3)) added to the incremental GLOBE Model rebate amount multiplied by (1 *minus* “percentage of time drug was currently in shortage during the applicable calendar quarter” as determined in accordance with 42 CFR 427.401(b)(3)).

Further, CMS proposes to apply a reduction of the *incremental GLOBE Model rebate amount* as determined under 42 CFR 513.510(d)(2) to all the NDCs under the relevant billing and payment code as specified in 42 CFR 427.401(c). We codify our proposal in proposed 42 CFR 513.500(d). As discussed in section II.G.8. of this proposed rule, any applied reductions would be identified in the GLOBE Model Rebate Report.

As an alternative to our proposed approach, we considered whether, for purposes of the GLOBE Model, the applicable percent reduction should be greater than or less than the applicable percentage reduction specified in 42 CFR 427.401(b)(2). To maintain consistency with the Medicare Part B Drug Inflation Rebate Program and avoid creating different manufacturer incentives for addressing shortages and supply chain disruptions, we decided to propose to apply, for purposes of the GLOBE Model, the same applicable percentage reduction as used under the Medicare Part B Drug Inflation Rebate Program.

(2) Reducing the Incremental GLOBE Model Rebate Amount for a GLOBE Model Drug When There Is a Severe Supply Chain Disruption

Under section 1847A(i)(3)(G)(ii) of the Act as codified in 42 CFR 427.402, CMS reduces the total rebate amount determined under 42 CFR 427.301(a), if any is owed, for a Part B rebatable biosimilar biological product when CMS determines there is a severe supply chain disruption during the applicable calendar quarter such as that caused by a natural disaster or other unique or unexpected event. Additional instructions for submitting rebate reduction requests are provided in the collection of information that was approved on July 22, 2024, under OMB control number 0938–1474 and can be found on [reginfo.gov](https://www.reginfo.gov). As discussed in section II.B.1. of this proposed rule, we are proposing to exclude biosimilar biological products from the definition

of GLOBE Model drugs. But, if after notice and comment that proposal is not finalized, we are proposing that, for any GLOBE Model drug that is a biosimilar biological product as set forth in section 1847A(c)(6)(H) of the Act, CMS would reduce the incremental GLOBE Model rebate amount, if any, when there is a severe supply chain disruption during the applicable calendar quarter in the same manner as specified in 42 CFR 427.402, including the limitation on rebate reductions in 42 CFR 427.402(b)(4).

Specifically, to the extent that CMS finalizes a definition of GLOBE Model drugs that were to include biosimilar biological products, when CMS reduces the total rebate amount determined under 42 CFR 427.301(a), if any is owed, for a Part B rebatable biosimilar biological product that is a GLOBE Model drug for an applicable quarter, CMS would likewise reduce the *incremental GLOBE Model rebate amount* determined pursuant to 42 CFR 513.500(b), if any is owed, using the specifications for calculation of the reduced rebate amount set forth in 42 CFR 427.402(b), substituting “the *incremental GLOBE Model rebate amount*” for “the total rebate amount”, subject to the eligibility requirements set forth in 42 CFR 427.402(c), and to apply that rebate reduction only if the eligibility criteria in 42 CFR 427.402(c) are met. Our intent is to maintain the meaning and use of other terms and provisions within 42 CFR 427.402. In other words, to the extent that biosimilar biological products are included in the GLOBE Model, CMS intends to reduce the incremental GLOBE Model rebate amount for such GLOBE Model drug, if any is owed, when there is a severe supply chain disruption using the same criteria and percentage reduction that CMS applied under 42 CFR 427.402 for such GLOBE Model drug for the applicable calendar quarter.

We note that, if our proposal to exclude biosimilar biological products from the definition of GLOBE Model drugs is finalized in a final rule establishing the GLOBE Model, our proposal for reduction of the incremental GLOBE Model rebate amount for GLOBE Model drugs that are biosimilar biologicals when there is a severe supply chain disruption would not be necessary and we would not include such provision in such final rule.

(3) Other Considerations for Reducing the Incremental GLOBE Model Rebate Amount for GLOBE Model Drugs in Shortage and When There Is a Severe Supply Chain Disruption

Previous ASPE analysis showed that a small number (3 percent) of Part B drugs and biological products were listed in the FDA list of current shortages in January 2023.¹¹⁹ The same study showed that most of the products in shortage were injectables and products that have been approved longer than 11 years. Using the FDA's lists of drugs in shortage,^{120 121} we identified three Part B drugs associated with a shortage in 2024, but none of these drugs was a proposed GLOBE Model drug. Prior work that examined the extent to which changes in U.S. volume and price of drugs in shortage affect volume and prices of the same drugs in other OECD countries concluded there is little evidence that U.S. shortages are associated with volume and price changes in the sample of OECD countries examined.¹²² Although the potential number of GLOBE Model drugs associated with a shortage or supply chain disruption may be small, the impacts of a single shortage may be large in terms of costs to patients and health care providers when managing a shortage as well as negative impacts on patient health due to delayed or unavailable treatments;^{123 124 125} for this

reason and for consistency with section 1847A(i)(3)(G)(i) and (ii) of the Act, we are proposing to reduce the incremental GLOBE Model rebate amount for GLOBE Model drugs in shortage and, to the extent biosimilar biological products are included in the model, when there is a severe supply chain disruption as discussed in section II.G.4.d.(2). of this proposed rule. We also considered not reducing the incremental GLOBE Model rebate amount or applying a smaller or larger reduction than determined under 42 CFR 427 subpart E.

We seek comments on our proposal for reduction of the incremental GLOBE Model rebate amount for GLOBE Model drugs in shortage and for GLOBE Model drugs that are biosimilar biologicals when there is a severe supply chain disruption.

5. Proposed Payment Responsibilities

As discussed in section II.E. of this proposed rule, we propose that model participants would be manufacturers of GLOBE Model drugs. Consistent with the Medicare Part B Drug Inflation Rebate Program, under the GLOBE Model, we propose that a “*manufacturer*” would be identified using the same approach used for reporting ASP and the Medicaid Drug Rebate Program data. The manufacturer of a GLOBE Model drug would be responsible for all GLOBE Model rebate payments for each applicable GLOBE Model drug. We propose that manufacturers of GLOBE Model drugs with a total GLOBE Model rebate amount due of \$0 or greater would be provided a rebate report which would serve as an invoice for the *total GLOBE Model rebate amount due*, using an *incremental GLOBE Model rebate amount*, as described in section II.G.4.c. of this proposed rule. As discussed in section II.G.8. of this proposed rule, CMS is proposing to include the *total GLOBE Model rebate amount* and *incremental GLOBE Model rebate amount* in either the Preliminary Rebate Report and Rebate Report provided to the manufacturer pursuant to 42 CFR 513 subpart H (which would be the same rebate reports used for the Medicare Part B Drug Inflation Rebate Program) or in separate Preliminary

GLOBE Model Rebate Report and GLOBE Model Rebate Report that CMS would provide to the manufacturer.

When multiple manufacturers are linked to a single HCPCS Level II code that represents a GLOBE Model drug (for example, GLOBE Model drugs that have NDCs involving multiple labeler codes), we propose to apportion the *incremental GLOBE Model rebate amount* as set forth in paragraph (b) or (c) of 42 CFR 427.301 as applicable. That is, a manufacturer's liability for the *incremental GLOBE Model rebate amount* would be calculated by CMS and would be proportionate to the manufacturer's total billing units sold during the applicable calendar quarter. This approach adopts CMS' current operational approach for the Medicare Part B Drug Inflation Rebate Program and is necessary for testing the model in an efficient and consistent manner.

We seek comment on this proposed approach for calculating the manufacturer payment responsibility for total GLOBE Model rebate amounts due, if any, for a GLOBE Model drug for an applicable calendar quarter.

6. Proposed Reporting Requirements and Process for Voluntary Manufacturer-Provided Data

In order for CMS to identify a per unit Method II benchmark in the alternative inflation rebate amount calculation for a given GLOBE Model drug, a manufacturer must voluntarily report international pricing data. A manufacturer must submit this data in accordance with reporting requirements and process set forth for voluntary manufacturer-provided data. For CMS to determine that the submission is an “applicable submission”, we propose in 42 CFR 513.610(a)(3)(i) that the data must include all the basic data elements (as set forth in 42 CFR 513.610(b) and described in section II.G.6. of this proposed rule) required for each “applicable international analog” as defined in 42 CFR 513.600 that corresponds to a GLOBE Model drug. An applicable international analog means a non-U.S. analog whose scientific or nonproprietary name, dosage form, and route of administration (if applicable) align with a GLOBE Model drug and that are sold in one or more reference countries during the applicable ASP calendar quarter, excluding those identified in their respective country as a generic or biosimilar biological product according to the country's own regulations.

In addition, the submission must contain all the net pricing data elements (as set forth 42 CFR 513.610(c)) required under one of the two options

¹¹⁹ Beleche, T., Parasrampur, S., and Adetunji, O. Characteristics of Part B Drugs in Shortage. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. December 2024. Available at: <https://aspe.hhs.gov/sites/default/files/documents/d38b00602b2f24f02b85ca4731457616/part-b-drug-shortages-ib.pdf>.

¹²⁰ Food and Drug Administration. Current and Resolved Drug Shortages and Discontinuations reported to FDA. Available at: <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.

¹²¹ Food and Drug Administration. CBER-Regulated products: Current Shortages. Available at: <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-regulated-products-current-shortages>.

¹²² Mulcahy, A.W., Rao, P., Karedy, V., and Agniel D. Assessing Relationships Between Drug Shortages in the United States and Other Countries. RAND Research, October 27, 2021. Available at: https://www.rand.org/pubs/research_reports/RRA1070-1.html.

¹²³ Office of the Assistant Secretary for Planning and Evaluation and NORC at the University of Chicago. Impact of Drug Shortages on Patients in the United States: A Case Study of Three Drugs. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. April 2024. Available at: <https://aspe.hhs.gov/reports/shortages-three-drugs>.

¹²⁴ Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Impact of Drug Shortages on Consumer Costs. May 2023. <https://aspe.hhs.gov/sites/default/files/documents/87781bc7f9a7fc3e6633199dc4507d3e/aspe-rtc-costs-drug-shortages.pdf>.

¹²⁵ Beleche, T., and Kolbe, A. Medical Product Shortages in the United States: Demographic and Geographic Factors and Impacts. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. July 2024. Available at: https://aspe.hhs.gov/sites/default/files/documents/1c348191e0660572cfe642e2fbca572c/ASPE_IssueBrief_shortages-2024-07-05_edited_ASPE_508c.pdf.

manufacturers can select to submit net pricing data (as described in section II.G.6.b. of this proposed rule). We also propose in 42 CFR 513.610 that the submission must be complete, meaning the submission—(1) has a proper and full execution of the manufacturer data agreement; (2) has a proper and full attestation by the manufacturer's authorized representative; (3) was submitted using the proper portal and all security requirements within; (4) was executed in the manner and form required by CMS; and (5) includes supporting documentation that explains how each of the elements of the submission were compiled or calculated and any reasonable assumptions that were applied. Incomplete submissions, as determined by CMS, would not be assessed for validity and would not be used by CMS for purposes of identifying a per unit Method II GLOBE Model benchmark.

In addition, we propose that complete data submissions would be assessed by CMS for validity. As discussed previously in section II.G.1. of this proposed rule, to do so, CMS would utilize all available existing data sources and information to assess the extent to which the submission reflects international drug net pricing for the applicable international analogs that were sold in the reference countries during the applicable ASP calendar quarter. To inform the review, as determined by CMS, CMS may use available data sources. We propose that CMS may choose to request additional supporting information and/or data from the manufacturer who submitted the data to inform CMS' assessment of the validity of the submission. Because the amount of time that CMS would have to complete the review would be minimal (for example, approximately 2 weeks), CMS would limit the amount of time that a manufacturer would have for submission of additional supporting information to no more than 5 business days from the agency's request for additional supporting information or data or both.

a. Basic Data Requirements

Under the data agreement, manufacturers may make submissions for one or more GLOBE Model drugs for any applicable ASP calendar quarter. If a manufacturer chooses to make a submission for a GLOBE Model drug to enable identification of a per unit

Method II GLOBE Model Benchmark, the manufacturer would include all applicable international analogs as defined by 42 CFR 513.600. We also propose that the basic data element requirements would consist of data elements, including but not limited to presentation level information, that manufacturers must submit in order for CMS to corroborate that an applicable international analog (as defined in 42 CFR 513.600) which is included in the manufacturer submitted data corresponds to a GLOBE Model drug and to verify the results of the manufacturer's conversion to HCPCS billing units. To verify a manufacturer's conversion to HCPCS billing units, CMS proposes to calculate the number of HCPCS billing units (as defined in 42 CFR 513.20) in the applicable international analog, by dividing the quantity of drug in the package by the HCPCS dosage (quantity of drug represented in one HCPCS billing unit).

In 42 CFR 513.610, we propose that the required basic data elements that would be used by CMS to identify the international net pricing data that corresponds to a GLOBE Model drug, would include the GLOBE Model drug brand name, nonproprietary name, and HCPCS Level II code. We also propose that the basic data elements provided by the manufacturer contain a list of every applicable international analog as defined in 42 CFR 513.600 that was sold in that reference country for the applicable ASP calendar quarter. The list is the required basic data elements including presentation level information. We propose that a complete submission must have these data elements for all of the applicable international analogs as defined in 42 CFR 513.610 by reference country:

- Scientific or nonproprietary name.
- Brand name, all international drug names.
- HCPCS Level II code.
- Names of manufacturers, marketers, or licensees.
- Non-U.S. country regulatory approval status ¹²⁶ (international

¹²⁶ As defined at proposed 42 CFR 513.600 “non-U.S. country regulatory approval status” means information relevant for CMS to determine whether each applicable international drug's regulatory approval status (according to the applicable reference country's regulatory framework), is an international generic (international non-originator drug), international biosimilar biological product (international non-originator drug), international

originator drug or international non-originator drug).

- Dosage form and route of administration (if applicable).
- Strength.
- Volume per item (for example, 10 ml in one vial).
- Package type (for example, syringe, vial, ampule, etc.).
- Number of items per package (for example, 10 vials in a package).
- HCPCS dosage (published by CMS each for HCPCS Level II code).
- Number of HCPCS billing units.

We propose that these data elements would be required to be submitted for all applicable international analogs sold in the reference country during the applicable ASP calendar quarter that corresponds to a GLOBE Model drug. If there are missing data elements, the submission would be considered incomplete and would be deemed unacceptable for identifying a per unit Method II benchmark until the manufacturer provides all the necessary data elements to CMS no later than 30 calendar days after the end of the applicable ASP calendar quarter. This means that if, for a GLOBE Model drug, there are six applicable international analogs in a reference country, the manufacturer submitted data must include the basic data elements for every applicable international analog in that reference country. If an applicable international analog was sold in multiple reference countries, then the manufacturer submitted data must also include the basic data elements for all applicable international analogs in each of the reference countries. That is, the basic data element requirements necessitate submitting the data elements separately for each applicable international analog for each reference country. This information would be necessary to allow CMS to identify each applicable international analog within each reference country where the drug is sold.

Figure 2. Illustrative Example of Basic Data Elements

originator drug, or other. Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug pricing information in the proposed GLOBE Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved and non-U.S.-approved products.

1. GLOBE Model drug elements for identification: brand name, non-proprietary name, and HCPCS Level II code; and
2. For every reference country where at least one applicable international analog was sold during the applicable ASP calendar quarter:

[illegible]

We recognize the complexities inherent in international pharmaceutical markets, including variations in strengths, formulations, and routes of administration; packaging differences; and diverse relationships between U.S. and international entities responsible for product marketing and distribution. CMS seeks comments on whether the proposed voluntary framework, which includes basic required data elements to ensure applicable international analogs correspond with GLOBE Model drugs, adequately addresses these market complexities. We also seek comments on whether additional basic data elements should be required or if any of the proposed elements presents significant data collection, analysis, or submission challenges.

We also propose in 42 CFR 513.610 that manufacturers who elect to submit

Under the streamlined option, CMS proposes that manufacturers would be required to report a set of net pricing data elements for the applicable international analogs that correspond to the GLOBE Model drug. For the purposes of the streamlined option, we propose to define in 42 CFR 513.600 that “gross sales” refers to each sale the manufacturer made in that reference country to a purchaser, the amount of money owed to a manufacturer by the purchasers, before subtracting any discounts, rebates, or other price concessions. We propose to define “purchaser” in 42 CFR 513.600 as the entities or organizations acquiring the drug product for subsequent sale within

the pharmaceutical supply chain or for administration or dispensing to a human. It may include, among others, wholesalers, distributors, hospitals, pharmacies, and other healthcare providers and practitioners. For “price concessions”, we propose the following definition in 42 CFR 513.600 to mean the sum of the value of the following types of transactions and items whether at the time of sale or afterwards:

- Volume discounts: “Volume discounts” are also known as quantity discounts or bulk discounts where the price per unit is reduced when purchased in larger quantities.
- Prompt pay discounts: The term “prompt pay discounts”, also known as early payment discounts, means any reduction in the total value of units purchased routinely offered to a purchaser when a payment is made within a specified timeframe and consistent with customary business practices for payment.
- Cash discounts: The term “cash discounts” refers to reductions on the price per unit when payment is made in cash. This may be facilitated through discount cards, coupons, or other agreements.
- Free goods includes samples or other benefits provided to purchasers or patients that are contingent on any purchase requirement.
- Chargebacks: This term refers to retrospective payments made from manufacturers to purchasers.
- Rebates: This term refers to reimbursements made by a manufacturer to a wholesaler or other purchaser, for the difference between the price the wholesaler or other purchaser initially paid for the product and the lower price at which the

wholesaler or other purchaser sold the product.

- Other price concessions that lower the amount realized by the manufacturer.

We also propose to define in 42 CFR 513.600 that “net sales amount” means for each sale the manufacturer made in that reference country to a purchaser, the amount of money owed by the purchaser exclusive of any price concessions. Each net sales amount would have a corresponding sales volume, expressed in HCPCS billing units. The net sales amount is not a list price (for example., the equivalent of WAC in the United States); rather, it is based on the net price of the applicable international analog sold in each reference country. We propose “net price level,” defined at 42 CFR 513.600, to mean with respect to sales of applicable international analogs, means all sales of the applicable international analogs in a reference country at the same price net of price concessions during the applicable ASP calendar quarter. We also propose the submission include the net sales amount in the reference country currency, what the local currency is (for example, euro, yen, etc.), and its equivalent U.S. dollar amount, at the net price level. This means the data submitted would report each sales transaction’s net sales amount, at an aggregated net price level, along with the corresponding volume sold expressed in HCPCS billing units. In addition, we propose the gross sales amount and net sales amount to be rounded to 5 decimal places.

We recognize that manufacturers may not have access to every sale in a reference country if they are not the ones who are making the sale. Under

our proposal, we would expect the manufacturer to obtain data for every transaction that is made directly to health care entities, distributors, wholesalers, or other international purchasers and aggregate those that share a price and concession amount resulting in sales by the net price level.

In Table 7 an example of a voluntary submission of net pricing data by the manufacturer of GLOBE Model drug I is shown. This fictitious GLOBE Model drug I has more than one applicable international analog in 3 reference countries, A, B and C. In reference country A it has 2 applicable international analogs, in reference country B it has 4, and in reference country C it has 3. For reference country A, the applicable international analog 1 has 5 net price levels, thus an applicable submission would include gross and net sales amounts and volume sold expressed in HCPCS billing units for each of the 5 levels. In the same reference country A, applicable international analog 2 has 3 net price levels, thus the acceptable submission includes 3 gross and net sales amounts with the corresponding volumes. This logic is repeated in Table 7 for the other reference countries with applicable international analogs to GLOBE Model drug I. Because the net price level represents all sales transactions that occurred at the same net price during the applicable ASP calendar quarter, there may be multiple individual sales of each applicable international analog. However, all such sales were aggregated into a single net price level when they share the same net price after applying any applicable price concessions.

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TABLE 7. TABLE SHOWING NET PRICE DATA ELEMENTS REQUIRED UNDER THE STREAMLINED OPTIONS FOR ILLUSTRATIVE GLOBE MODEL DRUG “I”

Reference Country	Applicable International Analog	Net Price Levels	Gross Sales Amount (Local Currency)	Net Sales Amount (Local Currency)	Volume (in HCPCS Billing units)	Average Net-to-Gross Ratio	Exchange Rate (Local Currency to USD)	Volume-weighted Net Price per HCPCS billing units (U.S. Dollars)	GDP (PPP)-Adjuster	Across Country Volume-weighted Average GDP (PPP)-Adjusted Net Price per HCPCS billing unit (U.S. Dollars)
Streamlined Option										
A	1	1	100.00000	65.00000	5	0.54947	0.800	187.00231	1.000	182.761
		2	460.00000	350.00000	20					
		3	367.00000	270.00000	15					
		4	80.00000	30.00000	10					
		5	204.00000	48.00000	15					
	2	1	321.00000	132.00000	14					
		2	245.00000	89.00000	6					
		3	123.00000	60.00000	23					
B	1	1	540.00000	340.00000	89	0.61368	10.000	38.10080	1.300	
		2	345.00000	140.00000	90					
		3	76.00000	70.00000	35					
		4	345.00000	260.00000	72					
		5	222.00000	90.00000	34					
	2	1	678.00000	540.00000	90					
		2	856.00000	345.00000	104					
		3	1,020.00000	589.00000	302					
		4	345.00000	140.00000	120					
	3	1	567.00000	300.00000	270					
		2	908.00000	650.00000	309					
	4	1	345.00000	301.00000	190					
		2	284.00000	187.00000	102					
		3	401.00000	302.00000	201					
C	1	1	207.00000	130.00000	40	0.58011	0.860	533.03 078	1.500	
		2	196.00000	89.00000	36					
	2	1	467.00000	123.00000	60					
		1	178.00000	90.00000	40					
	3	2	376.00000	201.00000	32					
		3	999.00000	777.00000	222					
		4	111.00000	60.00000	3					

Notes: Net price level means the sum of individual sales or volume sold for an applicable international analog in a reference country at the same price and price concession amounts; this means there can be more than one sale in each net price level. Gross and net sales amounts are in local currency for the reference country in this table and must include what the local currency is. Volume in this table is expressed in HCPCS billing units that aligns with those of the GLOBE Model drug I. The exchange rate is for currency conversion (local currency to USD); in this case the sales amount is divided by the exchange rate to convert from local currency to U.S. dollars. The volume-weighted net price is obtained by adding for a reference country the products of the net sales amounts in U.S. dollars multiplied by the corresponding volume and then dividing by the total volume (this includes all net price levels for all applicable international analogs in a reference country). The across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit is obtained by adding for all reference countries the products of the net sales amounts in U.S. dollars multiplied by the corresponding reference country's GDP (PPP)-adjuster and multiplied by the corresponding volume and then dividing by the total volume (this includes all net price levels for all applicable international analogs in all reference countries).

In addition, under the streamlined option, we propose that manufacturers provide one “average net-to-gross ratio” for each GLOBE Model drug per reference country. For the purposes of the streamlined option, we propose to define the “average net-to-gross ratio” to be the total net sales of the applicable international analogs in the reference country divided by the total gross sales of the applicable international analogs in the reference country. We also propose the average net-to-gross ratio to be rounded to 5 decimal places. An example of how the average net-to-gross ratio would be reported is shown in Table 7. In Reference Country A, the sum of all net sales amount for all applicable international analogs is 1044.00000 and the sum of all gross sale amount for the same set of drugs is 1900.00000. Thus, the average net-to-gross ratio would be all net sales amount divided by the sum of all gross sales amounts resulting in 0.54947. A more detailed calculation is shown later in this section.

In addition, we propose manufacturers would be required to report for each country, the volume-weighted net price across all applicable international analogs, in U.S. dollars. We also propose to define “volume-weighted net price” to mean exclusive of any price concessions, the volume-weighted reference country average net price in U.S. dollars where the weights are volumes in HCPCS billing units. In addition, we propose volume of the applicable international analog in HCPCS billing units must be expressed using the same number of decimals places as the submitted GLOBE Model Drug’s HCPCS billing units. The volume-weighted net price per reference country must also be rounded to 5 decimal places.

Using again the example of reference country A shown in Table 7, each of the net price sales amounts for both applicable international analogs contribute to the volume-weighted net price according to how much volume was sold. The net sales amounts are converted from local currency to U.S. dollars using an exchange rate that is described by 3 decimal places and expressed as number of local currency units to U.S. dollars. In other words, net sales amounts are converted to U.S. dollars by dividing the net sales by the exchange rate. Our proposal for exchange rate considerations is discussed in section II.G.6.c. of this proposed rule. For this example, each net sale is divided by 0.800. This results in an average price for one HCPCS billing unit of GLOBE Model Drug I in reference country A being \$187.00231.

A more detailed calculation is shown later in this section.

We also propose that manufacturers would be required to submit, across all the reference countries, the *across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit*, which is the volume-weighted average GDP (PPP)-adjusted net price of all the applicable international analogs corresponding to a GLOBE Model drug in U.S. dollars along with the GDP (PPP) adjuster that was used for the adjustment. We propose to define at 42 CFR 513.20, the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit to mean a volume-weighted average for all reference countries of GDP (PPP)-adjusted net prices, where the weights are the volume in HCPCS billing units for each reference country, in U.S. dollars from international drug net pricing data from an applicable submission. In addition, we propose the across volume-weighted average GDP (PPP)-adjusted net price per HCPCS billing unit to be reported and rounded to 3 decimal places.

We propose that the GDP-adjustment would be based on PPP and that manufacturers must use the GDP (PPP)-adjuster from CMS that aligns with the applicable ASP calendar quarter as specified by CMS. CMS would publish a supplemental document on the GLOBE Model website with details on which GDP (PPP) adjuster would be used for each applicable ASP calendar quarter. To establish the GDP (PPP) adjuster for each ASP calendar quarter, we propose to use the most recent data of GDP per capita based on purchasing power parity for a country (GDP (PPP)) available in the CIA World Factbook at the start of the applicable ASP calendar quarter (as defined in 42 CFR 513.20) as determined by CMS. CMS would publish this GDP (PPP) adjuster at the beginning of each applicable calendar quarter.

An example of the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit for all reference countries can also be observed in Table 7. In this example for GLOBE Model Drug I, there is only one across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit for all three reference countries. Each net sales amount for all applicable international analogs in the three reference countries contribute to this average according to the volume sold. Each of the 29 net sales amounts are converted to U.S. dollars using the appropriate exchange rate (0.800 for the 8 net sales amounts for reference country A, 10.000 for the 14

net sales amounts for reference country B, and 0.860 for the 7 net sales amounts for reference country C) and adjusted by the reference country’s GDP (PPP) adjuster (1.000 for reference country A, 1.300 for reference country B, and 1.500 for reference country C). In this illustrative example for GLOBE Model drug I, the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit in all reference countries where it is sold is \$182.761, having accounted for how much quantity is sold, the country’s currency, and its PPP.

As a summary, after manufacturers have identified applicable international analogs as defined in 42 CFR 513.600, for an applicable ASP calendar quarter, we propose manufacturers use the following steps to identify average net-to-gross ratio, volume-weighted net price per reference country, and across country volume-weighted average net GDP (PPP) adjusted net price per HCPCS billing unit for all reference countries for each GLOBE Model drug:

Step 1: By reference country, apply the following data checks. Identify and discard data as follows:

- a. Exclude sales for international biosimilar biological products and international generic products. In other words, sales data must be based on international originator drugs.
- b. Exclude international drug pricing data without both sales and volume data that are greater than zero.

Step 2: By reference country, convert the volume data to unit of measurement delineated in the GLOBE Model drug’s HCPCS Level II code descriptor (for example, mg, ml, mcg, etc.), as applicable, for each applicable international analog and net price level. Volume must be expressed using the same rounding convention as the corresponding GLOBE Model Drug. We propose to calculate the number of HCPCS billing units in the applicable international analog as defined in 42 CFR 513.610 by dividing the quantity of drug in the package by the HCPCS dosage (quantity of drug represented in one HCPCS billing unit, which is the identifiable quantity of a drug or biological product associated with a billing and payment code (for example, a HCPCS Level II code), as established by CMS).

Step 3: By reference country, aggregate gross sales amount, in local currency, for each applicable international analog that has the same net price level for each reference country. Gross sales amount must be rounded to 5 decimal places. Report what the local currency is.

Step 4: By reference country, aggregate net sales amount, in local currency, for each applicable international analog for the corresponding GLOBE Model drug that have the same net price level for each reference country. Net sales amount must be rounded to 5 decimal places. Report what the local currency is.

Step 5: By reference country, calculate the average net-to-gross ratio, in local currency, for each reference country. Report what the local currency is.

a. Sum the gross sales amount for all net price levels of all applicable international analogs.

b. Sum the net sales amount for all net price levels for all applicable international analogs.

c. Divide the sum determined in Step 5b. by the sum determined in Step 5a., resulting in the average net-to-gross-ratio per reference country. The average net-to-gross-ratio must be rounded to 5 decimal places.

Step 6: By reference country, convert the net sales amount, in local currency, to U.S. dollars. Divide the net sales, in local currency, by, the exchange rate to convert to U.S. dollars and round to 5 decimal places.

Step 7: By reference country, calculate the per unit volume-weighted net price—

a. Multiply the net sales, in U.S. dollars, by the volume in HCPCS billing unit for each applicable international analog and net price level.

b. Add together the sums determined in Step 7a.

c. Sum together the volume sold in HCPCS billing units for all applicable international analogs and all net price levels.

d. Divide the sum determined in Step 7b by the sum determined in Step 7c, resulting in the average volume-weighted net price per HCPCS billing unit per reference country. Round the average volume-weighted net price per reference country to 5 decimal places.

Step 8: Calculate the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit for all applicable international analogs to a GLOBE Model drug for all reference countries.

a. Per reference country, multiply the average volume-weighted net price calculated in Step 7d by the applicable GDP (PPP) adjuster per applicable ASP calendar quarter (to be published by CMS in a supplemental document).

b. Per reference country, multiply the sum in Step 8a by the sum in Step 7c. (total volume sold in HCPCS billing unit for all applicable international analogs and all net price levels).

c. Sum together the amounts in Step 8b and divide by the total billing units for all applicable international analogs in all reference countries, resulting in the across country average volume-weighted GDP (PPP) adjusted net price per HCPCS billing unit for all applicable international analogs to a GLOBE Model drug across all reference countries. Round the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit to 3 decimal places.

We propose that manufacturers submit information on how the data elements were compiled and computed and consistent with ASP reporting, any reasonable assumptions that were made during this process. We also propose manufacturers provide any other pertinent information that CMS should consider in its verification process for the data. Examples of information to submit include if a third party was used to gather, analyze, or submit the net pricing data element, or if the manufacturer made any reasonable assumptions to determine the average gross-to-net ratio (for example, expected clawbacks and other price concessions based on past historical data that may have delayed reporting to the manufacturer and would not be available to the manufacturer in time to be included in the manufacturer's data submission to CMS no later than 30 days after the end of the applicable ASP calendar quarter). We seek comments on reasonable assumptions manufacturers may make during their reporting of average gross-to-net ratio and net sales such as how they account for clawbacks and other price concessions that may have delayed reporting to the manufacturer.

We also recognize that manufacturers may need to allocate gross and net sales amounts to the applicable international analogs in order to provide the data elements required. We propose in 42 CFR 513.610 that any allocation and calculations be done in a manner consistent with the generally acceptable accounting principles (GAAP), international financial reporting standards (IFRS), or other internationally recognized accounting approaches.¹²⁷ We solicit feedback on whether there are other accounting approaches that CMS should consider.

(2) Limited Option

Under the limited option, we propose that manufacturers would be required to

submit a set of data elements that are aggregated at higher levels than CMS is proposing under the streamlined option. For all the applicable international analogs to a corresponding GLOBE Model drug, as defined in 42 CFR 513.600, and for each reference country, we propose that manufacturers submit the *total* gross sales amount in local currency and its equivalent U.S. dollar amount, which would be computed as the sum of all gross sales amounts for the applicable international analogs in the reference country's currency, the *total* net sales amount in local currency and its equivalent U.S. dollar amount, which would be computed as the sum of all net sales amounts for the applicable international analogs in the reference country's currency, and the corresponding *total* sales volume in HCPCS billing units. In other words, the total gross sales, total net sales, and total sales volume by reference country is an aggregate of all the applicable international analogs and net price levels. For the purposes of the limited option, we propose to use the same definition as the streamlined option for "gross sales amount" and "net sales amount" as defined in 42 CFR 513.600. Manufacturers must also report what the local currency is (for example, euro, yen, etc.) We also propose the total gross sales and total net sales to be rounded to 5 decimal places and that the total sales volume must be expressed using the same number of decimals places as the corresponding GLOBE Model Drug's HCPCS billing units.

We recognize that manufacturers may not have access to every sale in a reference country if they are not the ones who are making the sale. Under our proposal, we would expect the manufacturer to obtain every transaction that is made directly to health care entities, distributors, wholesalers, or other international purchasers. In addition, we propose to require manufacturers to submit the average net-to-gross ratio for each of the reference countries where the applicable international analogs were sold for a GLOBE Model drug. We propose to define the "average net-to-gross ratio" for the limited option to be the same as the streamlined option which is the total net sales of the applicable international analogs in the reference country divided by the total gross sales of the applicable international analogs in the reference country. We propose manufacturers round the average net-to-gross ratio to 5 decimal places.

We also propose manufacturers to report, for each country, the volume-weighted net price across all applicable international analogs corresponding to a

¹²⁷ Sean Ross, *GAAP vs. IFRS: What's the Difference?*, Investopedia (Apr. 18, 2025), Available at <https://www.investopedia.com/ask/answers/011315/what-difference-between-gaap-and-ifrs.asp> (Last accessed Nov. 4, 2025).

GLOBE Model drug, as defined in 42 CFR 513.600, in U.S. dollars. To convert from local currency to U.S. Dollars, the net sales amount, in local currency, is divided by an exchange rate with 3 decimal places expressed as number of local currency units to U.S. dollars. Our proposal for exchange rate considerations is discussed in section II.G.6.c. of this proposed rule. For the limited option, we also propose to define the “volume-weighted net price” the same as the streamlined option, which is the volume-weighted reference country average net price in U.S. dollars where the weights are volume in HCPCS billing units exclusive of any price concessions as defined in 42 CFR 513.600. The volume-weighted net price per reference country must be rounded to 5 decimal places.

In addition, we propose that manufacturers would be required to submit, across all the reference countries, the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit of all the applicable international analogs to a corresponding GLOBE Model drug, as defined in 42 CFR 513.600, in U.S. dollars along with the GDP (PPP) adjuster that was used for the adjustment. The limited option would use the same definition as the

streamlined option for the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit as defined in 42 CFR 513.610. This across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit for all reference countries must be rounded to 3 decimal places.

We propose that the GDP adjustment would be based on PPP and that manufacturers must use the GDP (PPP) adjuster from CMS that aligns with the applicable ASP calendar quarter. CMS would publish a supplemental document on the GLOBE Model website with details on which GDP (PPP) adjuster to use for each applicable ASP calendar quarter. To establish the GDP (PPP) adjuster for each ASP calendar quarter, we propose to use the most recent data of GDP per capita based on purchasing power parity for a country (GDP (PPP)) available in the CIA World Factbook at the start of the applicable ASP calendar quarter (as defined in 42 CFR 513.20) as determined by CMS. We would publish this GDP (PPP) adjuster at the beginning of each applicable calendar quarter.

The across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit would represent the average net price per HCPCS billing

unit of the applicable international analogs corresponding to a GLOBE Model drug, as defined in 42 CFR 513.600, across all reference countries where the applicable international analogs are sold and would include an adjustment using GDP (PPP). To calculate the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit in all reference countries where applicable international analogs are sold, the volume-weighted net price per reference country (in U.S. dollars) is multiplied by the GDP (PPP) adjuster per reference country and then the weighted mean for all reference countries is calculated using the sum of volume in HCPCS billing units for each reference country as the weights.

Table 8 shows the net pricing data elements that would be required for GLOBE Model Drug I for the limited option. In this option, while there may be multiple applicable international analogs to GLOBE Model Drug I and multiple net pricing levels, only total gross sales, total net sales, total volume, average net-to-gross-ratio, volume-weighted net price in U.S. dollars per reference country, and across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit in U.S. dollars is reported.

TABLE 8 TABLE SHOWING NET PRICE DATA ELEMENTS REQUIRED UNDER THE STREAMLINED OPTIONS FOR ILLUSTRATIVE GLOBE MODEL DRUG “I”

Reference Country	Gross Sales Amount (Local currency)	Net Sales Amount (Local currency)	Volume	Reference Country	Gross Sales Amount (Local currency)	Net Sales Amount (Local currency)	Volume	Reference Country
Limited Option								
A	1,900.00000	1,044.00000	108	0.54947	0.800	187.00231	1.000	182.761
B	6,932.00000	4,254.00000	2,008	0.61368	10.000	38.10080	1.300	
C	2,534.00000	1,470.00000	433	0.58011	0.860	533.03078	1.500	

Notes: Gross and net sales amounts are in local currency for the reference country in this table. Manufacturers would also report the type of local currency. Volume in this table is expressed in HCPCS billing units that aligns with those of the GLOBE Model drug I. The exchange rate is for currency conversion (local currency to USD). In this case the sales amount is divided by the exchange rate to convert from local currency to U.S. dollars. The volume-weighted net price is obtained by adding for a reference country the products of the net sales amounts in U.S. dollars multiplied by the corresponding volume and then dividing by the total volume. The across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit is obtained by adding for all reference countries the products of the net sales amounts in U.S. dollars multiplied by the corresponding reference country’s GDP (PPP) adjuster and multiplied by the corresponding volume and then dividing by the total volume.

As a summary, after manufacturers have identified applicable international analogs sold that correspond to a GLOBE Model drug for an applicable ASP calendar quarter, we propose manufacturers use the following steps to identify average net-to-gross ratio, volume-weighted net price per reference country, and across country volume-

weighted average GDP (PPP) adjusted net price per HCPCS billing unit for all reference countries for each GLOBE Model drug:

Step 1: By reference country, apply the following data checks. Identify and discard data as follows:

a. Exclude sales for international biosimilar biological products and

international generic products. In other words, sales data must be based on international originator drugs.

b. Exclude international drug pricing data without both sales and volume data that are greater than zero.

Step 2: By reference country, convert the total volume data to the unit of measurement delineated in the GLOBE

Model drug's HCPCS Level II code descriptor, as applicable, for all applicable international analogs. Total volume must be expressed using the same rounding convention as the corresponding GLOBE Model Drug. We propose to calculate the number of HCPCS billing units in the applicable international analog as defined in 42 CFR 513.610 by dividing the quantity of drug in the package by the HCPCS dosage (quantity of drug represented in one HCPCS billing unit, which is the identifiable quantity of a drug or biological product associated with a billing and payment code (for example, a HCPCS Level II code), as established by CMS).

Step 3: By reference country, aggregate gross sales amount, in local currency, for all applicable international analogs. Gross sales amount must be rounded to 5 decimal places. Report what the local currency is.

Step 4: By reference country, aggregate net sales amount, in local currency, for all applicable international analogs. Net sales amount must be rounded to 5 decimal places. Report what the local currency is.

Step 5: By reference country, calculate the average net to gross ratio, in local currency, for each reference country:

a. Sum the gross sales amount for all net price levels of all applicable international analogs.

b. Sum the net sales amount for all net price levels for all applicable international analogs.

c. Divide the sum determined in Step 5b by the sum determined in Step 5a, resulting in the average net-to-gross-ratio per reference country. Round the average net-to-gross-ratio to 5 decimal places.

Step 6: By reference country, convert the net sales amount, in local currency, to U.S. dollars. Divide the net sales, in local currency, by, the exchange rate to convert to U.S. dollars and round to 5 decimal places.

Step 7: By reference country, calculate the per unit volume-weighted net price.

a. Multiply the net sales, in U.S. dollars, by the volume in HCPCS billing unit for each applicable international analog.

b. Add together the sums determined in Step 7a.

c. Sum together the volume sold in HCPCS billing units for all applicable international analogs.

• Divide the sum determined in Step 7b by the sum determined in Step 7c, resulting in the average volume-weighted net price per HCPCS billing unit per reference country and round to 5 decimal places.

Step 8: Calculate the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit for all applicable international analogs to a GLOBE Model drug across all reference countries.

a. Per reference country, multiply the average volume-weighted net price calculated in Step 7d by the applicable GDP (PPP) adjuster per applicable ASP calendar quarter (to be published by CMS in supplemental document).

b. Per reference country, multiply the sum in Step 8a by the sum in Step 7c (total volume sold in HCPCS billing unit for all applicable international analogs).

c. Sum together the amounts in Step 8b and divide by the total billing units for all applicable international analogs in all reference countries, resulting in the across country average volume-weighted GDP (PPP) adjusted net price per HCPCS billing unit for all applicable international analogs to a GLOBE Model drug across all reference countries. Round the across country average volume-weighted GDP (PPP) adjusted net price per HCPCS billing unit for all reference countries to 3 decimal places.

c. Exchange Rate Considerations

For both options for submitting net pricing data elements, we are proposing that certain data elements would be submitted in U.S. dollars and the manufacturer would report the exchange rate for the currency conversion rounded to 3 decimal places, which CMS proposes would mean the conversion rate used by the manufacturer to convert from the currency of each reference country to U.S. dollars for data included in the submission. We propose manufacturers use either the World Bank Atlas (for a conversion method in lieu of a straight exchange rate),¹²⁸ IMF exchange rates data,¹²⁹ the Federal Reserve Bank foreign exchange rates,¹³⁰ or exchange rates from country-specific sources to identify the average exchange rate. If the data source chosen uses an exchange rate frequency that is less than annual (for example, daily, weekly, monthly, quarterly), the exchange rate for the

currency conversion would correspond to an average exchange rate of the chosen frequency for the applicable ASP calendar quarter during which international sales occurred. We also propose manufacturers use the same exchange rate for currency conversion for all applicable international analogs, as defined in 42 CFR 513.600, in a reference country. In other words, all net pricing data in a reference country must use the same exchange rate. We also propose that once an exchange rate data source is identified that the manufacturer continues to use the same data source for all subsequent data submissions, unless the data source is no longer available, and that the exchange rate data source is reported with each voluntary submission. This approach is necessary so that a manufacturer's submitted international net pricing data per GLOBE Model drug is in a consistent format and CMS would be able to combine the data appropriately for purposes of testing an alternative rebate calculation methodology. We solicit feedback on other data sources manufacturers would consider for currency conversion; the methods that would be used; the challenges that might arise; and any other pertinent information related to this topic.

d. Attestation and Submission

While manufacturer reporting is voluntary, submitted data must meet completeness, and validity standards in proposed 42 CFR 513.610 and must be determined by CMS to be an applicable submission in order to be used by CMS to identify the per unit Method II GLOBE benchmark for a GLOBE Model drug for an applicable calendar quarter, as discussed in section II.G.2.b. of this proposed rule. In 42 CFR 513.610, we propose that if the manufacturer is electing to submit international drug net pricing data, the data must be submitted within 30 days after the end of the applicable ASP calendar quarter and the data that is contained within the submission must correspond to the applicable ASP calendar quarter. As such, we propose that an authorized representative, on behalf of the manufacturer, provide an attestation that the submissions are accurate and complete to the manufacturer's knowledge, prepared in compliance with the requirements specified under § 513.610 (including, but not limited to the requirements for basic data elements and streamlined or limited option), and that the authorized representative has the authority to make such attestation on behalf of the manufacturer. Authorized representatives for the

¹²⁸ *The World Bank Atlas Method: Detailed Methodology*, World Bank, Available at <https://datahelpdesk.worldbank.org/knowledgebase/articles/378832-the-world-bank-atlas-method-detailed-methodology> (Last accessed Sept. 24, 2025).

¹²⁹ *IMF Data Explorer: Exchange Rate Data (4.0.1)*, International Monetary Fund, Available at [https://data.imf.org/en/Data-Explorer?datasetUrn=IMF.STA:ER\(4.0.1\)](https://data.imf.org/en/Data-Explorer?datasetUrn=IMF.STA:ER(4.0.1)) (Last accessed Sept. 24, 2025).

¹³⁰ *Foreign Exchange Rates—G.5A Annual*, Board of Governors of the Federal Reserve System (Jan. 6, 2025), Available at <https://www.federalreserve.gov/releases/g5a/current/> (Last accessed Sept. 24, 2025).

manufacturer must provide their contact information and attest as such. We propose the authorized representatives must be legally authorized to bind the manufacturer to the terms and conditions contained within the data agreement. The authorized representatives are also designated by a manufacturer to submit data, manage all related communications, and attest to the completeness and accuracy of the submission on the manufacturer's behalf. We propose that authorized representatives must specify if they are a third-party organization that is submitting data on behalf of the manufacturer. We propose that a data submission would not be considered complete if it does not include all requirements of attestation such as contact information of the authorized representative, whether a third-party organization is submitting on behalf of the manufacturer, and the attestation itself. The submission would also be considered incomplete if the required basic data elements defined in 42 CFR 513.610 and the required net pricing data elements in the selected streamlined or limited option, as defined in 42 CFR 513.600, are missing, or if the basic data elements and net pricing data elements do not correspond to the applicable ASP calendar quarter that is submitted.

In 42 CFR 513.610, we propose that the attestation and data submission process would occur through a CMS designated system. We intend to designate the CMS Health Plan and Management System (HPMS), which is currently used for Manufacturer Discount Program reporting, reporting for the Medicare Drug Price Negotiation Program, and for the Medicare Part B Drug Inflation Rebate Program. Leveraging existing technology and systems would facilitate executing the GLOBE Model data agreements and attestations, submitting data templates for the various data submission pathways, and provide a method for protecting submitted information. While we intend to designate HPMS, we may designate a different CMS system for submission, if necessary.

We propose that, pursuant to an effectuated GLOBE Model data agreement, CMS would not disclose manufacturer-submitted international net pricing information in a form which discloses the identity of a specific manufacturer and their international net pricing and sales data except as CMS determines to be necessary to carry out 42 CFR 513.210 and 42 CFR 513.500 regarding the determination and implementation of the GLOBE Model rebate amount, the GLOBE Model

beneficiary coinsurance, and adjusted Medicare payment amount.

We also propose a manufacturer selects one submission option for net pricing data elements, either limited or streamlined, for all applicable international analogs to a GLOBE Model drug. That is, for all applicable international analogs to a GLOBE Model drug for an applicable ASP calendar quarter, the manufacturer could not use one submission option for net pricing data elements for some of the reference countries and a different submission option for net pricing data elements for other reference countries for which international net pricing and sales data is submitted. Similarly, the manufacturer would continue to use the same submission option for net pricing data elements (either streamlined or limited) to submit all their international net pricing data for that GLOBE Model drug for subsequent applicable ASP calendar quarters. That is, once the manufacturer chooses to voluntarily submit international net pricing data, the manufacturer must continue to do so for the duration of the GLOBE Model so long as sales of applicable international analogs have occurred. This approach is necessary so that a manufacturer's submitted international net pricing data per GLOBE Model drug is in a consistent format and that CMS would be able to combine the data appropriately for purposes of testing an alternative rebate calculation methodology. We also propose that CMS reserves the right to terminate the data agreement if a manufacturer chooses to stop submitting voluntary international net pricing even when sales of the applicable international analogs have occurred. If the data agreement has been terminated, we propose the per unit Method I international benchmark is used for the GLOBE Model drug for the remainder of the model duration.

e. Corrections and Resubmissions

We recognize errors may occur during a manufacturer's submission of international pricing data and are proposing to allow corrections of a submission within 30 days of the submission deadline. For example, if a manufacturer submits international net pricing data for the applicable ASP calendar quarter ending December 31, 2026, to CMS no later than January 30, 2027, in accordance with the requirements for submission of such data, the manufacturer would be allowed to correct the submitted data by submitting a full replacement data submission and attestation for that applicable ASP calendar quarter to CMS (in accordance with the requirements

for submitting corrected data) no later than March 1, 2027. We propose to limit the timeframe for submission of corrected international net pricing data to CMS for an applicable ASP calendar quarter to 30 days after the deadline for the initial submission to potentially allow CMS to revise the GLOBE Model beneficiary coinsurance percentage for applicable GLOBE Model drugs prior to the start of the applicable quarter. CMS must complete the calculation of the GLOBE Model beneficiary coinsurance percentage approximately 30 days prior to the start of an applicable quarter. Therefore, allowing 30 days for manufacturers to submit corrected international net pricing data to CMS is the maximum amount of time that could be permitted for such correction and also allow CMS a small window of time to recalculate the GLOBE Model beneficiary coinsurance percentage and make the results available within the Medicare Part B claims processing systems timely.

f. Alternatives Considered

We considered offering a more comprehensive option for manufacturers. Under this option, in addition to the data elements noted in the streamlined and limited options, manufacturers would have been required to submit more granular information and a greater number of data elements. Specifically, in addition to submitting net sales amount at the net price level, manufacturers would be required to submit the corresponding amount of any discounts, rebates, or other price concessions for each net sales amount at the net price level. As part of the submission, manufacturers would also submit an across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit in U.S. dollars across all the applicable international analogs corresponding to the GLOBE Model drug and across all the reference countries where the applicable international analogs are sold. However, we decided not to offer this option due to concerns of manufacturer and CMS reporting burden.

We also considered offering an option that allows manufacturers to submit for the entire set of applicable international analogs that correspond to a GLOBE Model drug, the total gross revenue, total net revenue, and total volume for each reference country. Under this potential option, manufacturers could combine the gross revenue, net revenue, and volume across all the applicable international analogs and report this to CMS along with other necessary data elements (volume weighted average net

price by reference country and across country volume weighted average GDP (PPP) adjusted net price). However, we decided against including this option in the proposal because our ability to verify this information would be limited. We also considered whether manufacturers would be required to calculate the volume weighted-average net price for each reference country and the across country volume-weighted GDP (PPP) adjusted net price per HCPCS billing unit or whether CMS would calculate these values. We decided against the policy of CMS calculating values because we believe that the burden related to doing the calculations given the other data elements that are required is minimal. In addition, we considered whether to require the manufacturer to also identify the lowest net price among the set of reference countries for the set of applicable international analogs that correspond to a GLOBE Model drug. However, as this information is already part of the submission, we did not believe it was necessary. We seek feedback on these policies.

In addition, we considered providing manufacturers the set of applicable international analogs for which they must submit the international net pricing data. However, we believe that manufacturers have this information, and it would not be burdensome to them to identify the set of applicable international analogs that are sold in the reference countries. We also considered the possibility of accepting a submission without the full set of applicable international analogs included in the submission and using the data that is submitted along with existing information to calculate an updated benchmark. However, we decided against this approach because of concerns about combining different data sources and whether it would be logical to do so. We also considered allowing manufacturers to submit an explanation for why they cannot provide pricing information for the full set of applicable international analogs for all reference countries where they are sold and for CMS to review the explanation to determine if this meets the requirement of an applicable submission. However, we believe manufacturers have access to pricing information for where their drugs or biological products are sold and can make a reasonable assumption of their net to gross ratio. We seek feedback on our proposed policy as well as the alternatives presented, including whether CMS should provide the set of applicable international analogs for

which data would be submitted for each corresponding GLOBE Model drug.

We recognize the complexities inherent in international pharmaceutical markets, including variations in strengths, forms, and routes of administration; packaging differences; and diverse relationships between U.S. and international entities responsible for product marketing and distribution. For these reasons, we also considered only requesting this data for the set of applicable international analogs that correspond to a GLOBE Model drug that are sold directly by the manufacturer and not by any other subsidiary or company in the reference countries. We also considered an option where manufacturers would only submit the data for the set of applicable international analogs that they directly sell in the reference countries. However, we believe that manufacturers have relationships with subsidiaries, wholesalers, and other businesses involved in selling the set of applicable international analogs in the reference countries and can obtain the requested data under this option. We were also concerned that allowing manufacturers to only submit for applicable international analogs sold directly by the manufacturer would potentially result in manufacturers choosing which applicable international analogs to sale directly and which ones to be sold by other entities to reduce the manufacturer's GLOBE Model rebate liability. We balanced multiple policy priorities, including administrative burden for manufacturers and CMS; the need for complete and verifiable data submissions; and potential concerns that may arise from disclosing detailed international drug pricing information. CMS welcomes feedback on our proposed policy, the alternatives presented, and situations in which manufacturers may find it challenging to report the proposed net pricing information to CMS.

We also considered two alternatives for exchange rate for currency conversion. In the first option considered, CMS would not specify which exchange rate data source to use, allowing manufacturers maximum flexibility. In the second option, we considered publishing the exchange rate for currency conversion on the GLOBE Model website that would align to the applicable ASP calendar quarter, which would provide the most data standardization. We considered these alternatives and believed allowing maximum flexibility would lead to significant data standardization issues that may pose a challenge in testing an alternative rebate calculation

methodology. We also believed that while the second option would provide for maximum data standardization it would limit manufacturer's ability to determine the most appropriate exchange rate and data source for when the sale of the applicable international analog occurred. As such, we believe our approach of allowing manufacturers to choose within a set of exchange rate data sources but requiring manufacturers to use the same data source within a reference country and for subsequent submission of the drugs, balances the need for flexibility and data standardization.

In addition, we also considered alternatives such as a longer timeline, 90 days after the end of the applicable ASP calendar quarter, for initial submission of international drug net pricing data as manufacturers may need additional time for reconciliation of pricing data after the end of the applicable ASP calendar quarter. We understand that manufacturers' processes and timelines for data gathering, calculations and reporting may vary widely by manufacturer, applicable international analog, reference country, and distribution arrangements. CMS balanced the timing needed to calculate the GLOBE Model beneficiary coinsurance percentage and manufacturers' process and timelines for data gathering and we believe that manufacturers would be able to make reasonable assumptions of net sales based on historical data. Therefore, we believe requiring initial data submission to occur within 30 days after the end of the applicable ASP calendar quarter provides sufficient time for manufacturers to assess any reasonable assumptions needed for net sales reporting.

We also considered allowing manufacturers up to one year after initial data submission to correct data and account for any delayed price concessions such as clawbacks. As such, CMS would invoice manufacturers for any additional rebates identified after this corrected data submission, but would be unable to update the GLOBE Model beneficiary coinsurance percentage without reprocessing paid claims to apply retrospective changes to the coinsurance percentage which would be administratively burdensome for GLOBE Model beneficiaries, healthcare providers that submitted claims for GLOBE Model drugs that were furnished to GLOBE Model beneficiaries, CMS, and supplemental insurers, as well as confusing for impacted beneficiaries which could increase beneficiary requests for assistance through 1-800-Medicare and

from their healthcare providers. We considered this alternative and decided that since manufacturers are only required to report average net-to-gross price ratios and because most manufacturers likely have an estimate of expected clawbacks and other price concessions with data lag from historical data, manufacturers could make a reasonable assumption on their average net-to-gross ratio. We seek comments on whether the proposed timeline provides sufficient timing for manufacturers to submit pricing data (for example, clawbacks or other types of price concessions), whether manufacturers have sufficient information to make a reasonable assumption on their average net-to-gross ratio within the reported timelines proposed for attestation, and if there are other types of reasonable assumptions manufacturers may make to meet the proposed submission requirements.

7. Proposed GLOBE Model Beneficiary Coinsurance Adjustment and Adjusted Medicare Payment for GLOBE Model Drugs

As part of the GLOBE Model design, in 42 CFR 513.210, CMS proposes to test an alternative calculation for beneficiary coinsurance for GLOBE Model eligible beneficiaries who receive a GLOBE Model drug for which separate Medicare Part B payment is allowed. In general, for a separately payable Part B drug, the basic allowable charges that a participating provider or supplier may charge the beneficiary are the Part B annual deductible and 20 percent of the Medicare allowed amount in excess of that deductible, subject to the limitation described in 42 CFR 419.41(c)(4)(1) when applicable (that is, in certain circumstances, such as under the OPPIs, beneficiary coinsurance does not exceed the inpatient deductible amount).¹³¹ In the case of a Part B rebatable drug, the basic allowable charges that a participating provider or supplier may charge the beneficiary are the Part B annual deductible and 20 percent of the inflation-adjusted payment amount for the rebatable drug in excess of that deductible, which is applied as a percent to the payment amount for such calendar quarter, as set forth in 42 CFR 489.30(b)(6).

For the GLOBE Model, we propose to calculate the GLOBE Model beneficiary coinsurance adjustment for GLOBE Model drugs with respect to an applicable calendar quarter using a methodology that is similar to the

coinsurance adjustment under the Medicare Part B Drug Inflation Rebate Program as set forth in 42 CFR 427.201. Specifically, we propose that, for a GLOBE Model drug for an applicable calendar quarter, to determine if the GLOBE Model beneficiary coinsurance adjustment applies, CMS would compare the payment amount, as set forth in 42 CFR 427.201(b)(3) (that is, CMS would use the published payment amount in quarterly pricing files published by CMS as the *payment amount* in this determination), to the *per unit GLOBE Model benchmark amount* as set forth in proposed 42 CFR 513.400. If the *payment amount* exceeds the *per unit GLOBE Model benchmark amount*, the GLOBE Model beneficiary coinsurance adjustment would apply and the *GLOBE Model beneficiary coinsurance* would be calculated by multiplying the *per unit GLOBE Model benchmark amount* by 0.20. To apply this amount as a percent to the *payment amount* for an applicable calendar quarter, we propose that CMS would then calculate the *GLOBE Model beneficiary coinsurance percentage* by dividing the result by the *payment amount* and rounding the result to the third decimal place.

If the *payment amount* does not exceed the *per unit GLOBE Model benchmark amount*, we propose that the GLOBE Model beneficiary coinsurance adjustment would not apply. In such cases, the GLOBE Model beneficiary coinsurance would be calculated using the non-model coinsurance to ensure that beneficiary liability for a GLOBE Model beneficiary is not greater than it would be absent the model. We note that, in such cases, the non-model coinsurance would likely equal the usual coinsurance (that is, 20 percent of the Medicare Part B allowed amount, assuming no other beneficiary liability would apply, as set forth in 42 CFR 489.30(b)(1)) because such cases would occur when neither the GLOBE Model beneficiary coinsurance nor a coinsurance reduction under the Medicare Part B Drug Rebate Program would apply.

CMS would determine and apply the *GLOBE Model beneficiary coinsurance percentage* to the payment amount when processing a claim for a separately payable GLOBE Model drug that was furnished to a GLOBE Model eligible beneficiary on a date of service within the applicable calendar quarter. CMS' calculation and application of the *GLOBE Model beneficiary coinsurance percentage* would not be subject to appeal.

Using the illustrative data for Method I presented in Table 6, the illustrative

payment amount of \$44.42 exceeds the illustrative *per unit GLOBE Model benchmark amount* of \$16.16). In this case, the illustrative *GLOBE Model beneficiary coinsurance* would be \$3.23, calculated by multiplying the *per unit GLOBE Model benchmark amount* by 0.20. The illustrative *GLOBE Model beneficiary coinsurance percentage* would then be 7.2 percent, which is the result of dividing \$3.23 by the illustrative *payment amount* of \$44.42.

Using illustrative 2024 data, calculations for the Method I benchmark estimated that for 73 percent of the illustrative GLOBE Model drugs, the beneficiary coinsurance would be reduced between 10 and 20 percent. Further, our analysis showed that for 17 percent of the illustrative GLOBE Model drugs, the beneficiary coinsurance would be reduced between 0 and 10 percent. For the remaining 10 percent of illustrative GLOBE Model drugs, there would not have been a change in the coinsurance as a result of being in the model.

In conjunction with testing an alternative calculation for beneficiary coinsurance, we propose that CMS would adjust the Medicare payment to the provider or supplier for a separately payable GLOBE Model drug claim in the same manner as under the Medicare Part B Drug Inflation Rebate Program as set forth in 42 CFR 410.152(m) and, for hospital outpatient department services, 42 CFR 419.41(e). That is, when the GLOBE Model beneficiary coinsurance adjustment applies, we propose that the Medicare payment amount (the adjusted Medicare payment amount) would be equal to the allowed amount for the GLOBE Model drug minus the product of the *GLOBE Model beneficiary coinsurance percentage* and the allowed amount, assuming no other claim adjustment applies. For example, if the Medicare Part B allowed amount under the GLOBE Model is \$100 and the GLOBE Model beneficiary coinsurance percentage is 10 percent (instead of the usual 20 percent), the Medicare Part B program payment to the provider or supplier would be adjusted and would be \$90 (instead of the usual \$80) and the beneficiary financial responsibility would be \$10. The formula in this example is $100 - (0.100 \times 100) = 90$.

We note that claims for any Part B rebatable drug that is excluded from the GLOBE Model for an applicable calendar quarter or is not separately payable would not be subject to the GLOBE Model beneficiary coinsurance percentage and payment adjustment.

We welcome comments on this proposed approach for testing an alternative calculation for beneficiary

¹³¹ A non-participating supplier can bill the beneficiary for an extra 15 percent beyond the 20 percent coinsurance.

coinsurance and the Medicare Part B payment for GLOBE Model drugs that are furnished to GLOBE Model eligible beneficiaries during an applicable calendar quarter during the model performance period.

8. Proposed Approach for GLOBE Model Rebates Reports, Invoicing, and Reconciliation

In this section of this proposed rule and in proposed 42 CFR 513 subpart H, we present two alternative approaches for how CMS would invoice manufacturers for GLOBE Model rebates. After considering future comment on this proposed rule, CMS intends to adopt one of these approaches, or a similar approach that emerges from CMS' consideration of comments and further analysis of the alternatives and establish corresponding regulatory text. Hence, although this proposed rule includes two options for proposed invoicing processes in subpart H, CMS has only described one option within the regulatory text and only intends to include one option in a final rule that would establish the GLOBE Model.

One option we considered is called the “combined” approach. Under a combined approach, using the waiver authority under section 1115A of the Act, CMS would delay Medicare Part B Drug Inflation Rebate Program Preliminary Rebate Reports for all manufacturers by up to 2 months and would provide a combined report to all manufacturers of Part B rebatable drugs for both the Medicare Part B Drug Inflation Rebate Program and the GLOBE Model. The combined report would show, in one report, the information included in a Medicare Part B Drug Inflation Rebate Program Rebate Report as specified in 42 CFR 427.501 and further discussed in section II.G.8.a. of this proposed rule. Because there would be a single combined report and rebate amount due, we propose that the Suggestion of Error process specified in 42 CFR 427.503 would be used such that manufacturers would use one submission if the manufacturer believes that there is a mathematical error or errors to be corrected before the Rebate Report or a subsequent reconciliation of the rebate amount due for both the Medicare Part B Drug Inflation Rebate Program and the GLOBE Model (if any), is finalized. We note that, as discussed in section II.G.4. of this proposed rule, the *total GLOBE Model rebate amount* invoiced would be an incremental amount (the *incremental GLOBE Model rebate amount*), which represents the amount of the GLOBE Model rebate that is in excess of the rebate amount for the

Medicare Part B Drug Inflation Rebate Program that applies to the *total number of GLOBE Model billing units*.

The combined approach would present information in a single report which may enhance transparency for manufacturers of GLOBE Model drugs. In a single report, GLOBE Model Rebate Report information would not appear in Rebate Reports for Part B rebatable drugs that are not GLOBE Model drugs. For CMS, the increased operational complexity of combining data from the Inflation Rebate Program and the GLOBE Model into a single report would lengthen the time necessary for creating Preliminary Rebate Reports for all manufacturers of Part B rebatable drugs, which, correspondingly, would extend the time following the end of an applicable calendar quarter for manufacturers to pay rebates.

Another option we considered is called the “incremental” approach. Under the *incremental* approach, GLOBE Model reports and invoicing would not disrupt the Medicare Part B Drug Inflation Rebate Program reports and invoicing timelines. This approach would use a separate report and invoicing process that would run approximately two months after the Medicare Part B Drug Inflation Rebate Program reports and would invoice manufacturers of GLOBE Model drugs for the incremental GLOBE Model rebate amount due as set forth in 42 CFR 513.500(b). Under this two-stage process, the Medicare Part B Drug Inflation Rebate Program reports would show information specified for that program and the GLOBE Model reports would show information specific to the model as proposed in 42 CFR 513.710 and further discussed in section II.G.8.b. of this proposed rule. In 42 CFR 513.710(b), we propose that a GLOBE Model Preliminary Rebate Report would be provided to each manufacturer of a GLOBE Model drug at least 1 month prior to the issuance of the GLOBE Model Rebate Report which would be provided no later than 8 months after the end of each applicable calendar quarter.

Consistent with our proposed timing of invoicing activities described later in this section, the GLOBE Model Preliminary Rebate Report would reflect any revisions identified through the Suggestion of Error process specified in 42 CFR 427.503 related to the Medicare Part B Drug Inflation Rebate Program Rebate Report, and the GLOBE Model Rebate Report (or subsequent GLOBE Model report) would reflect such revisions as applicable. In addition, because there would be separate reports, in 42 CFR 513.720, we propose a

separate Suggestion of Error process such that a manufacturer would submit its Suggestion of Error within 10 calendar days from the date of receipt of a GLOBE Model Preliminary Rebate Report (or a report detailing the preliminary reconciliation of a GLOBE Model rebate amount) for the applicable calendar quarter, using a method and process established by CMS, if the manufacturer believes that there is a mathematical error or errors to be corrected before the GLOBE Model Rebate Report or a subsequent reconciliation of the GLOBE Model rebate amount, as applicable, is finalized.

The incremental approach using a two-step reporting and invoicing process and separate Suggestion of Error process could facilitate administrative efficiencies for CMS and manufacturers of GLOBE Model drugs compared to the combined approach. Separate reports could avoid potential confusion for manufacturers of Part B rebatable drugs that are not GLOBE Model drugs.

Under each approach CMS would need to calculate the *incremental per unit GLOBE Model rebate amount* for an applicable calendar quarter after the Part B rebate amount has been calculated as set forth in 42 CFR 427.301, CMS would need additional time following the end of an applicable calendar quarter for providing incremental GLOBE Model Rebate Reports to manufacturers of GLOBE Model drugs and, similarly, for manufacturers to pay rebates. We estimate that the extended time would be about the same under either the combined or incremental approach, and the amount of additional time that would be necessary would be about two months.

At 42 CFR 513.700, we propose, that “date of receipt” would have the same meaning as set forth in 42 CFR 513.500. This term would be applicable to both options discussed in this section of this proposed rule.

We welcome feedback on these proposed approaches for reports and reconciliation and potential refinements to them as well as potential alternative approaches that would support efficient testing and evaluation of the GLOBE Model and transparency for manufacturers while minimizing adverse impacts on manufacturers of Part B rebatable drugs and CMS' systems, operations, and financial resources.

The following sections describe the proposed reports under the combined and incremental approaches in more detail.

a. Proposed Changes to the Rebate Report and Reconciliation Under the Combined Approach

Under a combined approach for rebate invoicing, to operate the GLOBE Model in a streamlined efficient manner, we propose that the total GLOBE Model rebate amount due would be invoiced to the manufacturer using the Medicare Part B Drug Inflation Rebate Program rebate report processes with some minor changes to convey GLOBE Model information within one Preliminary Rebate Report (and subsequent reports) for an applicable calendar quarter and allow CMS more time to make reports available to manufacturers.

Specifically, we propose to waive 42 CFR 427.501(c) to the extent necessary such that CMS would provide each manufacturer of a Part B rebatable drug a Rebate Report that is the invoice for the total rebate amount due under both the Medicare Part B Drug Inflation Rebate Program and the GLOBE Model (if applicable), if any, no later than 8 months after the end of each applicable calendar quarter instead of 6 months after the end of each applicable calendar quarter. The extended timeline would apply to all Part B rebatable drugs and manufacturers not just those that are GLOBE Model drugs and GLOBE Model participants. We do not believe that it would be feasible to extend the timeframe solely for GLOBE Model drugs and GLOBE Model participants because CMS confirms the identification of GLOBE Model drugs and the manufacturer(s) of such drugs as CMS completes the steps to compile all Rebate Reports and the additional GLOBE Model considerations would increase the level of effort and time necessary for CMS to complete all rebate calculations and report generation steps.

In addition, we propose to waive 42 CFR 427.501 to the extent necessary to include GLOBE Model rebate information within the Rebate Report (and subsequent reports). We propose that, for a calendar quarter, a Preliminary Rebate Report (and subsequent related rebate reports) would include the information set forth in 42 CFR 427.501(b)(1) as well as GLOBE Model information specified in new 42 CFR 427.520(b)(2), which we propose would include but not be limited to the following: the NDC(s) billing and payment codes identified for the GLOBE Model drug as determined by CMS; the total number of GLOBE Model billing units as set forth in 42 CFR 513.520; the total number of billing units as determined under 42 CFR 427.303; the per unit Method I GLOBE Model benchmark (as described in

section II.G.2.a. of this proposed rule and identified under 42 CFR 513.410); the per unit Method II GLOBE Model benchmark, if available (as described in section II.G.2.b. of this proposed rule and identified under 42 CFR 513.420); the per unit GLOBE Model benchmark amount as set forth in 42 CFR 513.400; the per unit GLOBE Model rebate amount as set forth in 42 CFR 513.510(a); the incremental per unit GLOBE Model rebate amount as set forth in 42 CFR 513.510(b); the applicable calendar quarter specified amount as determined under 42 CFR 427.302(b); the amount, if any, by which the specified amount as determined under 42 CFR 427.302(b) exceeds the inflation-adjusted payment amount as determined under 42 CFR 427.302(g) for the Part B rebatable drug for the applicable calendar quarter as set forth in 42 CFR 427.302; the total GLOBE Model rebate amount as set forth in 42 CFR 513.500; the incremental GLOBE Model rebate amount due as set forth in 42 CFR 513.500; any applied reductions as determined under 42 CFR 513 subpart F; the proportion of manufacturer-reported ASP units, if applicable; and the reduced incremental GLOBE Model rebate amount, if any. The total rebate amount due would be the combined rebate amount due under both the GLOBE Model and the Medicare Part B Drug Inflation Rebate Program. The GLOBE Model information specified at proposed 42 CFR 513.710(b)(1) would only be populated in Preliminary Rebate Reports (and subsequent related rebate reports) for manufacturers of GLOBE Model drugs. For a Rebate Report for a manufacturer of a Part B rebatable drug that is not GLOBE Model drug for an applicable calendar quarter, the total rebate amount due would equal the amount specified in 42 CFR 427.501(b)(1)(ix) which is the rebate amount due as determined under the Medicare Part B Drug Inflation Rebate Program at 43 CFR 427.301(a).

We note that, while we propose to issue the Preliminary Rebate Reports 2 month later, under the combined invoicing approach, the cadence for rebate reports and reconciliation under 42 CFR 427.501(b) and (d) would be unchanged. For example, preliminary rebate reports would be issued 1 month before Rebate Reports. Similarly, payment of rebate amounts owed would be due no later than 11:59 p.m. Pacific Time (PT) on the 30th calendar day after the date of receipt of information regarding the total rebate amount. To specify how this cadence would apply to Rebate Reports, invoicing, and

reconciliation, we propose several amendments to 42 CFR 427.501(b)(2), (c) and (d). Specifically, we propose that 42 CFR 427.501(c) would waive to the extent necessary that CMS would provide each manufacturer of a Part B rebatable drug no later than 8 months after the end of each applicable calendar quarter a GLOBE Model Rebate Report with the total GLOBE Model rebate amount due for a GLOBE Model drug for that applicable calendar quarter. We propose that 42 CFR 427.501(d)(1) would be applied such that CMS would perform one regular reconciliation of the rebate amount within 12 months of the date of receipt of the Rebate Report for each applicable calendar quarter. As discussed in section II.O. of this proposed rule, under the combined approach, we propose to use the waiver authority under section 1115A of the Act, to the extent necessary to delay Medicare Part B Drug Inflation Rebate Program invoicing for manufacturers of GLOBE Model drugs by up to 2 months.

We propose the GLOBE Model information would be added to the Preliminary Rebate Reports, Rebate Reports, and Reconciliation Rebate Reports for an applicable calendar quarter under 42 CFR 427 subpart F. Because the Suggestion of Error process specified in 42 CFR 427.503 would apply to the GLOBE Model rebate information included in the Preliminary Rebate Report or Preliminary Reconciliation Rebate Report, manufacturers would use one submission if the manufacturer believes that there is a mathematical error or errors to be corrected before the Rebate Report or a subsequent Reconciliation Rebate Report, as applicable, is finalized, and as such we are not proposing a separate Suggestion of Error process for the GLOBE Model information under the combined approach.

If the combined approach is adopted for the GLOBE Model, CMS would inform manufacturers of the revised Rebate Report format by posting information on the CMS website and issuing a memorandum to all manufacturers of Part B rebatable drugs.

b. Proposed Changes to the Rebate Report and Reconciliation Under the Incremental Approach

Under the incremental approach, the GLOBE Model rebate amount would be invoiced to the manufacturer using a process that would be separate from, but harmonized with, the Medicare Part B Drug Inflation Rebate Program rebate invoicing process. As such, in 42 CFR 513.710 and 42 CFR 513.720, we propose regulatory text for GLOBE

Model Rebate Reports and reconciliation, including a Suggestion of Error process, that aligns as applicable with the Medicare Part B Drug Inflation Rebate Program as set forth at 42 CFR 427 subpart F. The Medicare Part B Drug Inflation Rebate Program reporting and reconciliation would continue as specified under 42 CFR 427 subpart F.

In 42 CFR 513.710(c), for the GLOBE Model rebate reporting activities, we propose that CMS would provide each manufacturer of a GLOBE Model drug a GLOBE Model Rebate Report no later than 8 months after the end of each applicable calendar quarter. For a calendar quarter, the GLOBE Model Preliminary Rebate Report would include the information set forth in 42 CFR 513.710(b)(1), including the following: the NDC(s) billing and payment codes identified for the GLOBE Model drug as determined by CMS; the total number of GLOBE Model billing units as set forth in 42 CFR 513.520; the per unit Method I GLOBE Model benchmark as identified under 42 CFR 513.410; the per unit Method II GLOBE Model benchmark as identified under 42 CFR 513.420; the per unit GLOBE Model benchmark amount as set forth in 42 CFR 513.400; the per unit GLOBE Model rebate amount as set forth in 42 CFR 513.510; the incremental per unit GLOBE Model rebate amount as set forth in 42 CFR 513.510; the applicable calendar quarter specified amount as determined under 42 CFR 427.302(b), the amount, if any, by which the specified amount as determined under 42 CFR 427.302(b) exceeds the inflation-adjusted payment amount as determined under 42 CFR 427.302(g) for the Part B rebatable drug for the applicable calendar quarter as set forth in 42 CFR 427.302; the amount, if any, by which the specified amount as determined under 42 CFR 427.302(b) exceeds the per unit GLOBE Model rebate amount as determined under 42 CFR 513.510 for the GLOBE Model drug

for the applicable calendar quarter as set forth in 42 CFR 513.500; the total GLOBE Model rebate amount as set forth in 42 CFR 513.500; the incremental GLOBE Model rebate amount as set forth in 42 CFR 513.500; the proportion of manufacturer-reported ASP units, if applicable; any applied reductions as determined under 42 CFR 513 subpart F; and the reduced incremental GLOBE model rebate amount, if applicable.

In 42 CFR 513.710, we propose that the incremental GLOBE Model rebate amount would be invoiced to the manufacturer using a process that would be harmonized with, but separate from, the Medicare Part B Drug Inflation Rebate Program rebate invoicing process. First, in accordance with 42 CFR 427.501(c), CMS would provide each manufacturer of a Part B rebatable drug a Rebate Report that is the invoice for the rebate amount due for a Part B rebatable drug under the Medicare Part B Drug Inflation Rebate Program (if any) no later than 6 months after the end of each applicable calendar quarter. For an applicable calendar quarter, the Rebate Report includes the information set forth in 42 CFR 427.501(b)(1), including the total number of billing units as determined under 42 CFR 427.303 and the rebate amount due as determined under 42 CFR 427.301(a), if any. Second, via an additional invoice that is specific to the GLOBE Model for an applicable calendar quarter, we propose that CMS would provide each manufacturer of a GLOBE Model drug a GLOBE Model Rebate Report that would be the invoice for the incremental GLOBE Model rebate amount (if any) which, when considered with the rebate amount already invoiced under the Rebate Report for the Medicare Part B Drug Inflation Rebate Program, reconciles the rebate amount due under the GLOBE Model to the total GLOBE Model amount. The incremental amount due (and invoiced on the GLOBE Model

Rebate Report) would be calculated by multiplying the incremental per unit rebate amount by the total number of GLOBE Model billing units as proposed under 42 CFR 513.520. The amount that would be reflected in the second GLOBE Model-specific *incremental* invoice for a GLOBE Model drug for a manufacturer would be the additional amount owed within 30 days of receipt of the GLOBE Model rebate report. The GLOBE Model also adopts the reconciliation approach under the Medicare Part B Drug Inflation Rebate Program specified at 42 CFR 427.501(d). That is, within 12 months of the issuance of the GLOBE Model Rebate Report, a report of the reconciled incremental GLOBE Model rebate amount will be provided to each manufacturer of a GLOBE Model drug to account for certain updates (for example, updates to the GLOBE Model billing units or restatement of inputs to the specified amount under 42 CFR 427.302(b)) that may affect the GLOBE Model rebate amount calculation. One month prior to the issuance of this report with the reconciled incremental GLOBE Model rebate amount, CMS will conduct a preliminary reconciliation of the incremental GLOBE Model rebate amount as set forth in proposed 42 CFR 513.710(d). CMS would provide the GLOBE Model report to manufacturers of GLOBE Model drugs 2 months after the Medicare Part B Drug Inflation Rebate Program provides a report for the applicable calendar quarter. Under the Medicare Part B Drug Inflation Rebate Program, for an applicable calendar quarter, there are four reports. Table 9 shows the four reports for an applicable calendar quarter, the timing for each report, and an example of how the timing for these reports would occur for the first applicable calendar quarter during performance year 1 of the GLOBE Model assuming the proposed model start on October 1, 2026.

**TABLE 9: ILLUSTRATION OF THE PROPOSED TWO-STEP INVOICING TIMELINE
FOR GLOBE MODEL REBATE AMOUNTS: EXAMPLE FOR APPLICABLE
CALENDAR QUARTER OCTOBER – DECEMBER 2026**

First Invoice Medicare Part B Drug Inflation Rebate Program			Second (Incremental) Invoice GLOBE Model		
Report	Report Provided By	Example Timeline	Report	Report Provided By	Example Timeline
Preliminary Rebate Report (See 42 CFR 427.501(b))	At least 1 month prior to the issuance of the Rebate Report	May 31, 2027	GLOBE Model Preliminary Rebate Report (See 42 CFR 513.710(b))	At least 1 month prior to the issuance of the GLOBE Model Rebate Report	July 31, 2027
Rebate Report (See 42 CFR 427.501(c))	No later than 6 months after the end of each applicable calendar quarter	June 30, 2027	GLOBE Model Rebate Report (See 42 CFR 513.710(c))	No later than 8 months after the end of each applicable calendar quarter	August 31, 2027
Rebate Report – Preliminary Reconciliation (See 42 CFR 427.501(d)(1)(i))	At least 1 month prior to the issuance of a report with the reconciled rebate amount	May 31, 2028	Rebate Report – Preliminary Reconciliation (See 42 CFR 513.710(d)(1)(i))	At least 1 month prior to the issuance of a report with the reconciled rebate amount	July 31, 2028
Rebate Report – Regular Reconciliation (See 42 CFR 427.501(d)(1))	Within 12 months of the issuance of the Rebate Report	June 30, 2028	Rebate Report – Regular Reconciliation (See 42 CFR 513.710(d)(1))	Within 12 months of the date of issuance of the GLOBE Model Rebate Report	August 31, 2028

We propose that GLOBE Model rebate invoicing would occur after invoicing under the Medicare Part B Drug Inflation Rebate Program to create a unified framework for testing the GLOBE Model while maintaining harmonization between the model and non-model activities. We believe that up to 2 months would be a reasonable timeframe during which CMS would gather the necessary information to calculate the incremental GLOBE Model rebate amount due and perform data quality checks prior to providing each manufacturer of a GLOBE Model drug a GLOBE Model Rebate Report that would be the invoice for the incremental GLOBE Model rebate amount due (if any). We are proposing to harmonize the model and non-model activities, including the proposed incremental GLOBE Model invoicing approach, to maintain consistency and transparency for manufacturers with respect to the Medicare Part B Drug Inflation Rebate Program while minimizing administrative impacts on manufacturers and complexity for CMS operations of the Medicare Part B Drug Inflation Rebate Program during the GLOBE Model test.

As discussed in section II.G.4.d. of this proposed rule and proposed at 42 CFR 513.500, we propose to, when applicable, reduce the incremental GLOBE Model rebate amount for drugs in shortage and/or when there is a severe supply chain disruption or likely shortage, if applicable. Under the incremental approach, CMS would apply any reductions as determined under sections 42 CFR 427.401 and 42 CFR 427.402 to the total GLOBE Model rebate amount due such that the GLOBE Model rebate amount due would reflect such reductions (if applicable). In

addition, we propose that CMS would provide a GLOBE Model Rebate Report for each GLOBE Model drug for each applicable calendar quarter even in cases when the incremental per unit GLOBE Model rebate amount equals zero.

If the incremental approach is adopted for the GLOBE Model, CMS would establish a GLOBE Model Rebate Report format that would be similar to the current Rebate Report format and would inform manufacturers of the GLOBE Model Rebate Report format by posting information on the CMS website and issuing a memorandum to all manufacturers of Part B rebatable drugs.

c. Proposed Suggestion of Error Process Under the Incremental Approach

In 42 CFR 513.720, we propose a Suggestion of Error process for the GLOBE Model such that a manufacturer would submit its Suggestion of Error to CMS, for its discretionary consideration, for the applicable calendar quarter within 10 calendar days from the date of receipt of a GLOBE Model Preliminary Rebate Report or a GLOBE Model Preliminary Reconciliation Rebate Report using a method and process established by CMS if the manufacturer believes that there is a mathematical error or errors to be corrected before the GLOBE Model Rebate Report or a subsequent GLOBE Model Reconciliation Rebate Report, as applicable, is finalized. CMS would make available a method for a manufacturer to submit a Suggestion of Error for GLOBE Model reports that would be substantially similar to the method used for the Medicare Part B Drug Inflation Rebate Program. Further, we propose that CMS would include any revisions to the calculation of the

GLOBE Model rebate amount, if determined necessary by CMS based on the manufacturer's Suggestion of Error, prior to providing the GLOBE Model Rebate Report or any GLOBE Model Reconciliation Rebate Report, if applicable. CMS would notify the manufacturer whether CMS revised its calculation of the rebate amount based on the Suggestion of Error. CMS notes that the scope of the Suggestion of Error process set forth in 42 CFR 513.720 would be limited to GLOBE Model information and any corrections would not impact the information in the Reconciliation Rebate Report as set forth in 42 CFR 427.501(d)(ii).

We welcome comment on our proposal for a separate Suggestion of Error process that would be included for the incremental approach if such approach is adopted for the model.

H. Proposed Program Compliance Requirements and Enforcement

1. Enforcement Action

a. Enforcement of GLOBE Model Rebate Amount Payments by Manufacturers

As described in section II.J. of this proposed rule, CMS proposes that the manufacturer of a GLOBE Model drug would be required to pay the incremental GLOBE Model rebate amount by 11:59 p.m. Eastern Time on the 30th calendar day after receipt of the GLOBE Model Rebate Report.

Manufacturer payment of GLOBE Model rebate amounts is critical to model test integrity; without these payments, there would be limited ability to test potential savings to the Federal Supplementary Medical Insurance Trust Fund or impacts to quality of care. Given that CMS would reduce coinsurance for GLOBE Model

eligible beneficiaries who have received a GLOBE Model drug, CMS must collect GLOBE Model rebate amounts in order to recoup what it has spent on GLOBE model drugs where it paid more than 80 percent of the allowed amount. CMS would need to terminate the GLOBE Model given the statutory requirement in section 1115(A)(b)(3) of the Act to terminate or modify models that are not expected to reduce spending (or those that improve the quality of care while reducing spending). Given the importance of these rebates, CMS may utilize available civil money penalty (CMP) authority at section 1847A(i)(7) of the Act or section 1128A of the Act to ensure timely compliance with payment of GLOBE Model rebate amounts due.

Consistent with the Medicare Part B Drug Inflation Rebate Program and the regulations at 42 CFR 427.600 and 513.800, CMS proposes that manufacturers of a GLOBE Model drug that have failed to timely pay the incremental GLOBE Model rebate amount would be subject to a CMP in an amount equal to at least 125 percent of the incremental GLOBE Model rebate amount for such GLOBE Model drug and applicable calendar quarter which would be in addition to any unpaid incremental GLOBE Model rebate amount due. However, this GLOBE Model CMP is separate from and in addition to any civil money penalty assessed under 42 CFR 427.600.

CMS further proposes to rely on the general CMP authority in section 1128A of the Act as codified in 42 CFR part 423, subpart T. Specifically, section 1128A(a)(8) of the Act allows a CMP to be imposed against anyone who “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items or services furnished under a Federal health care program.” CMS believes that any manufacturer that knowingly fails to comply with GLOBE Model requirements as set forth in a regulation that establishes the GLOBE Model, including provisions in the GLOBE Model data agreement, could be subject to a CMP in addition to any incremental GLOBE Model rebate amount due.

If CMS assesses a CMP for a manufacturer, the manufacturer would be held responsible for paying the incremental GLOBE Model rebate amount of any CMP amount imposed, and any amount imposed for late payment. The CMP payment would be due within 60 days after the date of notice of imposition of the CMP according to section 1128A of the Act.

In the event of non-payment of any portion of the total GLOBE Model rebate amount, CMS considered other potential enforcement approaches. For example, CMS could refer manufacturers to the Department of Justice (DOJ) for breach of contract or false certification, Department of the Treasury for their use of the Debt Management or Recovery Offset Programs, or the Department of Health and Human Services’ (HHS’) Office of Inspector General (OIG) for use of their CMP authority and for further review and investigation. However, given the importance of recovering GLOBE Model rebate amounts due from manufacturers, CMS believes it would be appropriate to pursue CMPs in order to enforce payments of the total GLOBE Model rebate amount.

In the event that a manufacturer declares bankruptcy, as described in Title 11 of the United States Code, and as a result of the bankruptcy, fails to pay either the full GLOBE Model rebate amount owed or the total sum of CMP imposed, or both, the government intends to reserve the right to file a proof of claim with the bankruptcy court to recover the unpaid amount of the GLOBE Model rebate amount and/or CMP owed by the manufacturer as set forth in 42 CFR 513.800.

We propose to codify civil money penalty and appeals procedures for GLOBE Model rebate amounts at 42 CFR part 513, subpart I.

b. Other Enforcement Actions

We propose that CMS could impose one or more enforcement actions such as CMP or terminating the data agreement if CMS determines that the following has occurred, which is not an exhaustive list:

- The GLOBE participant has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the GLOBE Model.
- The GLOBE participant is subject to investigation or action by HHS (including the HHS–OIG, CMS, or FDA) or the DOJ due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint or filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the Federal Government has intervened, or similar action.

We propose that CMS may take one or more of the following enforcement actions if CMS determines that one or more of the grounds for enforcement action described in section H.1. of this proposed rule had taken place:

- Suspending or terminating the data agreement with the manufacturer.
- Require the manufacturer to provide additional requested information to CMS or its designees.
- Subject the manufacturer to additional monitoring, auditing, or both.

As part of the Innovation Center’s monitoring and assessment of the impact of models tested under the authority of section 1115A of the Act, CMS has a special interest in ensuring that these model tests do not interfere with the program integrity interests of the Medicare program. For this reason, CMS monitors actions of GLOBE participants for compliance with model terms, as well as other Medicare program rules. When CMS becomes aware of noncompliance with these requirements, it is necessary for CMS to have the ability to impose certain administrative enforcement actions on a noncompliant model participant. We seek comment on these proposed provisions regarding the proposed grounds for enforcement actions, enforcement actions generally, and whether additional types of enforcement action would be appropriate.

I. Proposed Collection of GLOBE Model Rebate Amounts

1. Proposed Systems To Collect GLOBE Model Rebate Amounts

In 42 CFR 513.740, we propose that the deadline and process for payment of rebate amounts, including rebate amounts owed by a manufacturer, failure to pay a rebate amount, and potential refunds to a manufacturer, as articulated in 42 CFR 427.505 would apply to GLOBE Model rebate amounts calculated under the GLOBE Model. The process for manufacturer access to rebate reports as codified in 42 CFR 427.504 would apply to Rebate Reports including GLOBE Model rebate amounts (that is, combined rebate amounts, under the combined invoicing approach described in section II.G.8. of the proposed rule and incremental GLOBE model rebate amounts under the incremental invoicing approach described in section II.G.8. of the proposed rule, as applicable) calculated under the GLOBE Model, including any report of reconciled rebate amounts. In addition, we propose that the date of receipt, 30 days after which payment is due, as codified in 42 CFR 427.500, would be the calendar day following the day on which a report of a GLOBE Model rebate amount (as set forth in 42 CFR 513.510) is made available to the manufacturer of a GLOBE Model drug by CMS.

J. Proposed Quality Measures

1. General

Consistent with the evaluation provisions of section 1115A(b)(4) of the Act, CMS proposes utilizing quality measures to monitor and evaluate whether quality of care, including as measured through patient-level outcomes, changes as a result of the proposed alternative Part B inflation rebate amount calculation approach for GLOBE Model drugs. Payments to manufacturers or providers would not be adjusted based on quality of care. CMS would consider multiple domains of monitoring as outlined below, including but not limited to out-of-pocket costs, utilization of care, and access to GLOBE Model drugs.

2. Collection of Quality Measures

CMS proposes utilizing claims-based measures or existing national surveys, such as the Medicare Current Beneficiary Survey, when possible, to monitor the quality of care in a way that directly reflects patient-level factors. These may include measures to monitor—

- Part B drug utilization and prescribing patterns—such as changes in medication treatment, or cessation of treatment earlier than expected given disease course;
- Out-of-pocket costs for Part B drugs that were administered—comparing costs for beneficiaries with and without supplemental prescription drug coverage based on available data;
- Frequency and regularity of administration of Part B drugs, such as inappropriate gaps between administration of infusions or injections;
- Changes in site of service for a beneficiary receiving administration of Part B drugs;
- Changes in site of service for outpatient clinic appointments;
- Changes in prescriber of the Part B drug; and
- Downstream health care utilization, such as hospitalizations or emergency room visits.

CMS may also find it necessary to supplement claims-based measures with voluntary surveys of providers who administer Part B drugs to assess variables including but not limited to changes in: (1) perceived prescribing practices as a result of this alternative payment approach; (2) site of service for administration of clinician-administered drugs; and (3) interactions between patient and provider.

When developing this proposed quality strategy, CMS considered a range of quality measures, including

high-value prescribing of efficacious Part B drugs, medication management, barriers to access, medication adherence, patient experience of care measures, and drug-related adverse events.

CMS does not anticipate this test of a new payment approach would impact high value prescribing as the payment incentive directly to the prescribers is equivalent between the intervention and control group (ASP +6 percent).

Accurate measurement of medication management and medication adherence for Part B clinician-administered drugs is challenging because dosing schedules are variable, clinical assessment is required, and insurance claims lack sufficient clinical context.¹³² To limit additional burden upon beneficiaries, CMS proposes using existing national surveys wherever possible. If necessary to assess how the GLOBE Model has affected patient quality of care, CMS may consider implementing a beneficiary survey.

This proposed model does not test the efficacy of prescription drugs, but rather, it tests the impact of an alternative payment approach. Thus, CMS does not propose new monitoring of changes to drug-related adverse events. CMS would monitor changes in downstream health care utilization, such as changes in rates of emergency room visits, hospitalizations, or use of other clinical services. Any additional measures, including potentially beneficiary surveys, utilized by CMS would not add significant burden to GLOBE Model participants or beneficiaries.

CMS welcomes comments on the proposed quality measures above to monitor changes in the quality of care that may result from this alternative Part B inflation rebate amount calculation approach.

K. Proposed Beneficiary Protections

1. General

CMS recognizes stakeholders may have concerns over potential disruptions to beneficiary access to Medicare Part B drugs, including those that are GLOBE Model drugs, as a result of the GLOBE Model changing financial incentives for manufacturers. To alleviate these concerns, CMS has considered various options to protect beneficiary access to Medicare Part B drugs during the model performance period.

¹³² Lam WY, Fresco P. Medication Adherence Measures: An Overview. Biomed Res Int. 2015;217047. <https://pmc.ncbi.nlm.nih.gov/articles/PMC4619779/>.

One potential option CMS has considered is creating a reporting system where stakeholders, such as providers or beneficiaries, could notify CMS that a particular drug has become harder to source or obtain after the implementation of the GLOBE Model. A reporting system such as this could allow CMS to gather information to inform potential follow-up investigations to determine if any drug access issues are occurring. As such, CMS proposes setting up a GLOBE Model reporting system open to providers and beneficiaries to notify CMS that a particular drug has become harder to source or obtain. CMS also proposes to conduct investigations as appropriate based on information reported to the system, including but not limited to requesting additional information from the submitter and conducting additional analyses to determine whether the report requires further action from CMS or other governmental entities. One possibility for how this system could work is including GLOBE Model reporting within the 1-800-Medicare system. Additionally, CMS could develop an email inbox to receive reports from providers and beneficiaries. CMS may develop multiple ways to receive reports. Instructions for how to report, using one or more methods, would be posted on the CMS website for awareness. CMS could also consider making beneficiaries aware of the available reporting methods by sending letters to eligible GLOBE Model beneficiaries with reporting instructions.

CMS welcomes comments on a potential plan to build a GLOBE reporting and monitoring system for stakeholders and any other methods to protect beneficiaries.

2. Alternatives Considered

CMS Innovation Center models frequently include various policies to protect beneficiaries from any negative intended or unintended consequences of models. One of the most common forms of beneficiary protections CMS Innovation Center Models include are policies that allow beneficiaries to choose to be excluded from a model. These usually take the form of a letter sent to beneficiaries that would be included in the Innovation Center Model outlining what the model is and how it might impact beneficiaries. These letters then usually include a section allowing the beneficiary to opt-out of the model by changing to a provider not included in the model, or some other general opt-out mechanism.

CMS has considered including a beneficiary opt-out within the GLOBE Model as an additional protection for beneficiaries but has chosen to not move forward with a beneficiary opt-out at this time. While CMS acknowledges the GLOBE Model may affect drug access, CMS believes that the likelihood of reduced access is relatively low. GLOBE Model beneficiaries are expected to benefit from the program through lower coinsurance costs for GLOBE Model drugs, removing the potential for downside risk for beneficiaries. Not including a beneficiary opt-out would enhance the model test integrity and improve the generalizability of results, as there would not be a selection bias among beneficiaries who choose to remain in the model if an opt-out were offered. CMS believes that beneficiaries would benefit by being categorized as an eligible GLOBE Model beneficiary due to the potentially reduced coinsurance percentage that would apply for eligible GLOBE Model drugs for GLOBE Model beneficiaries.

CMS seeks comment on the decision not to include a beneficiary opt-out and whether variations of a beneficiary opt-out could be considered.

L. Proposed Monitoring and Compliance Actions

1. General Provisions: Monitoring and Compliance

The CMS Innovation Center has described general provisions for monitoring and compliance for CMS Innovation Center models at 42 CFR 512.150. However, we note that many of these provisions would not apply to the GLOBE Model, and the GLOBE Model is substantially different from other mandatory CMS Innovation Center models.

Instead, CMS intends to monitor for specific potential issues that could arise as part of the GLOBE Model. CMS intends to monitor for major changes in beneficiary access, as viewed through changes in site of care, provider, and other measures described in section II.J. of this proposed rule. CMS may also monitor changing list prices in the U.S. to determine whether any changes to model policies or duration could be necessary in future performance periods. CMS may also consider monitoring impacts on drug innovation, research & development, and timing of drugs coming to market in the U.S. CMS also proposes to collaborate with the Food & Drug Administration (FDA) to review shortage lists and determine whether the number of drugs or length of time on the shortage list changes over time. To the extent that CMS identifies

an issue through regular monitoring that would require a change to model policies or duration under section 1115A(b)(3)(B) of the Act, CMS would take necessary action to change a model policy or model duration based on its finding.

2. Appeals Process

CMSI proposes that the appeals processes established in 42 CFR 427.600, subpart T would apply. Additionally, the enforcement provisions of section 1847A(i)(8) of the Act and the judicial review section 1847A(j) of the Act would apply.

We seek comment on our proposal to apply administrative procedures established in 42 CFR 427.600, subpart T, along with judicial review provisions of section 1847A(i)(8) and (j) of the Act.

M. Interaction With Other Models and Programs

1. Approach for Overlap With Other Models

In designing each CMS Innovation Center model, CMS considers potential overlap between a new model and other ongoing and potential models and programs. Based on the type of overlap, such as participating entity, health care provider or beneficiary, operating rules may be established for whether or not entities, health care providers and beneficiaries can be part of both models as well as how to handle overlap when it occurs. These policies help to ensure that the evaluation of model impact is not compromised by issues of model overlap and that double counting of health care providers, beneficiaries and dollars across different models does not occur.

As discussed in section II.F. of this proposed rule, CMS is proposing to test the GLOBE Model in selected geographic areas because we believe that this approach would best allow the model evaluation to observe the impacts of the model. We considered whether additional design modifications, such as testing models in different geographic areas, or operational adjustments would be necessary for a robust test of the GLOBE Model in situations where ongoing and potential models and programs would also apply and concluded that none were warranted at this time because we intend for the GLOBE Model monitoring activities and evaluation to observe for potential behavioral changes (such as in prescribing or patterns of care) and other potential impacts on non-model aspects of the Medicare program and other models and programs. For example, as discussed in section II.J. of

this proposed rule, we propose to monitor for prescribing shifts and potential impacts on beneficiaries' access to care. If, during implementation of the proposed GLOBE Model, we were to observe unintended impacts on beneficiaries or model operations (for example, in GLOBE Model geographic areas we observe an increase in Part D utilization of clinician-administered drugs), we intend to propose appropriate operational adjustments to the GLOBE Model through notice and comment rulemaking.

In developing the proposed GLOBE Model, CMS conducted an internal review of which models and programs could have potential overlap with the GLOBE Model. As a result of our review, we expect there may be situations where an eligible GLOBE Model beneficiary who receives a GLOBE Model drug would also be assigned, aligned, or attributed to another Innovation Center model or CMS program or initiative. Overlap could also occur among health care providers and suppliers, health plans, prescription drug plans, and other entities that participate in such models, programs or initiatives. We do not believe that health care provider or beneficiary overlap between the GLOBE Model and other models, programs and initiatives would impact our ability to conduct the GLOBE Model evaluation or interpret findings. Therefore, we are not proposing adjustments to the GLOBE Model when there is overlap of health care providers that prescribe, pharmacies and other entities that furnish or dispense, or beneficiaries who receive GLOBE Model drugs. Instead, other CMS Innovation Center models and CMS programs and initiatives, as determined by CMS, would make adjustments as necessary to accommodate the GLOBE Model test and maintain the integrity of such models, programs and initiatives. For example, the Enhancing Oncology Model (EOM)¹³³ uses standardized payment amounts¹³⁴ and, as applicable, other adjustments to ensure that expenditures included in EOM calculations (such as benchmarks and performance year expenditures) reflect amounts that would have been paid by Medicare in the absence of other CMS

¹³³ For information about the EOM, see: <https://www.cms.gov/priorities/innovation/innovation-models/enhancing-oncology-model>.

¹³⁴ Standardized payments also exclude geographic differences and certain Medicare payment adjustments (for example, graduate medical education payments) to make Medicare payments comparable across providers nationwide. For more information, please see the CMS Payment Standardization Overview provided by the Research Data Assistance Center (ResDAC).

initiatives, and that payments or recoupments are not double counted. Specifically, EOM uses standardized allowed amounts in calculations that include Part B drug claims. The Medicare Part B allowed amount represents the Medicare payment limit before beneficiary cost sharing liability is applied. Therefore, the proposed GLOBE Model beneficiary coinsurance percentage adjustment when applicable is not expected to impact EOM calculations. Other CMS Innovation Center models and CMS programs also use standard payment amounts in calculations (for example, to calculate benchmarks, target expenditures, total cost of care, and shared savings) and would also not be expected to be impacted by claims that would be paid under the proposed GLOBE Model, and the proposed reduced beneficiary coinsurance was applied. Of note, some existing models and programs would not have overlap at the health care practitioner or participant level and do not impact manufacturers due to the way in which the model or program operates and makes payments.

In response to the proposed GLOBE Model beneficiary coinsurance adjustment policy discussed in section II.G.7. of this proposed rule, health care providers and beneficiaries may increase use of GLOBE Model drugs that qualify for lower coinsurance and/or manufacturers may adjust the sales price of GLOBE Model drugs. To the extent that changes in drug prices and/or beneficiary coinsurance amounts result in more appropriate provision of care, other CMS Innovation Center models and CMS programs and initiatives that reward efficient use of Medicare and Medicaid services could experience additional impacts from the design of such models, programs and initiatives because of overlap with the proposed GLOBE Model.

We anticipate model overlap may occur between the proposed GLOBE Model and future CMS models or programs not yet implemented. If the proposed GLOBE Model is finalized, CMS would take the GLOBE Model into consideration in the development of future model designs to address potential impacts of overlap with the GLOBE Model.

In summary, we are not proposing to modify or adjust any CMS Innovation Center model or CMS program or initiative where model overlap with the proposed GLOBE Model would occur. If, in the future, CMS determines a modification or adjustment to the GLOBE Model or other CMS Innovation Center model or CMS program or initiative is necessary for purposes of

testing the GLOBE Model or other CMS Innovation Center model or to operate a CMS program or initiative, CMS would pursue such modification or adjustment at such time through the appropriate mechanisms, for example, modifications or adjustments to the GLOBE Model would be pursued through notice and comment rulemaking whereas it might be appropriate for modifications or adjustments to other CMS Innovation Center models or CMS programs and initiatives to be pursued through updates to model policies and data agreements, or program participation criteria or requirements.

We seek comments on our proposed approach to address overlap between the proposed GLOBE Model and other ongoing or future CMS Innovation Center models and CMS programs as described in this section of this proposed rule. We also seek comment on the potential need for any specific modifications or adjustments to the proposed GLOBE Model that would be necessary to support a robust model test of the proposed GLOBE Model or other CMS Innovation Center model. We also welcome comments on the potential ways the proposed GLOBE Model may impact CMS programs and initiatives and the potential need for modifications or adjustments to the proposed GLOBE Model that may be necessary to minimize overlap impacts.

2. Quality Payment Program

The proposed GLOBE Model would not qualify as an Alternative Payment Model (APM) under the Quality Payment Program (QPP) or as a Merit-based Incentive Payment System (MIPS) Alternative Payment Model (MIPS APM).¹³⁵ Specifically, the proposed GLOBE Model participants would be manufacturers of GLOBE Model drugs, and those entities are not health care providers and do not qualify to participate in the QPP or MIPS APM. Medicare allowed amounts for claims for GLOBE Model drugs submitted by health care providers that are eligible for participation in the QPP would not be changed under the proposed GLOBE Model. Therefore, the cost element of the QPP would not be impacted by the proposed GLOBE Model.

N. Interaction With Other Federal Programs

The proposed GLOBE Model may have impacts on other federal programs, such as Medicaid, the 340B Program, the Veterans Health Administration, the Department of Defense, the Public

Health Service, the Coast Guard, and Medicare.

1. Impact on Medicaid

a. Impact on Medicaid “Best Price”

With respect to single source or innovator multiple source drugs (which Medicaid recognizes to include biologicals), the term “Medicaid Best Price” is the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity or governmental entity within the U.S. with certain exclusions. That is, a manufacturer’s best price determination represents the lowest price available from the manufacturer during a rebate period (a quarter) to best price eligible entities or purchasers in the U.S. only. In accordance with section 1927(c)(1)(C)(ii)(I) of the Act, a manufacturer’s best price determination is inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates other than rebates under section 1927 of the Act, section 1847A(i) of the Act, or section 1860D–14B of the Act. Because proposed GLOBE Model rebates would be paid by manufacturers pursuant to section 1847A(i) of the Act, the proposed GLOBE Model rebates themselves would not be included in the manufacturer’s best price determination.

We expect that the proposed GLOBE Model would lead manufacturers to seek to adjust prices in order to lower the amount of GLOBE Model rebates they would owe. In addition, awareness of the proposed GLOBE Model would likely drive an increase in purchasers’ interest in obtaining lower drug prices from manufacturers. The model may indirectly impact a manufacturer’s best price to the extent that a manufacturer’s U.S. best price would be lower than what it would be otherwise. In other words, if during the course of the GLOBE Model, market forces result in manufacturers reducing prices available to purchasers and such prices are included in a manufacturer’s determination of best price, a manufacturer’s best price could potentially be lower and possibly increase Medicaid rebates. This is particularly possible because the proposed GLOBE Model rebates would be based in part on pricing outside of the U.S., which are typically lower than prices in the U.S., and may impact the prices made available by the manufacturer in the U.S.

¹³⁵ For more information about APMs and MIPS APMs see <https://qpp.cms.gov/apms/overview>.

b. Impact on Average Manufacturer Price (AMP)

AMP is defined at section 1927(k)(1) of the Act. Generally, AMP is determined based on the average price paid to the manufacturer for a covered outpatient drug in the U.S. by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer with certain exclusions. The proposed GLOBE Model would focus on certain Part B rebatable drugs. Because Part B rebatable drugs are typically furnished in the outpatient setting and these drugs are most likely injected or infused, the AMP for GLOBE Model drugs that are identified as 5i drugs¹³⁶ may be impacted by the model. The AMP computation for 5i drugs includes sales that are not generally dispensed through retail community pharmacies (see section 1927(k)(1)(B)(i)(IV) of the Act, 42 CFR 447.504(d)), such as sales to physicians, pharmacy benefit managers (PBMs) and hospitals.

Because proposed GLOBE Model rebates would be paid by manufacturers pursuant to section 1847A(i) of the Act, the GLOBE Model rebates themselves would not be included in a manufacturer's AMP for a GLOBE Model drug in accordance with section 1927(k)(1)(B)(i)(VII) of the Act. If the manufacturer lowers prices for GLOBE Model drugs in the U.S., the manufacturer's AMP for a GLOBE Model drug may be lower. If a drug's AMP decreases, it may result in potentially lowering the applicable Medicaid drug rebate paid (the rebate, in part, is based on a percentage of AMP). However, as previously discussed in section VI.D. of this proposed rule, the GLOBE Model may also have indirect impacts that could lower a manufacturer's best price for a GLOBE Model drug. The resulting effect on the Medicaid drug rebate would depend upon the relationship of any AMP change and any best price change.

We also note that if the AMP for a GLOBE Model drug is lowered it may be more likely that, in accordance with section 1847A(d) of the Act, the Inspector General may find that the ASP for a GLOBE Model drug exceeds the AMP for such drug, and that, in accordance with section 1847A(d)(3)(C)(ii) of the Act, the circumstances in which 103 percent of AMP is substituted for the ASP-based price in CMS' determination of the payment allowance for such drug would occur.

2. Interaction With 340B Program

The Health Resources and Services Administration (HRSA) administers the 340B Drug Pricing Program that allows certain hospitals and other health care providers ("covered entities") to obtain discounted prices on "covered outpatient drugs" (as defined at 1927(k)(2) of the Act) from drug manufacturers. HRSA calculates a 340B ceiling price for each covered outpatient drug, which represents the maximum price a manufacturer can charge a covered entity for the drug that is provided to an eligible patient. Several types of hospitals as well as clinics that receive certain federal grants from the HHS may enroll in the 340B program as covered entities. Billing units associated with claims for GLOBE Model drugs that are submitted with a 340B modifier and paid for under Part B would be excluded from the total GLOBE Model rebate amount in accordance with 42 CFR 427.303(1) as discussed in section II.G.4. of this proposed rule.

a. Impact on 340B Ceiling Price

Covered entities that enroll in the 340B Program can purchase covered outpatient drugs at no more than a "ceiling price," which is calculated as AMP minus Medicaid unit rebate amount.¹³⁷ We note that some 340B hospitals can obtain covered outpatient drugs at less than the ceiling price. Since the Medicaid unit rebate amount is based partly on AMP minus best price, to the extent the proposed GLOBE Model may indirectly affect a drug's AMP and best price, the 340B prices would be affected.

3. Interaction With Medicare

a. Medicare Part B

As discussed in section VI.D. of this proposed rule, we believe the proposed GLOBE Model would result in lower net Medicare spending for GLOBE Model drugs, including lower beneficiary cost-sharing, and in overall reduced Federal Supplementary Medical Insurance Trust Fund expenditures, which in turn could lower Medicare FFS expenditures and beneficiaries' Part B premiums. We estimate that total Medicare Part B FFS savings would amount to \$8.4 billion over the model test period and that there would be additional beneficiary premium savings of \$1.4 billion over the model test period.

As discussed in section VI.D. of this proposed rule, manufacturers' ASPs for GLOBE Model drugs may be higher or

lower than they otherwise would be absent the proposed GLOBE Model. In turn, Medicare Part B FFS payments (before sequestration) to providers and suppliers for GLOBE Model drugs could be higher or lower than what the payments would have been absent the model. We note that, consistent with section 1927(c)(1)(C)(ii)(I) of the Act and section 1847A(c)(3) of the Act, because the GLOBE Model rebate amounts are rebates under section 1847A(i) of the Act, manufacturers would not include GLOBE Model rebates in the calculation of Medicaid Best Price and the manufacturer's average sales price.

We note that if the AMP for a GLOBE Model Part B drug is lowered it may be more likely that, in accordance with section 1847A of the Act, the Inspector General may find that the ASP for a GLOBE Model drug exceeds the AMP for such drug, and that the circumstances in which 103 percent of AMP is substituted for ASP in CMS' determination of the payment allowance for such drug would occur.

b. Medicare Advantage

Medicare Advantage (MA) plans and beneficiaries enrolled in MA plans would not be included in the proposed GLOBE Model. We note that when MA plans pay non-contracted, out of network providers who have administered a GLOBE Model drug to an enrollee, the amount paid would continue to be based on the Medicare FFS payment amount (that is, the amount that MA plans would pay to these providers would reflect the non-model payment amount) and the beneficiary coinsurance must not exceed 50 percent of the plan's total financial liability or the non-model Medicare FFS allowed amount per 42 CFR 422.100(f)(6)(i). When MA plans pay contracted, in-network providers who have administered a GLOBE Model drug to an enrollee, beneficiary coinsurance must not exceed the coinsurance percentage listed in the applicable non-model quarterly ASP file), consistent with the requirements of 42 CFR 422.100(j)(1).

As discussed in section IV.B. of this proposed rule, we expect the proposed GLOBE Model would lower overall net Medicare FFS expenditures; that is, Medicare Part B net payment amounts for GLOBE Model drugs would be lower than such payment would be absent the model, and the model would result in an overall reduction in Medicare expenditures. The overall decrease in Medicare FFS expenditures would be considered in determining the historical FFS claims experience for calculating the rates for plan service areas.

¹³⁶ Inhalation, infusion, instilled, implanted or injectable drugs.

¹³⁷ For more information about the 340B ceiling price calculation see <https://340bpricing.submissions.hrsa.gov/Help/Manufacturer/Pricing%20Formulas/Pricing%20Formulas.htm>.

Payments to MA organizations may be lower than they would be absent the model, resulting from lower MA benchmarks and bids. At a high level, the FFS component of the non-ESRD MA rates is based on the product of the projected national per-capita spending and a county-level relative cost index. Thus, if the proposed GLOBE Model is finalized, the MA rate book calculations would reflect changes in actual FFS spending due to the impact of the GLOBE Model. We note that this approach is consistent with treatment of payments made under other CMS Innovation Center models and the Medicare Shared Savings Program.

As discussed in section IV.D. of this proposed rule, we estimate that MA benchmarks and bids may be lower, resulting in \$10.4 billion in savings over the model period. In turn, MA plans may reduce supplemental benefits and increase MA beneficiary out-of-pocket costs. We note that there is much uncertainty around the assumptions for this estimate.

O. Medicare Program Waivers

1. Overview

We believe it may be necessary to waive certain requirements of title XVIII of the Act for the testing of the GLOBE Model. We propose to issue these waivers using our waiver authority under section 1115A(d)(1) of the Act. Section 1115A(d)(1) of the Act provides authority for the Secretary to waive such requirements of title XVIII of the Act as may be necessary solely for the purposes of carrying out section 1115A of the Act with respect to testing models described in sections 1115A(b) of the Act. This provision affords broad authority for the Secretary to waive statutory Medicare program requirements as necessary to carry out the provisions of section 1115A of the Act with respect to testing models.

We welcome comments on other possible waivers under section 1115A of the Act of certain Medicare program rules beyond those specifically discussed in this proposed rule that might be necessary to test this model. We would consider the comments received during the public comment period and may make future proposals regarding program rule waivers during the course of the model test.

2. Waiver of the Calculation of the Rebate Amount

In proposed 42 CFR 513.1000(a), we propose to waive program requirements that are necessary solely for the purposes of testing the GLOBE Model. Specifically, we propose to waive the

Medicare Part B inflation rebate calculation provisions, as described in section 1847A(i)(3) of the Act and 42 CFR 427.302 and 42 CFR 427.301, which describes the calculation of the rebate amount. We believe this is necessary in order to implement the proposed alternative calculation for the GLOBE Model rebate amount as described in section II.G. of this proposed rule. We seek comment on our proposed waiver of the Medicare Part B inflation rebate calculation provisions as described in section 1847A(i)(3) of the Act.

We believe that section 1115A of the Act is broad and grants us significant flexibility in the design and implementation of new models. Further, section 1115A(b)(2)(A) the Act provides the Secretary with broad authority to test alternative payment models where “there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures.” We believe this supports our implementation of the GLOBE Model test and innovative payment models. This model test modifies the Part B inflation rebate amount calculation for GLOBE Model drugs using international drug pricing information to identify a benchmark that reflects prices paid in a set of economically comparable countries. CMS expects these modifications would reduce program expenditures for Medicare Part B while preserving or enhancing beneficiaries’ quality of care. Further, the Secretary has the authority under section 1115A(d)(1) of the Act to waive certain Medicare and Medicaid statutory requirements “as may be as may be necessary solely for purposes of carrying out this section with respect to testing models.”

As such, we believe the proposed waiver of the Medicare Part B inflation rebate amount calculation provisions section 1847A(i)(3) of the Act is necessary in order to implement the proposed alternative calculation for the rebate amount as described in section II.G. of this proposed rule. Specifically, we believe waiving the existing calculation for the rebate amount under section 1847A(i)(3) of the Act as part of the GLOBE Model is necessary in order to implement an alternative calculation for the rebate amount using international pricing information.

We seek comment on our proposed waiver of the Medicare Part B inflation rebate amount calculation provisions as described in section 1847A(i)(3) of the Act.

3. Waiver of Timing Requirements

In proposed 42 CFR 513.1000(b), we propose to waive program requirements that are necessary solely for the purposes of testing the GLOBE Model. As described in section II.G.8. of this proposed rule, we are considering two proposals for invoicing GLOBE Model rebate amounts. Under both approaches, we propose to waive section 1847A(i)(1) of the Act and instead we propose the following deadlines, effective dates, and time period requirements for the GLOBE Model under either option.

For the *combined* invoicing approach, we note that the increased operational complexity would lengthen the time necessary for creating Rebate Reports, which would extend the time following the end of an applicable calendar quarter for manufacturers to pay rebates. As described in section II.G.8. of this proposed rule, we propose that no later than 8 months after the end of each calendar quarter beginning October 1, 2026, CMS would, for all Part B rebatable drugs and for each GLOBE Model Drug, report to the manufacturer the information described in section II.G.8. of this proposed rule and the information in 42 CFR 427.501. We also propose, for each calendar quarter beginning on or after October 1, 2026, the GLOBE manufacturer of a GLOBE Model Drug shall, for such drug, not later than 30 days after the date of receipt of the information for such calendar quarter, provide to CMS the total GLOBE Model rebate amount as set forth in 42 CFR 513.520 for such drug for such calendar quarter.

For the *incremental* invoicing approach, we note that the Preliminary Rebate Reports and Rebate Reports issued as part of the Medicare Part B Drug Inflation Rebate Program must necessarily be delivered before the GLOBE Model Preliminary Rebate Report and GLOBE Model Rebate Report can be issued. As such, we similarly propose that for each calendar quarter we propose that no later than 8 months after the end of each calendar quarter beginning October 1, 2026, CMS would, for each GLOBE Model Drug, report to the manufacturer the information described in section II.G.8. of this proposed rule. We also propose, for each calendar quarter beginning on or after October 1, 2026, the GLOBE manufacturer of a GLOBE Model drug must, for such drug, not later than 30 days after the date of receipt of the information for such calendar quarter, provide to CMS the total GLOBE Model rebate amount as set forth in 42 CFR 513.520 for such drug for such calendar quarter.

As described in section II.G. of this proposed rule, we believe these waivers are necessary to implement the GLOBE Model on the timeline proposed herein given various operational considerations necessary to calculate GLOBE Model rebate amounts. Under the combined invoicing approach, we believe that by issuing Rebate Reports 2 months later than specified in section 1847A(i)(a)(1) of the Act, CMS would be able to both calculate the necessary information for a comprehensive Rebate Report as well as align with the need to provide information about Medicare Part B drug inflation rebate amounts and GLOBE Model rebate amounts to GLOBE Manufacturers timely. As such, under the combined invoicing approach we propose waiving section 1847A(i)(1)(A) of the Act to the extent necessary to allow CMS to issue Rebate Reports no later than 8 months after the end of a calendar quarter during the GLOBE Model performance period. Under the incremental invoicing approach, we believe that delivering the incremental GLOBE Model Rebate Report 2 months later than specified in section 1847A(i)(a)(1) of the Act, CMS would be able to conduct the necessary calculations in order to provide the information needed for the incremental GLOBE Model Rebate Report. As such, under the incremental invoicing approach, we propose waiving section 1847A(i)(1)(A) of the Act to the extent necessary to allow CMS to provide the rebate amount information to manufacturers.

We seek comments on our proposed waiver of section 1847A(i)(1) of the Act.

4. Waivers of Section 1833 of the Act (Payment of Benefits)

As described in section II.E.6. of this proposed rule, we intend to implement an alternative calculation for beneficiary coinsurance and, in conjunction with this calculation, adjust the Medicare payment for the GLOBE Model drug claim. Accordingly, we believe it would be necessary to waive sections 1833(a)(1), 1833(a)(1)(S), 1833(a)(1)(EE), and 1833(t) of the Act in order to implement these changes as they relate to payment to providers and beneficiary coinsurance amount. In addition, we believe it would be necessary to waive provisions in 42 CFR 410.152(m), 419.41(e), 489.30(b)(1), and 489.30(b)(6). Without these waivers, CMS would not be able to carry out the model test of implementing an alternative calculation for beneficiary coinsurance and correspondingly adjust the Medicare payment for the GLOBE Model drug claim in the same manner as under the

Medicare Part B Drug Inflation Rebate Program.

P. Evaluation

We would conduct an evaluation of the proposed GLOBE Model, as required under section 1115A(b)(4) of the Act. The evaluation would analyze the quality of care furnished under the model and the changes in spending under Medicare by reason of the model. The evaluation would include the collection of representative information from manufacturers of GLOBE Model drugs, drug purchasers, providers, and beneficiaries. The collection and analysis of these data would inform how the GLOBE Model might function if it were certified and expanded nationally.

All Innovation Center models, which would include the GLOBE Model, are rigorously evaluated on their ability to improve quality without increasing costs or reduce costs without reducing quality. In addition, we routinely evaluate monitoring data from Innovation Center models for potential unintended consequences that run counter to the stated objective of lowering costs without adversely affecting quality of care. The design and evaluation methods, the data collection methods, key evaluation research questions, the evaluation period and anticipated reports for the GLOBE Model are outlined as follows.

1. Evaluation Methods

The evaluation methodology accounts for GLOBE's innovative payment model that modifies the Part B inflation rebate amount calculation for certain Part B rebatable drugs that are single source drugs and sole source biological products to account for prices paid in economically comparable countries. CMS expects this would reduce program expenditures for Medicare Part B while preserving or enhancing beneficiaries' quality of care. The evaluation would employ a design to provide evidence that the proposed intervention would reduce the cost of these drugs and would maintain or enhance the quality of care for Medicare beneficiaries. The first objective would be to estimate the change in the net savings to Medicare due to the model intervention. The second objective would be to examine any changes to the quality of care and out-of-pocket costs of Part B rebatable drugs for the cohort of beneficiaries subject to the model intervention compared to a comparison cohort of eligible beneficiaries not randomized to the model intervention.

The impact of the model would be measured by comparing the change in key outcomes in GLOBE Model regions

to non-selected regions. We are considering several populations of interest for the GLOBE Model evaluation, such as Medicare beneficiaries who are likely to receive one of the Part B rebatable drugs based on recent diagnoses and/or prior treatment and populations defined by recent diagnoses (for example, those diagnosed with cancer, rheumatoid arthritis, ophthalmologic conditions) and/or prior treatment to capture the model's impact on beneficiaries directly affected by the changes due to the model.

Medicare spending would be examined in terms of total Part B drug spending for Part B rebatable drugs, total Part B drug spending for any Part B drugs, total Parts A and B spending, and potentially other spending measures for specific types of health care services (for example, inpatient hospital spending). The evaluation of the model's impact on quality of care would examine beneficiary out of pocket spending and drug access, measured by utilization (for example, rates of any use and duration of use) of both Part B drugs (including Part B rebatable drugs, GLOBE Model drugs, and other Part B drugs) and Part D drugs (particularly, for Part D drugs that can substitute for Part B rebatable drugs). We would also examine non-drug health care utilization that may change because of the GLOBE Model to estimate any impacts on access to care. Examples of other non-drug health care utilization include hospitalizations, emergency department visits, and condition specific utilization related to a given subgroup of beneficiaries. The impact estimates would reflect the collective effect of the GLOBE Model's changes to Medicare payments and beneficiary cost-sharing for GLOBE Part B rebatable drugs.

2. Data Collection Methods

We are considering multiple sources of data to evaluate the effects of the GLOBE Model. We expect to base much of our analysis on secondary data sources such as Medicare enrollment and claims data. Beneficiary level claims data would be analyzed to estimate expenditures in total and by type of drug and service. We would examine other sources of data that may include rebate or provider discount information, and international pricing data.

For Part B drugs, we would analyze data on drug utilization patterns, pricing, and expenditures in the original "fee-for-service" Medicare program. We would give strong preference to existing surveys and available data collected for

other purposes and would consider CMS evaluation contractor administered site visits, interviews or surveys with selected manufacturers, physicians/practitioners, wholesale drug purchasers, and beneficiaries necessary to measure quality of care. These qualitative sources would provide information that would help us understand better the dynamics and interactions occurring among the stakeholders in the GLOBE Model that cannot be estimated using the proposed secondary data sources.

3. Key Evaluation Research Questions

Our evaluation research questions are structured to assess the impact of the GLOBE Model on reducing Medicare expenditures and preserving or enhancing quality of care. To the extent possible, we would explore how net savings, if any, were related to specific aspects of the payment test, such as how the alternative benchmarks were identified (42 CFR 513.410 and 42 CFR 513.420, Identification of the per unit Method I GLOBE Model benchmark and Identification of the per unit Method II GLOBE Model benchmark, respectively), characteristics of the GLOBE Model drugs, manufacturers, and beneficiaries, and other secondary analyses. Our key evaluation questions would include, but are not limited to, the following:

- Medicare Payments. Did the GLOBE Model result in net savings to Medicare, and if so, how?
- Market Impact. How did manufacturer behavior change in response to the GLOBE Model? Is there evidence of broader changes to the pharmaceutical market, such as changes in the supply of drugs or to drug pricing?
- Quality. What was the impact of the GLOBE Model on the patient's quality of care? Did beneficiaries' cost sharing or access to drugs change under the model, and if so, how? Were there changes in drug or other health service utilization patterns that can be attributed to the model? Were there shifts in utilization from Part B to Part D drugs?
- Unintended Consequences. Did the GLOBE Model result in unintended consequences?

The GLOBE Model evaluation would gather evidence to inform certification through a rigorous, evidence-based process to determine how this model would perform if expanded nationally across the Medicare program. The evaluation would provide evidence to demonstrate if the model achieved its goals during the test period. It would also assess if the results were generalizable at a national scale and

financially and operationally sustainable.

4. Evaluation Period and Anticipated Reports

As proposed, the GLOBE Model would have a 7-year test period, including a 5-year performance period and a 7-year payment period beginning on October 1, 2026. The evaluation period would encompass the entire test period, with a baseline period of up to 3 years prior. Continued evaluation after the test period is necessary to assess the impact of the GLOBE Model on reducing Medicare expenditures and preserving or enhancing quality of care. We plan to evaluate the GLOBE Model on a continuous basis and release public evaluation reports annually.

We recognize that interim results are subject to changing policies and issues such as sample size and market fluctuations. Hence, while CMS intends to conduct periodic summaries to offer useful insight during the model test, a final analysis after the end of the model test period would be important for ultimately synthesizing and validating results.

If during our evaluation, results indicate statistically significant savings while preserving or enhancing the quality of care, the Secretary could recommend legislative action to facilitate the development or expansion of the model or a portion of the model.

III. Collection of Information Requirements

Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries while reducing program expenditures. As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this proposed rule need not be reviewed by the Office of Management and Budget.

IV. Preliminary Regulatory Impact Analysis

A. Statement of Need

As discussed in section I.B. of this proposed rule, studies have revealed that U.S. prices for prescription drugs are 422 percent higher than other countries.¹³⁸ Further, CMS data and

other studies show that Medicare Part B FFS drug spending¹³⁹ has grown by 85.8 percent (\$18.7 billion)¹⁴⁰ from 2014 to 2021 with the standard monthly Medicare Part B premium for beneficiaries increasing by 41.5 percent (\$104.90¹⁴¹ to \$148.50,¹⁴²) and that the pace of growth has varied across disease categories. For example, according to a recent report,¹⁴³ drugs classified in immunology, oncology, rheumatology, endocrinology and ophthalmology are among the top 20 therapeutic classes based on spending or prescriptions volume in the United States and drugs in these categories have shown notable growth between 2023 and 2024. This trend is also observed in Medicare Part B FFS drugs, where these five therapeutic classes represent at least \$24 billion in Medicare Part B FFS allowed charges in 2024.^{144 145 146} Under the IRA, some Medicare beneficiaries have seen savings for some drugs,¹⁴⁷ but recent surveys revealed that Medicare beneficiaries continue to experience challenges in access to medication due to cost.^{148 149 150 151} Further, according to

U.S. and Other Countries: Prices and Availability. Contractor Project Report, February 2024. Available at: <https://aspe.hhs.gov/sites/default/files/documents/f96a072f8f82f3ba546abd52bfcae57/aspe-cover-idr-pricing-availability.pdf>.

¹³⁹ Measured by drug allowed charges.

¹⁴⁰ Medicare Part B Drug Pricing, Office of the Assistant Secretary for Planning and Evaluation (June 9, 2023). Available at: <https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf>.

¹⁴¹ CMS announces major savings for Medicare beneficiaries. Available at: <https://www.cms.gov/newsroom/press-releases/cms-announces-major-savings-medicare-beneficiaries>.

¹⁴² 2021 Medicare Parts A & B Premiums and Deductibles. Available at: <https://www.cms.gov/newsroom/fact-sheets/2021-medicare-parts-b-premiums-and-deductibles>.

¹⁴³ HDA Research Foundation. HDA 96th Edition HDA Factbook. The Facts, Figures, and Trends in Healthcare (2025–2026). Available at: <https://www.hda.org/publications/>.

¹⁴⁴ CMS. Medicare Utilization for Medicare Part B FFS. Available at: <https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-fee-for-service-parts-a-b/medicare-utilization-part-b>.

¹⁴⁵ Dickson, S.R., and James, K.E. Treatments Associated with Manufacturer Payments to Ophthalmologists. *JAMA Health Forum*, 2023, 4 (9): e232951. doi:10.1001/jamahealthforum.2023.2951.

¹⁴⁶ Desai S., Sekimitsu, S., Rossin, E.J., Zebardast, N. Trends in Anti-Vascular Endothelial Growth Factor Original Medicare Part B Claims in the United States, 2014–2019. *Ophthalmic Epidemiology*, 2024, 31(5): 468–477. doi: 10.1080/09286586.2024.2310854.

¹⁴⁷ HHS Announces Cost Savings for 64 Prescription Drugs Thanks to the Medicare Prescription Drug Inflation Rebate Program established by the Biden-Harris Administration's Lower Cost Prescription Drug Law. CMS Newsroom, December 20, 2024. Available at: <https://www.cms.gov/newsroom/press-releases/hhs-announces-cost-savings-64-prescription-drugs-thanks-medicare-prescription-drug-inflation-rebate>.

¹⁴⁸ Nekui F, Galbraith AA, Briesacher BA, Zhang F, Soumerai SB, Ross-Degnan D, Gurwitz JH,

¹³⁸ Assistant Secretary for Planning and Evaluation. Comparing Prescription Drugs in the

a report,¹⁵² Medicare spending doubled between 2010 and 2023, increasing from \$0.05 trillion to \$1 trillion, and it is projected to reach nearly \$2 trillion by 2033. Studies have also shown that increased high drug costs limit access to care and treatment that lead to worse health outcomes, including avoidable hospitalizations and premature death.^{153 154} CMS analysis of claims data shows that total Medicare spending in 2024 was \$70.71 billion, and that almost two-thirds of this spending was attributed to Medicare Part B rebatable drugs. Separate data show that Medicare is the largest single purchaser of health care in the U.S., and accounts for 23 percent of total personal health care cost.¹⁵⁵ Further, data reveal that Medicare Part FFS program spending is highly concentrated among a small number of beneficiaries—the costliest 25 percent of beneficiaries accounted for 85 percent of Medicare spending.¹⁵⁶ The associated costs of medication non-adherence due to cost can be significant (up to \$290 billion per year).¹⁵⁷

Madden JM. *Cost-related Medication Nonadherence and Its Risk Factors Among Medicare Beneficiaries*. Medical Care. 2021;59(1):13–21. <https://doi.org/10.1097/MLR.0000000000001458>.

¹⁴⁹ Arnold Ventures, Commonwealth Fund, and PerryUndem. *Drug Costs and Their Impact on Care*. February 10, 2025. Available at: <https://www.arnoldventures.org/stories/drug-costs-and-their-impact-on-care>.

¹⁵⁰ Center for Opinion Research and I-MAK Survey. *Understanding Americans' Top Concerns on Drug Pricing: Corporate Greed and Patent Reform*. Available at: <https://www.i-mak.org/survey/>.

¹⁵¹ Ehsan AN, Wu CA, Minasian A, et al. *Financial Toxicity Among Patients With Breast Cancer Worldwide: A Systematic Review and Meta-analysis*. JAMA Netw Open. 2023;6(2):e2255388. doi:10.1001/jamanetworkopen.2022.55388.

¹⁵² MedPac. *National Health Care and Medicare Spending*. Section 1. National Health Care and Medicare Spending. July 2025. Available at: https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_Sec1_SEC.pdf.

¹⁵³ Ehsan AN, Wu CA, Minasian A, et al. *Financial Toxicity Among Patients With Breast Cancer Worldwide: A Systematic Review and Meta-analysis*. JAMA Netw Open. 2023;6(2):e2255388. doi:10.1001/jamanetworkopen.2022.55388.

¹⁵⁴ Nekui F, Galbraith AA, Briesacher BA, Zhang F, Soumerai SB, Ross-Degnan D, Gurwitz JH, Madden JM. *Cost-related Medication Nonadherence and Its Risk Factors Among Medicare Beneficiaries*. Medical Care. 2021;59(1):13–21. <https://doi.org/10.1097/MLR.0000000000001458>.

¹⁵⁵ MedPac. *Health Care Spending and the Medicare Program*. A Data Book. July 2025. Available at: https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf.

¹⁵⁶ MedPac. *Health Care Spending and the Medicare Program*. A Data Book. July 2025. Available at: https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf.

¹⁵⁷ Cutler, R.L., Fernandez-Llimos, F., Frommer, M., Benrimoj, C, et al. *Economic Impact of Medication Non-adherence by Disease Groups: A Systematic Review*. *BMJ Open*. 2018, 8(1): e016982. DOI: 10.1136/bmjopen-2017-016982.

This rulemaking is necessary to implement and test an innovative payment model that modifies the Part B inflation rebate amount for GLOBE Model drugs using international drug pricing information to reduce expenditures and improve quality of care. Specifically, as described in section II.G. of this proposed rule, the model test would include more than one method for identifying a benchmark amount for the modified rebate calculation and the model evaluation would assess the impacts of using different sources for international drug pricing information. CMS expects that the innovative alternative rebate calculation would reduce Medicare expenditures and beneficiary coinsurance amounts for Medicare Part B while preserving or enhancing beneficiaries' quality of care.

As detailed in sections II.A. through D. of this proposed rule, the proposed GLOBE Model would establish a 7-year GLOBE Model alternative payment test for a subset of separately payable Medicare Part B rebatable drugs that are furnished in the outpatient setting to Medicare beneficiaries who are in the cohort and that are paid under the GLOBE Model, or "Globe Model drugs." As described in section II.E. of this proposed rule, and subject to certain exclusions as discussed in section II.B.2. of this proposed rule, participants would include manufacturers of GLOBE Model drugs. GLOBE Model participants would be subject to the participation requirements, as applicable, during the GLOBE Model test period as described in sections II.E. and II.G.6. of this proposed rule.

B. Overall Impact

We have examined the impacts of this proposed rule as required by *Executive Order 12866* on Regulatory Planning and Review (September 30, 1993); *Executive Order 13132*, "Federalism"; *Executive Order 14192*, "Unleashing Prosperity Through Deregulation"; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Act (impact on small rural hospitals); and section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (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 regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory

action" as an 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 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 impacts 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 E.O. 12866.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. Based on our analysis, the Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant pursuant to section 3(f)(1) of E.O. 12866. Accordingly, we have prepared a regulatory impact analysis that presents the estimated costs and benefits associated with this proposed rulemaking.

C. Accounting Statement and Table

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 10, we have prepared an accounting statement showing the transfers and costs associated with the provisions of this proposed rule over a 7-year period versus a 10-year period reflecting the proposed 5-year performance period of the GLOBE Model beginning in October 2026 and the proposed 7-year payment period. This Table 10 was based on the analysis discussed in the "Estimated Impacts of the Proposal" section in this RIA. The costs for manufacturers to prepare submissions associated with voluntary net price reporting, discussed in section IV.D.3. of this proposed rule, was not directly included since after rounding, these costs are negligible. We estimate that the GLOBE Model would result in an overall savings of \$8.4 billion in Medicare Part B FFS net spending during the model before accounting for changes in the Part B premium. In this estimate, we assume manufacturer behavior changes and beneficiary utilization changes. We also estimate savings for the MA program of \$7.5 billion before accounting for changes in the Part B premium due to the way CMS calculates MA payments using Medicare FFS claims which would include claims paid under the

GLOBE Model beginning with rate setting for 2028, and savings for the Medicaid program of almost \$1.0 billion, of which roughly \$0.5 billion

would be federal savings and roughly \$0.3 billion would be state savings. When annualized over 2026 to 2032 we estimate that the GLOBE Model would

result in an overall cost savings in Medicare Part B FFS net spending of approximately \$2.3 billion at both the 3 and 7 percent rates of discount.

TABLE 10: ACCOUNTING STATEMENT: CLASSIFICATIONS OF ESTIMATED TRANSFERS AND COSTS FOR CONTRACT YEARS 2026 to 2032

Category	3% Discount Rate	7% Discount Rate
TRANSFERS (\$millions)		
Annualized monetized transfers, in 2025 dollars, from Manufacturers to the Medicare and Medicaid Trust Funds (\$millions)	2,358.7	2,299.7

D. Estimated Impacts of the Proposal

In this section we discuss the estimated overall impact of the proposed GLOBE Model on the Medicare and Medicaid programs. We also show the paperwork (information) burden.

1. Estimated Impacts to Medicare

The proposed GLOBE Model modifies the existing Part B inflation rebate amount calculation for certain rebatable drugs administered to beneficiaries under Medicare Part B. For beneficiaries in model geographic areas, the specified amount for model drugs would be compared to an international benchmark and the inflation-adjusted payment amount, with the manufacturer rebating any excess to CMS (referred to as the “incremental GLOBE Model rebate amount” as set forth in 42 CFR 513.510). The rebates would exclude units that are currently exempt from the existing Part B inflation rebate amount calculation, including 340B and most categories of dual eligible beneficiaries. Certain drugs may be excluded from the model based on therapeutic categories, spending thresholds, ineligibility for the Medicare Part B Drug Inflation Rebate Program, or competitive status within the market. These estimates assume that all manufacturers of proposed GLOBE Model drugs are included in this mandatory model. If certain manufacturers were excluded due to interactions with other CMS Innovation Center models or for any other reason, the impacts from this proposed demonstration could be significantly less than described in this analysis. The model does not change the Medicare Part B payment limit, including the add-on payment, which would remain at 6 percent of ASP for most Part B drugs. In developing our estimate of the potential

Medicare savings of the model we started with 2024 Part B claims data for GLOBE Model drugs. CMS’ Office of the Actuary (OACT) relied on CMS’ Innovation Center for a list of drugs that would have been included in the model had the proposed model been tested based in 2024 data, and we estimate that GLOBE Model drugs would have comprised approximately 54 percent of non-dual, non-340B Part B FFS drug spending for 2024. The model excludes drugs that are paid based on a maximum fair price that has been negotiated through the Medicare Drug Price Negotiation Program; as drugs are selected for the negotiation program and have a payment limit that is based on a maximum fair price, we expect the proportion of drugs included in the GLOBE Model would decrease over time. We estimated which drugs would have an effective maximum fair price during the model performance period and reduced the model rebate to account for the exclusion of these drugs from the model. OACT’s estimates of which drugs would be negotiated were developed independently, without input from Medicare Drug Rebate and Negotiation Group within CMS. By the end of the model window, we estimate that GLOBE Model drugs would comprise approximately 21 percent of non-dual, non-340B Part B FFS drug spending for 2024, which reflects the increased amount of spending expected to be subject to the Medicare Drug Price Negotiation Program over time. The model geographic areas would be selected to comprise 25 percent of Part B FFS beneficiaries further reducing the drug spending targeted by the GLOBE Model. Additionally, the numeric estimates of benefit savings (as displayed in Tables 11 and 12) in this analysis reflect the impacts of the incremental GLOBE Model rebate

amount, which would be the amount CMS would collect in addition to what CMS collects through the Medicare Part B Drug Inflation Rebate Program.

To reflect the international benchmarks that would be used in the model we relied on international data furnished from IQVIA MIDAS, after adjustments for GDP and purchasing power parity. On average these international benchmarks were 71 percent below the 2024 ASPs for GLOBE Model drugs. This would reflect the upper limit of potential savings as we expect that manufacturers and other stakeholders may engage in a variety of responses that may impact the potential savings of the model.

Our first anticipated manufacturer reaction is to report their international net price data to CMS in cases where that data show higher prices than the Method I GLOBE Model benchmark. Under the GLOBE Model, manufacturers would be eligible to report net international pricing data, and if those prices are higher than the Method I benchmarks, the Method II benchmarks would become the applicable benchmark for the GLOBE Model rebate calculation. This effect would have an upward pressure on applicable benchmarks over time and would reduce the GLOBE Model rebate amounts paid by manufacturers.

Our estimate assumes that the manufacturer reporting would reduce the total GLOBE Model rebate amount by 35 percent by the end of the model test period. This assumption is informed by the average difference between the lowest reference country price and prices averaged over all reference countries (after adjustments for GDP and purchasing power parity) for GLOBE Model drugs (see Table 11).

TABLE 11: ESTIMATES USED TO INFORM THE ANTICIPATED MANUFACTURER REPORTING ASSUMPTION

HCPC Code	Method I Benchmark	GDP and PPP Adjusted Average of all Reference Countries
JYYYY	\$100	\$135

Manufacturers that increase prices in response to the model will likely need time to implement changes to the international prices. Accordingly, we phased this adjustment into our analysis, beginning with a 10 percent

change to 2026 price data and reaching 35 percent in the 2029 price data. These factors are applied at an aggregate level to the rebates calculated under the Method I benchmarks. For example, the total GLOBE model rebate amount paid

based on 2026 fourth quarter utilization using the Method I benchmark is reduced by 10 percent in our impacts to reflect this manufacturer response. Table 12 shows the percentage adjustment by performance year.

TABLE 12: ESTIMATED ADJUSTMENTS TO ACCOUNT FOR POTENTIAL INCREASE IN PRICES AS A MANUFACTURER RESPONSE

	2026	2027	2028	2029	2030	2031
Phase-in of Method II Benchmark Adjustment	-10%	-20%	-30%	-35%	-35%	-35%

We also anticipate that there would be some collaboration between manufacturers and providers to incentivize the increased use of white-bagging, where drugs would be reimbursed for under the Part D benefit while still being administered in an office/facility setting, allowing the manufacturer to avoid owing a GLOBE Model rebate amount for those units. We compared current total Part B drug spending for GLOBE Model drugs to comparable NDC's in the Part D program to identify drugs that have a high potential to be moved to the Part D benefit. Combined with assumptions about how much utilization would move, we estimate that this effect would further reduce total GLOBE Model

rebate amounts by an additional 2.6 percent.

We also included an induced utilization effect reflecting the potential for increased use of drugs among FFS beneficiaries in model regions in response to lower cost sharing required for GLOBE Model drugs. As many FFS beneficiaries are either dual status or have supplemental prescription drug coverage, we estimate a relatively small 1.2 percent increase in total gross Part B drug spending on average in the first model year for beneficiaries in model geographic areas. This effect decays over time reflecting the lower expected total GLOBE Model rebate amounts over the life of the model.

After accounting for the above effects, we calculated the expected Medicare FFS benefit savings after accounting for

reduced coinsurances for beneficiaries in model geographic areas. We then calculated the expected changes in MA benchmarks and the corresponding change in MA payments, under the assumption that the model would be incorporated into the contract year 2028 rate development. The total federal savings account for the fact that the beneficiaries share the lower estimated benefit payments through reduced Part B premiums. Table 13 represents the final estimated benefit savings and the proportion reflected in beneficiary Part B premiums versus federal government savings on a fiscal year cash basis. No impact is shown for 2033 due to payments in 2033 relating to reconciling prior payments, and the amount of this reconciliation is not known at this time.

TABLE 13: ESTIMATED IMPACTS TO MEDICARE

Medicare Impacts (\$billions)	2026	2027	2028	2029	2030	2031	2032	Total
FFS Benefit Savings	0.0	0.0	2.2	1.9	1.7	1.5	1.1	8.4
Medicare Advantage Payment Savings	0.0	0.0	1.9	1.9	1.8	1.5	0.3	7.5
Premium Offset	0.0	0.0	1.0	1.0	0.9	0.7	0.4	4.0
Total Federal Savings	0.0	0.0	3.1	2.9	2.6	2.2	1.1	11.9

Note: Totals may not add up due to rounding.

In addition to changes from the model resulting in reduced MA benchmarks and bids, MA plans would likely need to reduce supplemental benefits as well. Since the MA plans that bid below their benchmarks are paid a portion of this difference as an MA rebate, it follows that a reduction in benchmarks reduce the MA rebates. MA plans use these

rebates for supplemental benefits, such as premium reductions or reductions in beneficiary cost-sharing, which would increase MA beneficiary out-of-pocket costs.

The model would result in beneficiary savings by reducing the Part B premium for all beneficiaries. Additionally, FFS beneficiaries would see a reduced

coinsurance on model drugs via the existing mechanism for adjusting the Part B coinsurance for drugs with a Medicare Part B drug inflation rebate amount. Table 14 shows impacts to beneficiaries on a calendar year basis.

TABLE 14: ESTIMATED IMPACTS TO MEDICARE BEBEBICIARIES

Beneficiary Impacts (\$ billions)	2026	2027	2028	2029	2030	2031	Total
Cost Sharing Savings for FFS Beneficiaries	0.1	0.3	0.3	0.2	0.2	0.2	1.4
Supplemental Benefit Savings for MA Beneficiaries	0.0	0.0	-0.2	-0.2	-0.2	-0.1	-0.7
Premium Savings for FFS Beneficiaries	0.0	0.2	0.4	0.4	0.3	0.2	1.6
Premium Savings for MA Beneficiaries	0.0	0.5	1.1	0.9	0.8	0.6	3.9
Total Out-of-Pocket Savings	0.1	1.1	1.7	1.3	1.2	0.9	6.2

Note: Totals may not add up due to rounding.

We also considered the following responses but either determined their impact would be small or that we lacked sufficient data to quantify the level of impact they would have on GLOBE Model rebates:

- We expect that manufacturers with drugs selected for the Medicare Drug Price Negotiation Program would be less inclined to give discounts below the statutorily specified ceiling price. We expect this effect to be small based on the ceiling prices specified by the Inflation Reduction Act of 2022 for Part B drugs.
- As 340B units are excluded from the GLOBE Model rebate amount, we would expect manufacturers to incentivize the increased utilization of these units. However, we do not believe there is much potential for this shift as most model drugs have a relatively low proportion of 340B units currently and the difference between 340B pricing and the benchmark prices for the model are unknown.
- As a change in list prices for model drugs would shift the balance between the GLOBE Model rebate amount and the Medicare Part B inflation rebate amount, there are incentives for manufacturers to raise list prices across

all payers to counteract the lost revenue from the model. This reaction could create additional effects on Medicaid or Federal Marketplace spending. The likelihood of this response increases the higher the spending is for a given drug outside of Medicare. We welcome comments on the probability and magnitude of this response to inform future analysis.

- Since drugs with an MFP that applies would be excluded from the model, we might expect manufacturers would try to change their pricing to become eligible for the Medicare Drug Price Negotiation Program if they see it being more favorable for their reimbursement. Given the criteria for being selected for the Medicare Drug Price Negotiation Program, we believe it would be difficult for manufacturers to achieve this. Additionally, the model does not impact reimbursement for all FFS beneficiaries as negotiations would, so this response would require dramatic pricing differences to be favorable to manufacturers.
- The GLOBE Model does not include MA plans and so manufacturers may be inclined to assist in efforts to increase MA enrollment if they find MA reimbursement would be higher than

Medicare FFS. It is not clear how much more favorable MA reimbursement would be for manufacturers and so we have not included this in our estimates. We seek comment on the potential response from manufacturers and corresponding impacts to MA plan enrollment and reimbursement to inform future analysis.

2. Estimated Impacts to Medicaid

Medicaid savings of the GLOBE Model would be reflected via the reduced cost sharing and premiums that Medicaid pays on behalf of dual beneficiaries in the model geographic areas. Based on historical experience we expect that 30 percent of the reduced cost sharing would come from dual beneficiaries, with the federal government retaining 57 percent of those savings and states retaining the rest. Based on historical experience we expect that approximately 19 percent of the Part B premiums are paid by Medicaid on behalf of dual beneficiaries, with the federal government retaining 57 percent of those savings and states retaining the rest. Table 15 shows Medicaid impacts on a calendar year cash basis.

TABLE 15: ESTIMATED IMPACTS TO MEDICAID

Medicaid Impacts (\$billions)	2026	2027	2028	2029	2030	2031	Total
Federal Cost Sharing Savings	0.0	0.1	0.0	0.0	0.0	0.0	0.2
State Cost Sharing Savings	0.0	0.1	0.0	0.0	0.0	0.0	0.1
Federal Premium Savings	0.0	0.1	0.1	0.1	0.1	0.1	0.5
State Premium Savings	0.0	0.0	0.1	0.1	0.1	0.0	0.3
Total Medicaid Savings	0.0	0.2	0.3	0.2	0.2	0.1	1.0

Note: Totals may not add up due to rounding.

3. Negligibility of Paperwork (Information) Burden

As discussed in section III. of this proposed rule, Chapter 35 of title 44, United States Code, does not apply to the testing and evaluation of models under section 1115A of the Act. That is,

models are exempt from paperwork (information) burden requirements. Nevertheless, and for discussional purposes only, we briefly review the main paperwork burden of this proposed rule and show it is negligible. The main information burden arises

from voluntary manufacturer-reported submission of international net pricing information. The analysis of cost is summarized in Tables 16 and 17 with line items explained afterwards. Table 16 presents an analysis of items for which we have an experience basis for

quantification. Table 17 discusses other items affecting the cost of submission requirements for which CMS has no prior experience on which to base

quantification. To meaningfully deal with this, we assume each item would increase the total quantifiable burden by some factor; a range of factors is

presented to account for our lack of precise quantification.

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TABLE 16: DISCUSSION OF QUANTIFIABLE BURDEN FOR SUBMISSION

Line ID	Description	2026	2027 - 2030	2031
(1)	Number of manufacturers	40	40	40
(2)	Quarters per year	4	4	4
(3)	Hours/Preparation	20	10	10
(4)	Hours/Submission`	6	3	3
(5)=(2)*((3)+(4))	Total hours per period per manufacturer	104	52	52
(6)=(1)*(5)	Total unadjusted aggregate hours for full period	4160	2080	2080
(7)	Percent applied for period	0.25	1	0.75
(8)=(6)*(7)	Total aggregate hours for period	1040	2080	1560
(9a)	Mean wage (Administrative Assistants)(43-6014)	\$22.90	\$22.90	\$22.90
(9b)	Mean wage (Health Service Managers)(11-9111)	\$66.22	\$66.22	\$66.22
(9c)	Mean wage (Software Developers, Programmers, Testers) (15-1250)	\$65.34	\$65.34	\$65.34
(9d)	Mean wage (Lawyers) (23-1011)	\$87.86	\$87.86	\$87.86
(9e)	Mean wage (Pharmacists)(29-1051)	\$65.97	\$65.97	\$65.97
(9f)=2/13*((9a - (9e)) +3/13*(9a)	Average weighted hourly wage for five professions	\$52.71	\$52.71	\$52.71
(10)	Factor for fringe benefits/Overtime	2	2	2
(11)=(9)*(10)	Adjusted mean wage	\$105.43	\$105.43	\$105.43
(12)=(11)*(8)	Total Estimated Cost	\$109,645	\$219,290	\$164,467
(13)=sum of row (12) with a weight of 4 for years for 2027-2030	Total Cost 5 Years	\$1,151,270	\$1,151,270	\$1,151,270

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We next explain the various line items in sequential order.

Line Item 1: To receive coverage of their drugs by Medicare, manufacturers

must comply with the requirements of 42 U.S.C. 1396r–8, 42 U.S.C. 256b, 38 U.S.C. 8126. As a subset of these manufacturers could be impacted by the GLOBE Model, we obtained a list of manufacturers, designated by labeler codes, of Medicare Part B rebatable drugs in 2024 as of June 2025. This list was based on initial, non-final data and there were 61 unique labeler codes on that list. Based on a hypothetical analysis of how many manufacturers would participate in the GLOBE Model using 2024 data, we concluded that the GLOBE Model would only apply to a subset of manufacturers of Part B rebatable drugs given the drug inclusions and exclusions described in section II.B. of this proposed rule. As a conservative estimate meant to include more manufacturers than likely would participate in the GLOBE Model, we used 40 manufacturers. This number is used for the initial estimate in Table 16, reflecting quantifiable information. A second table, Table 17, addresses the reasonable assumption that this number would fluctuate from year to year.

Line Items 3 and 4: The hours required for submission are split between preparation, including reading rules, gathering data, and so forth, and actual submission. We used similar estimates of submission to CMS from a Supporting Statement of the Manufacturer Submission of Average Sales Price (ASP) for Medicare Part B Drugs and Biologicals and Supporting Regulations in 42 CFR 414.800–806 (CMS–10110, OMB 0938–0921) from 2023. The supporting document listed 10 hours for preparation and 3 hours for submission. However, we believe that extra hours would be required for the first year, and in the absence of more reliable data we simply doubled the 10 and 3.

Line Item 7: The GLOBE Model performance period, during which manufacturers could choose to report, is proposed to last from October 2026 through September 2031. Hence, in 2026, the model performance period includes only 1 calendar quarter (25 percent of the year) and in 2031 the model performance period includes 3

calendar quarters (75 percent of the year).

Lines 9a through 9f: The \$21.90 is the mean wage obtained from the Bureau of Labor Statistics website for Secretaries and Administrative Assistants, Occupational Code 43–6014, for the latest year available at this time, 2024. Note that CMS still uses mean wages even though many agencies use median wages. However, replacing the mean by the median would not change the conclusion of negligibility. 43–6014 is the same occupational title used for estimates in OMB 0938–0921. However, we determined that this approach (using only administrative assistants) was overly simplified. While administrative assistants are appropriate staff for the 3 hours submission, we assume the preparation would involve a team of administrative assistants, health care managers, software engineers, lawyers, and pharmacists. The mean hourly wage of these staff for 2024 are displayed along with their occupational titles and code. The wages of these five staff are combined to produce a single mean hourly wage for the team. In the absence of further data, the weights assume that all five staff work equally in the 10 hours of preparation resulting in 2 hours per staff. The administrative staff exclusively work during the 3 hours of submission. Thus, the weights are five-thirteenths for administrative staff and two-thirteenths for each of the other staff.

Line 10: Per HHS guidance,¹⁵⁸ CMS uses a factor of 2 to account for overtime and fringe benefits.

We next turn to items for which we have no basis on which to quantify. The total analysis is presented in Table 17. As noted in Table 17, there are two non-quantifiable issues that have to be addressed.

New and departing participants: Each year, the group of GLOBE Model participants may change based on whether their drug meets the criteria for

inclusion in the GLOBE Model. We have no way of estimating with accuracy whether a given manufacturer would be included or excluded in the GLOBE Model. If we assume 4 new manufacturers, then bottom line estimates from Table 16 would increase 10 percent (4/40). This is a low estimate. In an alternative scenario, the number of participants might increase as much as 50 percent corresponding to a factor of 1.5; although this is unlikely, it helps define a range of possible costs.

19 Countries: If a manufacturer were to opt to report manufacturer-submitted data, they would do so for a set of reference countries, up to 19 countries as discussed in section II.G.1.e. of this proposed rule. The 10 hours of preparation assumed in Table 16 provides time for each GLOBE Model participant to address marketing, pricing, and licensing requirements. But likely, this is different for different countries. We do not have enough information to quantify this. We approach the extra time as a factor by which we increase cost. For example, assuming that half the countries require the same preparation time, we would multiply the bottom line cost burden by a factor of 9.5 (19/2). On the other hand, if data on licensing, marketing, and pricing for each individual country are readily available, it might only require an extra 2 hours of work resulting in an increase of 1.15 (2/13). We take these as the low and high estimates and insert an intermediate estimate.

To obtain a range of adjusted bottom line estimates we multiply the factors together. For example, as discussed previously, if half the countries require the same amount of work (resulting in a factor of 9.5) and if the number of participants increases 50 percent (resulting in a factor of 1.5) then we multiply the bottom line number from Table 10, \$1,151,270 by 14.25 (1.5 * 9.5) and obtain a high cost burden of \$16,405,603 million as shown in Table 17. As shown on the bottom line of Table 17, the resulting range of estimates of cost burden is between roughly \$1.5 million and \$16.5 million.

¹⁵⁸ ASPE, Guidelines for Regulatory Impact Analysis, 2016. Available at: https://aspe.hhs.gov/sites/default/files/private/pdf/242926/HHS_RIAGuidance.pdf.

TABLE 17: ADJUSTING COST BURDEN TO ACCOUNT FOR NON-QUANTIFIABLE ISSUES

LINE ID	Description	Low Factor	Intermediate Factor	High Factor
(1)	19 countries	1.16	5	9.5
(2)	New and departing participants	1.1	1.3	1.5
(3)=(1)*(2)	Product of factors	1.276	6.5	14.25
(4) (From Table 14)	Quantifiable burden	\$1,151,270	\$1,151,270	\$1,151,270
(5)=(4)*(3)	Range of possible adjusted cost burdens	\$1,469,021	\$7,483,258	\$16,405,603

Notes: (1) The GLOBE Model as proposed in this proposed rule would include 19 countries as part of the set of reference countries. For a discussion of the low and high factors or for a discussion of new and departing GLOBE Model participants see the paragraph immediately preceding Table 17.

E. Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief for small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and states are not included in the definition of a small entity. The RFA requires that CMS analyze regulatory options for small businesses and other entities unless CMS certifies that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the proposed rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

HHS considers a significant impact on a substantial number of small entities, to be one with a 3 percent revenue effect on 5 percent of small entities.¹⁵⁹ As discussed in section II. of this proposed rule, manufacturers that are GLOBE Model participants would pay GLOBE Model rebates to the Medicare Part B account in the Federal Supplementary Medical Insurance Trust Fund if the amount specified in section 1847A(i)(3)(A)(ii)(I) of the Act for a GLOBE Model drug exceeds a benchmark amount that would be based on available international drug pricing information (as described in section II.G.1. of this proposed rule), and would not be less than any rebate owed under

¹⁵⁹ Department of Health and Human Services. Guidance on Proper Consideration of Small Entities in Rulemaking of the U.S. Department of Health and Human Services, 2003. Available at: <https://aspe.hhs.gov/reports/proper-consideration-small-entities-rulemakings-us-dhhs>.

the Medicare Part B Drug Inflation Rebate Program. Our analysis shows that the proposed rule, would impact 7 percent of small entities, and the impact is estimated to represent up to 2.6 percent of the small entities’ annual revenue in the United States. Given the uncertainty on manufacturer response and available data, CMS concludes that this proposed rule, if finalized as proposed, would have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this proposed rule, serves as the Regulatory Flexibility Analysis, as required by the RFA.

1. Description and Number of Affected Small Entities

We use the North American Industry Classification System (NAICS) to identify the industry potentially affected by the proposed rule. We also use the Small Business Administration (SBA) size standards to identify small entities.¹⁶⁰ The SBA considers any “Pharmaceutical Preparation Manufacturing” firm (NAICS code 325412) with fewer than 1,300 employees as a small business.

We use financial and employment information publicly available on annual reports published on companies’ websites or submitted to the Securities and Exchange Commission (SEC) for 2024 to identify revenue and employment information for the potentially affected companies. Most companies self-identified as “global” and provided information separately for their global consolidated business and for the United States. For purposes of this analysis, we use revenue and

¹⁶⁰ Small Business Administration. Table of Size Standards, Available at: <https://www.sba.gov/document/support-table-size-standards>.

employment size information based on data reported for the United States. We used the Internal Revenue Service’s yearly average currency exchange rates for 2024 to convert revenue information into U.S. dollars when this information was provided in a foreign currency.¹⁶¹

We identified 30 manufacturers that would be associated with 61 GLOBE Model drugs. Using the financial data, we determined that two of the 30 manufacturers are subsidiaries of larger companies. For purposes of this analysis, we consider the impact on the 28 unique parent companies. Table 18 shows that 7 percent of the affected manufacturers would be considered small based on the SBA definition.¹⁶² In 2024, the total company revenue in the United States for these small companies exceeded \$2 billion (the average U.S. revenue per small company exceeded \$1 billion). These companies accounted for about 0.45 percent (\$2,045/\$456,292) of the total U.S. revenue among the 28 affected entities. The potential GLOBE Model drugs associated with these small entities are classified as immunological agents and antineoplastics for which there are at least a dozen other drugs that are in the same therapeutic class as determined by the number of HCPCS Level II codes in the USP DC classification category used for this analysis. Further, based on CMS expertise the potential GLOBE Model drugs associated with these small entities have therapeutically equivalent substitutes.

¹⁶¹ Internal Revenue Service. Yearly average currency exchange rates. Available at: <https://www.irs.gov/individuals/international-taxpayers/yearly-average-currency-exchange-rates>.

¹⁶² Using data on the total number of employees inside and outside the U.S., the estimated percent of small entities is 3.5 percent.

TABLE 18: NUMBER OF SMALL ENTITIES BY EMPLOYMENT SIZE AND REVENUE, 2024

Company Size	Total Number of Employees in the U.S.	Percent of Unique Companies	Total Global Revenue (\$million)	Total U.S. Revenue (\$million)	Average U.S. Revenue per Company (\$million)
Small	1300 or fewer	7%	\$4,649.87	\$2,045.11	\$1,022.56
Large	1300+	93%	\$786,811.00	\$454,246.70	\$17,471.03
Total		100%	\$791,460.88	\$456,291.81	\$16,296.14

2. Description of the Potential Impacts on Small Entities

CMS anticipates that payments to CMS in the form of GLOBE Model rebate amounts, as set forth in 42 CFR 513.500 of this proposed rule, would represent the largest impact to small entities. We estimate the impact using two approaches. Under the first approach, we use available data to estimate an average GLOBE Model rebate per company (\$26 million), including both large and small manufacturers. Using this estimate as an upper bound, we estimate that GLOBE Model rebates could represent up to 2.6 percent of a small entity's average revenue in the U.S. (\$26 million/\$1 billion). In the second approach we assume that 1.64 percent of the estimated incremental GLOBE Model rebate amount would be associated with small entities, and then estimate the

potential incremental GLOBE Model rebate amount for the small entities affected. The estimate of 1.64 percent was derived separately from OACT's analysis because OACT's overall estimates in the RIA represent aggregates across all companies. Using this estimate, and OACT's estimate of the total incurred calendar year GLOBE Model rebates, we estimate the incremental GLOBE Model rebate amounts would range from \$0.00 to \$49.37 million for small entities over the model performance period. Table 17 presents the estimated incremental GLOBE rebate amounts for small entities and the corresponding impact on total revenue. Based on our analysis and using available data on total revenue and estimated incremental GLOBE Model rebates, CMS estimates that the estimated incremental GLOBE Model rebate amounts would represent up to 2.4 percent of small entities' total

revenue, as measured in terms of revenue in the U.S. The administrative costs involved with reading and understanding this proposed rule are not included in these estimates. However, as noted in the RIA, these costs are estimated to be negligible.

CMS notes that these estimates are based on available data which could change in the future and as such, the estimated impacts could vary. Specifically, the estimates are based on the current status of rebatable drugs, employment and revenue information using 2024 or other available data as of the publication of this proposed rule. Given this uncertainty, CMS concludes that the proposed rule, if finalized as proposed, would have a significant impact on a substantial number of small entities. CMS welcome comments on our conclusion, approach, assumptions, and data used to estimate these impacts.

TABLE 19: ESTIMATED IMPACT ON SMALL ENTITIES

Description	2026	2027	2028	2029	2030	2031	2032
Estimated Incremental GLOBE Model Rebate Amount for Small Entities (\$millions)	12.59	49.37	45.88	35.88	32.08	23.70	0.00
Estimated Total GLOBE Model Rebate for Small Entities as Percent of Total U.S. Revenue of Small Entities	0.6%	2.4%	2.2%	1.8%	1.6%	1.2%	0.0%

As discussed previously, we also considered other responses, including limited price reductions for drugs selected for the Medicare Drug Price Negotiation Program, increased utilization of 340B units, changes in list pricing information, changes in incentives to participate in the Medicare Drug Price Negotiation Program, impacts to MA plans and Medicaid, and either determined their impact to be small or that there was insufficient data to properly quantify their impact. We note that there is much uncertainty around the assumptions for these estimates. We welcome comments on our estimate of significantly affected small manufacturers and the magnitude

of estimated effects. We also welcome comments on adjustments to the GLOBE Model that could be considered while preserving the innovative approach to payment in the GLOBE Model.

3. Alternatives To Minimize the Impact on Small Entities

CMS considered the following alternatives to minimize the impact on small entities: (1) establishing a different spending threshold; (2) establishing an exemption process; and (3) establishing different compliance dates.

- *Spending threshold:* As discussed in section II.B. of this proposed rule, CMS is proposing to include drugs or

biological products that meet the proposed definition of a GLOBE Model drug which would include a subset of Part B rebatable drugs that: (1) have the listed USP DC categories in Table 3 of this proposed rule; (2) are single source drugs or sole source biological products; (3) have a HCPCS Level II code with Medicare Part B FFS spending greater than \$100 million over a 12-month period; and (4) are not excluded from the GLOBE Model as proposed in 42 CFR 513.130(c). Based on the third criterion, CMS is excluding from the GLOBE Model those drugs with relative share of spending costs to drug spending lower than \$100 million. This spending threshold applies to all

manufacturers irrespective of size. While lowering the spending threshold increases the number of drugs that could be included in the GLOBE Model, it also increases the number of small manufacturers that could potentially be impacted. For this reason, CMS proposes not to select a lower threshold. Further, increasing the threshold reduces both the number of small and large manufacturers and the number of drugs in the GLOBE Model. For example, a threshold of \$125 million would exclude eight manufacturers including six large manufacturers (they employ more than 5,000 employees in the United States). Further, setting a threshold above \$186 million would exclude all identified small manufacturers as well as 16 drugs manufactured by large manufacturers and would result in a total of 50 included drugs. Selecting a different spending threshold higher than \$100 million would also reduce the estimated savings to the Medicare program and to beneficiaries and thereby shift the focus of the model test and limit the ability to evaluate the experiences of manufacturers of drugs with diverse characteristics.

- *Exempting small entities:* As discussed in section II.B.2. of this proposed rule, to avoid interactions with other initiatives and programs that focus on manufacturers of Medicare Part B drugs, CMS would exclude drugs assigned to HCPCS Level II codes when the Medicare Part B payment limit is based on a maximum fair price for drugs separately payable under Medicare Part B. Because small and large manufacturers could potentially be eligible for this proposed exclusion, we do not believe that additional processes for exemptions are needed. CMS seeks comments on other factors or considerations regarding exemptions for small entities.

- *Compliance dates:* CMS also considered the flexibility of providing different compliance dates to small manufacturers. While creating significantly different compliance dates could provide more time for small manufacturers to comply, it could interfere with the statutory requirement of evaluating the model to determine whether savings have occurred.

In summary, because the purpose of the GLOBE Model is to test an innovative payment model that modifies the Medicare Part B inflation rebate amount calculation for GLOBE Model drugs using international drug pricing information to identify a benchmark that reflects prices paid in economically comparable countries, which CMS expects would reduce program

expenditures for Medicare Part B while preserving or enhancing beneficiaries' quality of care, CMS therefore declined to propose the alternatives considered. We welcome comments on the alternatives considered as well as other factors that could be considered to mitigate the impact on small manufacturers.

F. Effects on Small Rural Hospitals

Section 1102(b) of the Act requires CMS to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds.

Providers and suppliers who furnish GLOBE Model drugs to Medicare FFS beneficiaries who are in the model cohort would not be GLOBE Model participants and would continue to buy and bill for GLOBE Model drugs as usual and receive separate payment under Medicare Part B if applicable. These providers and suppliers include hospital outpatient departments, physician practices, ambulatory surgical centers, pharmacies enrolled as durable medical equipment (DME) suppliers, and certain other provider and supplier types. When the GLOBE Model reduced beneficiary coinsurance applies, the portion of Medicare Part B allowed amount for a GLOBE Model drug paid by Medicare would be greater than the usual 80 percent. For example, if the Medicare Part B allowed amount under the GLOBE Model is \$100 and the GLOBE Model beneficiary coinsurance percentage is 10 percent (instead of the usual 20 percent), the Medicare Part B program payment to the provider or supplier would be adjusted and would be \$90 (instead of the usual \$80) and the beneficiary financial responsibility would be \$10.

According to 2025 data from the American Hospital Association¹⁶³ there are 6,093 hospitals in the United States. Using data from 2021 and 2025, we estimate that there are 1,524 small rural hospitals in the United States.¹⁶⁴ This represents 25 percent of all U.S. hospitals. We estimate that very small

rural hospitals, those with up to 25 beds, represent almost 60 percent (or 869) of all small rural hospitals, followed by hospitals with 25–50 beds (N=331) and 51–100 beds (N=323). It has been estimated that rural hospitals represent about 10.8 percent of the total share of Medicare Part B spending,¹⁶⁵ and that Medical Part B spending in all hospitals represented about 41 percent of total Part B spending in 2022 (\$19.3 billion/\$46.9 billion).¹⁶⁶ Assuming that these percentages have remained relatively unchanged, we estimate that slightly less than 4 percent (\$1.71 billion) of total Medicare Part B drug allowed charges in 2024 are associated with very small rural providers and suppliers.¹⁶⁷ The small rural hospitals are not expected to experience drug payment reductions and overall payment reductions similar to urban hospitals. As noted previously, CMS anticipates that there would be some collaboration between manufacturers and providers to incentivize the increased use of white-bagging. However, small rural hospitals are not expected to experience increased use of white-bagging as for these facilities white-bagging may already be a reasonable solution.¹⁶⁸ We tentatively conclude that this proposed rule, if finalized as proposed, would not have a significant impact on small rural hospitals. We seek comments on this conclusion, as well as data or other factors that have not been considered.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of 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.

¹⁶⁵ Avalere Health. CMS Site-neutral Payments Affect Share of Spending, January 10, 2024. Available at: <https://advisory.avalerehealth.com/insights/cms-site-neutral-payments-affect-small-share-of-spending>.

¹⁶⁶ MedPac. July 2025 Data Book Section 10: Prescription Drugs, Data Book, July 17, 2025. Available at: <https://www.medpac.gov/document/july-2025-data-book-section-10-prescription-drugs/>.

¹⁶⁷ We estimate the Medicare Part B spending for rural hospitals is 2024 is \$2.053 billion (= \$46.18 billion times 41 percent times 10.8 percent), and that the Medicare Part B spending for small rural hospitals is \$1.74 billion (= \$2.053 times 1524 divided by 1796, where \$2.05 (in billions) represents the estimated Medicare Part B spending in 2024, 0.108 represents the share of Medicare Part B spending for rural hospitals, 1524 is the number of small rural hospitals, 1796 is the number of rural hospitals).

¹⁶⁸ American Hospital Association. Health Insurer Specialty Pharmacy Policies Threaten Patient Quality of Care, March 2021. Available at: <https://www.aha.org/system/files/media/file/2021/03/AOMarch8white-bagging-0221.pdf>.

¹⁶³ American Hospital Association. Fast Facts on U.S. Hospitals, 2025. Available at: <https://www.aha.org/system/files/media/file/2025/01/Fast-Facts-on-US-Hospitals-2025.pdf>.

¹⁶⁴ American Hospital Association. Fast Facts on U.S. Rural Hospitals, 2023. Available at: <https://www.aha.org/system/files/media/file/2023/12/Fast-Fact-on-US-Rural-Hospitals-2023-Infographic.pdf>.

In 2025, that threshold is approximately \$187 million. This proposed rule would not impose a mandate that would 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. However, this proposed rule, if finalized as proposed, would result in additional impacts that we do not quantify associated with changes in behavior. We request comments, including on the potential magnitude of this impact and the extent to which it is a funded or unfunded mandate.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this proposed rule does not impose any substantial costs on State or local governments, preempt State law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

I. Unleashing Prosperity Through Deregulation

E.O. 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.”

V. Response to Comments

Because of the large number of public comments we normally receive on 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 December 10, 2025.

List of Subjects in 42 CFR Part 513

Administrative practice and procedure, Health facilities, Medicare, 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 by adding part 513 to read as follows:

SUBCHAPTER H—HEALTH CARE INFRASTRUCTURE AND MODEL PROGRAMS

PART 513—Global Benchmark for Efficient Drug Pricing (GLOBE) Model

Sec.

Subpart A—General Provisions

- 513.1 Basis, scope, duration, and severability.
- 513.20 Definitions.

Subpart B—Inclusion in the Model

- 513.100 GLOBE Model participants.
- 513.110 GLOBE Model Geographic Areas.
- 513.120 Identification of GLOBE Model beneficiaries.
- 513.130 GLOBE Model drugs and excluded drugs.

Subpart C—Coinsurance Adjustment and Adjusted Medicare Payment for GLOBE Model Drugs

- 513.200 Definitions.
- 513.210 Computation of GLOBE Model beneficiary coinsurance percentage and adjusted Medicare payment for GLOBE Model drugs.

Subpart D—GLOBE Model Data Sources

- 513.300 Definitions.
- 513.310 Included international data.

Subpart E—Determination of the Per Unit GLOBE Benchmark Amount

- 513.400 Identification of the per unit GLOBE Model benchmark amount.
- 513.410 Identification of the per unit Method I GLOBE Model benchmark.
- 513.420 Identification of the per unit Method II GLOBE benchmark.
- 513.430 Calculation of the GDP (PPP) adjuster.

Subpart F—Determination of the GLOBE Model Rebate Amount for GLOBE Model Drugs

- 513.500 Calculation of the total GLOBE Model rebate amount due.
- 513.510 Calculation of the per unit GLOBE Model rebate amount and the incremental per unit GLOBE Model rebate amount.
- 513.520 Identification of the total number of GLOBE Model billing units.
- 513.530 Manufacturer payment responsibilities.

Subpart G—Manufacturer-Submitted International Net Pricing Information

- 513.600 Definitions.
- 513.610 Submission and acceptance of international net pricing information.
- 513.620 GLOBE Model data agreement.

Subpart H—Reports of GLOBE Model Rebate Amounts, Reconciliation, Suggestion of Error, and Payments

- 513.700 Definitions.
- 513.710 Rebate reports and reconciliation-incremental approach.
- 513.720 Suggestion of error.

513.730 Manufacturer access to rebate reports.

513.740 Deadline and process for payment of rebate amount.

Subpart I—Enforcement of Manufacturer Payment of GLOBE Model Rebate Amounts

513.800 Civil money penalty notice and appeals procedures.

Subpart J—Quality Strategy, Beneficiary Protections, and Compliance Activities

513.900 Quality measures.

Subpart K—Waivers

513.1000 Waivers of Medicare program requirements for purposes of testing the GLOBE Model.

Authority: 42 U.S.C.1302, 1315(a), and 1395hh.

Subpart A—General Provisions

§ 513.1 Basis, scope, duration, and severability.

(a) *Basis.* This part implements the test of the Global Benchmark for Efficient Drug Pricing (GLOBE) Model under section 1115A of the Act. Except as specifically noted in this part, the regulations under this part do not affect payment, coverage, program integrity, or any other requirements that otherwise apply to providers of services, suppliers, and manufacturers under this chapter.

(b) *Scope.* This part sets forth the following:

(1) The manufacturers required to participate in the GLOBE Model and applicable requirements including, but not limited to, the requirement for manufacturers of GLOBE Model drugs to pay GLOBE Model rebates to the Federal Supplementary Insurance Trust Fund for each calendar quarter during the model performance period when a GLOBE Model rebate is owed in accordance with 42 CFR 513.510.

(2) The beneficiaries included in the GLOBE Model.

(3) The Part B rebatable drugs included in the GLOBE Model.

(4) The methodologies for establishing the GLOBE Model rebate amount.

(5) The methodologies for establishing the GLOBE Model beneficiary coinsurance percentage.

(6) The methodologies for establishing the Medicare Part B payment to providers of services and suppliers when the GLOBE Model beneficiary coinsurance percentage applies.

(c) *Duration.* The GLOBE Model has a 7-year test period consisting of a 5-year performance period and a 7-year payment period.

(1) The first performance year begins on October 1, 2026, and the final performance year ends on September 30, 2031, unless sooner terminated in accordance with 42 CFR 513.1500.

(2) The first payment year begins on October 1, 2026, and the final payment year ends on September 30, 2033, unless sooner terminated in accordance with 42 CFR 513.1500.

(d) *Severability*. Were any provision of this part to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, these provisions would be severable from this part and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 513.20 Definitions.

For the purpose of this part the following definitions are applicable unless otherwise stated:

Across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit means a volume-weighted average for all reference countries of GDP (PPP) adjusted net prices, where the weights are the volume in HCPCS billing units for each reference country, in U.S. dollars from international drug net pricing data from an applicable submission.

Add-on percentage amount means the amount of payment for a drug or biological product determined in accordance with section 1847A(b)(1)(B) of the Act above the drug or biological product's average sales price, expressed as a percentage of the average sales price or the wholesale acquisition cost.

Allowed charges has the same meaning set forth in 42 CFR 427.20.

Applicable ASP calendar quarter means the period that is 2 calendar quarters prior to the applicable calendar quarter.

Applicable calendar quarter has the same meaning set forth in 42 CFR 427.20.

Applicable threshold percentage means the percentage specified in 42 CFR 513.400.

Average sales price (ASP) has the same meaning set forth in 42 CFR 427.20.

Billing and payment code has the same meaning set forth in 42 CFR 427.20.

Billing unit has the same meaning set forth in 42 CFR 427.20.

Biosimilar biological product for the United States has the same meaning set forth in 42 CFR 427.20

International biosimilar biological product means a biological product approved or licensed in a reference country under that reference country's regulatory framework under a pathway similar to section 351(k) of the PHS Act in the U.S.

Country-level price means the unadjusted country-level price for a GLOBE Model drug at the unit of measurement delineated in the HCPCS Level II code descriptor as calculated in accordance with 42 CFR 513.410.

Currently in shortage has the same meaning set forth in 42 CFR 427.400.

Date of receipt has the same meaning as set forth in 42 CFR 427.500.

Drug shortage or shortage has the same meaning set forth in 42 CFR 427.400.

Eligible manufacturer means the manufacturer of a separately payable Medicare Part B rebatable single source drug or biological (as defined in section 1847A(c)(6)(D) of the Act) that could be a GLOBE Model drug during the model performance period.

Final action claim has the same meaning set forth in 42 CFR 427.20.

FDA stands for Food and Drug Administration.

GDP stands for gross domestic product.

GDP (PPP) adjuster means the country specific adjuster as calculated in accordance with 42 CFR 513.430.

GLOBE Model-adjusted beneficiary coinsurance percentage means the applicable coinsurance percentage as determined under 42 CFR 513.210.

GLOBE Model benchmark amount means the amount calculated in accordance with 42 CFR 513.400.

GLOBE Model beneficiary means a Medicare beneficiary who has been identified by CMS for inclusion in the model and added to the model cohort for some or a portion of the GLOBE Model performance period as set forth in 42 CFR 513.120.

GLOBE Model billing units means the billing units of the GLOBE Model drug furnished to a GLOBE Model beneficiary during the applicable calendar quarter, as identified by CMS as set forth in 42 CFR 513.520.

GLOBE Model drug means Medicare Part B rebatable drug described by a HCPCS Level II code included on the GLOBE Model Drug HCPCS Level II Codes List specified in 42 CFR 513.130(c).

GLOBE Model eligible beneficiary means a Medicare beneficiary meeting the criteria in 42 CFR 513.120(b)(1).

GLOBE Model Eligible Beneficiary List means the list recording the assignment of Medicare beneficiaries as eligible for the model cohort in accordance with 42 CFR 513.120(b)(1).

GLOBE Model geographic areas means the set of ZIP Codes identified in accordance with 42 CFR 513.110.

GLOBE Model participant means a manufacturer of a GLOBE Model drug that is required to participate in the

GLOBE Model in accordance with 42 CFR 513.100.

GLOBE Model payment period means the 7-year period of time beginning on October 1, 2027, through September 30, 2033, as specified in 42 CFR 513.1(c).

GLOBE Model performance period means the 5-year period of time beginning on October 1, 2026, through September 30, 2031, as specified in 42 CFR 513.1(c).

GLOBE Model rebate amount means the amount that is calculated in accordance with 42 CFR 513.510 for a Part B rebatable drug.

HCPCS stands for Healthcare Common Procedure Coding System.

HCPCS billing units are the standardized measurement quantities (such as milligrams, milliliters, or individual items) used to determine how medical services, procedures, supplies, and drugs are quantified and billed for reimbursement under the Healthcare Common Procedure Coding System, where the billing quantity is calculated by dividing the total amount administered or provided by the unit of measurement defined for that specific HCPCS Level II code.

HCPCS dosage means the quantity of drug represented in one HCPCS billing unit, which is the identifiable quantity of a drug or biological product associated with a billing and payment code (for example, a HCPCS Level II code), as established by CMS.

Inflation-adjusted payment amount means the amount determined under 42 CFR 427.302(g).

International generic means for a drug approved and marketed in a non-U.S. country under that non-U.S. country's regulatory framework under a pathway similar to section 505(j) of the FD&C Act in the U.S.

International net pricing information means the data specified in 42 CFR 513.610.

International originator drug means an original biological product or drug approved or licensed in a non-U.S. country under that non-U.S. country's regulatory framework under a pathway similar to 351(k) of the PHS Act or approved under a pathway similar to section 505(c) of the FD&A Act in the U.S.

List price means the manufacturer's price (also known as the ex-factory price or undiscounted price offered by a manufacturer to a purchaser) at the presentation level for a calendar quarter (expressed U.S. currency).

Manufacturer has the meaning as set forth in section 1847A(c)(6)(A) of the Act and 42 CFR 427.20.

Manufacturer average sale price information means the information

described in sections 1927(b)(3)(A)(iii) and 1847A(f)(2)(A) of the Act.

Manufacturer's average sales price has the same meaning as under 42 CFR 414.902 and means the price calculated and reported by a manufacturer under 42 CFR 414 Subpart J.

Maximum fair price has the same meaning as specified in section 1191(c)(3) of the Act.

Method I GLOBE Model benchmark means the lowest country-level price of the countries specified in 42 CFR 513.310 for a GLOBE Model drug as determined in 42 CFR 513.410.

Method II GLOBE Model benchmark means the volume-weighted average of the manufacturer's net pricing for sales within a set of countries specified in 42 CFR 513.310 for a GLOBE Model drug as determined in 42 CFR 513.420.

Natural disaster has the same meaning set forth in 42 CFR 427.400.

Net sales price means the total net sales divided by the number of units sold for a calendar quarter (expressed in U.S. currency).

OECD means Organisation for Economic Co-operation and Development.

Other unique or unexpected event has the same meaning set forth in 42 CFR 427.400.

Part B rebatable drug has the same meaning as identified in 42 CFR 427.20.

Payment year means a 12-month period beginning on October 1 and ending on September 30 during the GLOBE Model test period.

Plasma-derived product has the same meaning set forth in 42 CFR 427.400.

Performance year means a 12-month period beginning on October 1 and ending on September 30 during the first 5 years of the GLOBE Model test period.

Presentation level means, for a scientific and nonproprietary name, a unique combination of dosage form, strength, route of administration, pack size, and packaging sold in a reference country.

Presentation unit means the product represented at the presentation level, unless otherwise specified by CMS to account for situations where labeling indicates that the quantity of drug product represented by the presentation level varies.

Provider means a "provider of services" as defined under section 1861(u) of the Act and codified at 42 CFR 400.202 of this chapter.

Reference country means a country that is identified under 42 CFR 513.310(b).

Reference product means an FDA-licensed biological product approved under section 351(a) of the Public Health Service Act against which a

biosimilar biological product is evaluated in an application submitted to the FDA under section 351(k) of the Public Health Service Act.

Severe supply chain disruption has the same meaning set forth in 42 CFR 427.400.

Single source drug or biological product has the same meaning set forth in 42 CFR 427.20.

Sold or marketed has the same meaning set forth in 42 CFR 427.20.

Sole source biological means a biological product licensed by the FDA in under a BLA under section 351(a) of the PHS Act and that, at time of evaluating for inclusion into the GLOBE Model for each applicable ASP calendar quarter, is not the reference biological product, as defined in section 1847A(c)(6)(I) of the Act, for a biosimilar biological product licensed by the FDA in a BLA under section 351(k) of the PHSA Act. The biosimilar biological product must be recognized in the FDA's Purple Book and be identified as sold or marketed in FDA's NDC Directory. At the time of evaluating inclusion in the GLOBE Model for each applicable ASP calendar quarter, CMS uses FDA's NDC Directory, including historical information from NDC Directory files such as discontinued, delisted, and expired listings, provided by the FDA or published on the FDA website to identify whether the biosimilar biological product is being sold or marketed for purposes of the GLOBE Model.

Specified amount has the same meaning set forth in 42 CFR 427.20.

Supplier means a supplier as defined in section 1861(d) of the Act and codified at 42 CFR 400.202 of this chapter.

Unit has the same meaning set forth in 42 CFR 427.20.

U.S. originator drug means the original biologic and drug developed and licensed or approved via section 351(a) of the Public Health Services Act or submitted under section 505(b) and approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). U.S. originator drugs are also sometimes called brand name drugs, reference listed drug, or reference products.

U.S. stands for United States.

ZIP Code means a trademark of the United States Postal Service (USPS) created to coordinate mail handling and delivery. The USPS assigns ZIP Code ranges to regional post offices, which in turn assign ZIP Codes to delivery routes.

ZIP Code Tabulation Areas (ZCTAs) means approximate area representations of USPS five-digit Zonal Improvement Plan (ZIP) Code service routes that the

Census Bureau creates using whole blocks to present statistical data from censuses and surveys.

Subpart B—Inclusion in the GLOBE Model

§ 513.100 GLOBE Model participants.

(a) *GLOBE Model participants.* The GLOBE Model requires participation by all manufacturers of GLOBE Model drugs.

(b) *GLOBE Model participant requirements during the GLOBE Model performance period.* During the GLOBE Model performance period described in 42 CFR 513.1(c), GLOBE Model participants must do all of the following:

(1) Adhere to the GLOBE Model rebate invoicing and payment instructions in subpart H of this part and as established by CMS and its contractors responsible for providing GLOBE Model rebate reports and invoices, and processing GLOBE Model rebates, including without limitation those described in 42 CFR 513.500, to ensure appropriate and accurate GLOBE Model rebate payments.

(2) Participate in GLOBE Model monitoring and evaluation activities in accordance with 42 CFR 403.1110(b), including collecting and reporting of "protected health information" as the Secretary determines is necessary to monitor and evaluate the GLOBE Model.

(3) If electing to submit international drug net pricing data, adhere to the requirements set forth in 42 CFR 513.610 and the GLOBE Model data agreement (42 CFR 513.620).

(c) *GLOBE Model participant requirements prior to performance period 1.* If electing to submit international drug net pricing data for the applicable ASP calendar quarter beginning April 1, 2025, a GLOBE Model participant must adhere to the requirements set forth in 42 CFR 513.610 and the GLOBE Model data agreement (42 CFR 513.620).

(d) *GLOBE Model participant audit, record access, and record retention requirements and model termination.*

(1) *Right to audit.* The Federal Government, including CMS, HHS, and the Comptroller General, or their designees, has the right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of the GLOBE Model.

(2) *Access to records.* The GLOBE manufacturer must maintain and give the Federal government, including CMS, HHS, and the Comptroller General, or their designees, access to all such documents and other sufficient

evidence to enable the audit, evaluation, inspection, or investigation of the implementation of the GLOBE Model, including without limitation, documents and other evidence regarding all the following:

(i) The accuracy of voluntarily submitted data reported to CMS as set forth in 42 CFR 513.610 for the GLOBE Model.

(ii) Other CMS-identified program integrity issues.

(3) *Record retention.* The GLOBE manufacturer must maintain the documents and other evidence described in paragraph (d)(2) of this section for a period of 6 years from the last GLOBE Model rebate payment for the GLOBE manufacturer under the GLOBE Model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(i) CMS determines that there is a special need to retain a particular record or group of records for a longer period and notifies the manufacturer at least 30 days before the normal disposition date; or

(ii) There has been a termination, dispute, or allegation of fraud or similar fault against the manufacturer in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

(4) *Termination of the GLOBE Model.*

(i) CMS may terminate the GLOBE Model for reasons including, but not limited to, the following:

(A) CMS determines that it no longer has the funds to support the GLOBE Model.

(B) CMS terminates the model in accordance with section 1115A(b)(3)(B) of the Act.

(ii) If CMS terminates the GLOBE Model, CMS provides written notice to the model participants specifying the grounds for model termination and the effective date of the termination.

(iii) As specified in section 1115A(d)(2) of the Act, termination of the model in accordance with section 1115A(b)(3)(B) of the Act is not subject to administrative or judicial review.

§ 513.110 GLOBE Model geographic areas.

(a) *Identification of GLOBE Model geographic areas.*

The GLOBE Model geographic areas are identified by ZIP Codes in the United States, excluding U.S. territories that are aligned with ZCTAs that are randomly selected by CMS no later than 60 calendar days prior to the start of the model performance period. During the model performance period, if a ZIP

Code that is within the GLOBE Model geographic areas is split or redesignated, the new ZIP Code is not get reassigned to a GLOBE Model geographic area.

(b) *Selection process.* (1) The identified geographic areas are selected randomly based on the total Medicare population and expenditures, including Part B drug expenditures balanced on Medicare beneficiary population and Medicare expenditures nationwide.

(2) The identified GLOBE Model geographic areas must include ZIP Codes where approximately 25 percent of Medicare Part B FFS beneficiaries have an address of record as set forth in 42 CFR 513.120.

(c) No later than 30 calendar days in advance of model start, CMS provides a table on the GLOBE Model website that lists the GLOBE model geographic areas by ZIP code.

§ 513.120 Identification of GLOBE Model beneficiaries and comparison group.

(a) *General.* (1) The identification of GLOBE Model eligible beneficiaries and the comparison group is performed solely by CMS at certain points in time as determined by CMS and is not subject to review.

(2) CMS determines when the list of GLOBE Model eligible beneficiaries is created and updated, and the Medicare claims processing systems are updated with the most recent list of GLOBE Model eligible beneficiaries, the timing of such updates is not subject to review.

(3) For purposes of identifying a beneficiary's address in paragraph (b), CMS uses the beneficiary's address as recorded in CMS's Medicare Beneficiary Database (MBD), System No. 09–70–0536, as determined by CMS.

(b) *Initial assignment of beneficiaries as eligible for the Model cohort or comparison group.* Subject to paragraph (d) of this section, approximately 30 days prior to model start using available Medicare program administrative information as determined by CMS, CMS—

(1) Identifies the Medicare beneficiaries who are enrolled in Medicare Part B, have Traditional Medicare Part B as their primary payer, and have an address of record within the GLOBE Model geographic areas selected for inclusion in the model at model start (as identified by CMS under 42 CFR 513.110(c)), and adds such beneficiaries to the GLOBE Model Eligible Beneficiary List.

(2) Identifies Medicare beneficiaries who are enrolled in Medicare Part B, have Traditional Medicare Part B as their primary payer, and do not have an address of record within the GLOBE Model geographic areas selected for

inclusion in the model, and assigns such beneficiaries as eligible for the comparison group.

(c) *GLOBE Model Eligible Beneficiary List Updates.* Subject to paragraph (d) of this section, periodically (not more frequently than weekly), using available Medicare program administrative information as determined by CMS, CMS identifies the Medicare beneficiaries—

(1) Who are enrolled in Medicare Part B, have Traditional Medicare Part B as their primary payer, and have an address of record within the GLOBE Model geographic areas selected for inclusion (as identified by CMS under 42 CFR 513.110(c)), are not yet included on the GLOBE Model Eligible Beneficiary List, and are not assigned as eligible for the comparison group. CMS adds such beneficiaries to the GLOBE Model Eligible Beneficiary List at the next cohort update; and

(2) On the GLOBE Model Eligible Beneficiary List who no longer meet the criteria for a GLOBE Model eligible beneficiary and removes such beneficiaries from the GLOBE Model Eligible Beneficiary List at the next update.

(d) *Beneficiary exclusions.* Subject to paragraph (d)(3) of this section, the following are not eligible for assignment to the GLOBE Model Eligible Beneficiary List or comparison group:

(1) Beneficiaries who do not have Medicare Part B FFS as their primary payer; and

(2) Beneficiaries who are enrolled in a MA plan, section 1876 cost plan, section 1833 healthcare prepayment plans, or who have other group health coverage that is a primary payer (such as employer-sponsored health insurance).

(3) Beneficiaries who are identified by CMS as eligible for inclusion in the comparison group prior to model start remain eligible for the comparison group as determined by CMS.

(e) *GLOBE Model Beneficiaries.* GLOBE Model eligible beneficiaries who are furnished a GLOBE Model drug during the model performance period for which separate payment is made are GLOBE Model beneficiaries as determined by CMS.

§ 513.130 GLOBE Model drugs and excluded drugs.

(a) [Reserved.]

(b) *GLOBE Model drugs.* GLOBE Model drugs include Part B rebatable drugs (as identified by the applicable billing and payment code) in accordance with 42 CFR 427.101(a)(1)(ii) of this chapter that meet the following criteria:

(1) Drugs or biological products listed as antigout agents, antineoplastics, blood products and modifiers, central nervous system agents, immunological agents, metabolic bone disease agents, or ophthalmic agents as specified in the United States Pharmacopeia Drug Classification (USP DC) category.

(i) CMS identifies drugs or biological products that are Part B rebatable drugs at the start of the GLOBE Model as antigout agents, antineoplastics, blood products and modifiers, central nervous system agents, immunological agents, metabolic bone disease agents, or ophthalmic agents using the United States Pharmacopeia Drug Classification published in 2025 (USP DC 2025).

(ii) CMS identifies drugs or biological products that were not Part B rebatable drugs at the start of the GLOBE Model, but subsequently become Part B rebatable drugs, as antigout agents, antineoplastics, blood products and modifiers, central nervous system agents, immunological agents, metabolic bone disease agents, or ophthalmic agents identified using the latest, publicly available United States Pharmacopeia Drug Classification to identify their category.

(iii) CMS adds new USP DC categories that stem from the USP DC categories listed in § 513.130(b)(1) to the GLOBE Model inclusion criteria. CMS may make this determination based on a review of USP revision bulletins, revision histories, and corresponding change log information published by USP.

(2) Single source drugs or sole source biological products.

(3) Drug or biological products with total Medicare Part B FFS allowed charges greater than \$100 million over a 12-month period (as determined by CMS under paragraph (d) of this section) ending 6 months prior to the start of the applicable calendar quarter.

(i) This criterion is met if the drug or biological product meets this requirement (as determined by CMS under paragraph (d) of this section) at least one time during the duration of the GLOBE Model. If the drug or biological product meets this criterion for an applicable calendar quarter it continues to meet this criterion for subsequent applicable calendar quarters even if the Medicare Part B FFS allowed charges falls below \$100 million over a 12-month period ending 6 months prior to the start of the subsequent applicable calendar quarters.

(4) Drug or biological products that are not excluded from the GLOBE Model under paragraph (c) of this section.

(c) *Exclusions.* (1) The following are excluded from the GLOBE Model:

(i) A Part B rebatable drug for applicable calendar quarters prior to the first applicable calendar quarter for which CMS identifies a specified amount under 42 CFR 427.302(b).

(ii) A Part B rebatable drug for which a maximum fair price under the Medicare Drug Price Negotiation Program is in effect.

(iii) A drug or biological product that is no longer a Part B rebatable drug during the duration of the GLOBE Model is removed for the applicable calendar quarter in which it is no longer a Part B rebatable drug.

(d) *Medicare Part B FFS allowed charges.* For a GLOBE Model drug for an applicable calendar quarter, CMS calculates the total Medicare Part B FFS allowed charges for a consecutive 12-month period ending 6 months prior to the start of the applicable calendar quarter as follows:

(1) CMS identifies the Medicare Part B FFS final action claims with dates of service within the consecutive 12-month period ending 6 months prior to the start of the applicable calendar quarter that have separately payable allowed charges greater than \$0 for any billing and payment code used to describe the GLOBE Model drug.

(2) For the claims identified in paragraph (d)(1) of this section, CMS sums the allowed charges.

(e) *GLOBE Model Drug HCPCS Level II Codes List.* (1) Subject to paragraph (d)(2) of this section, prior to an applicable calendar quarter, CMS creates the GLOBE Model Drug HCPCS Level II Codes List for that applicable calendar quarter as follows:

(i) CMS adds all separately payable HCPCS Level II codes for a GLOBE Model drug identified in accordance with paragraphs (b) and (c) of this section to the GLOBE Model Drug HCPCS Level II Codes List for that applicable calendar quarter.

(ii) CMS identifies a United States Pharmacopeia Drug Classification Category for each HCPCS Level II code.

(A) HCPCS Level II codes included in the initial GLOBE Model Drug HCPCS Level II Codes List retain their USP DC category for the entire model duration.

(B) New HCPCS Level II codes that were not in the previously published GLOBE Model Drug HCPCS Level II Codes List is assigned a United States Pharmacopeia Drug Classification category at the time of identification of the new HCPCS Level II codes for a GLOBE Model drug, based on the United States Pharmacopeia Drug Classification available then. After identification, the new HCPCS Level II

codes retain their category for the remainder of the model duration.

(2) *Revisions.* As applicable, CMS revises the GLOBE Model Drug HCPCS Level II Codes List for an applicable calendar quarter to correct errors as determined by CMS.

(3) *Publication.* CMS makes the GLOBE Model Drug HCPCS Level II Codes List for an applicable calendar quarter available on the CMS GLOBE Model website.

Subpart C—Coinsurance Adjustment and Adjusted Medicare Payment for GLOBE Model Drugs

§ 513.200 Definitions.

As used in this subpart, the following definitions apply:

GLOBE Model beneficiary coinsurance percentage means the applicable coinsurance percentage as determined under this subpart.

Per unit GLOBE Model benchmark amount means the sum of the product of the per unit GLOBE Model benchmark as set forth in 42 CFR 513.400, the applicable threshold percentage, and the add-on percentage amount as set forth in 42 CFR 513.400(c).

§ 513.210 Computation of GLOBE Model beneficiary coinsurance adjustment and adjusted Medicare payment for GLOBE Model drugs.

(a) *General.* CMS uses the methodology set forth in this section to calculate the GLOBE Model beneficiary coinsurance, the GLOBE Model beneficiary coinsurance percentage and associated adjusted Medicare payment for GLOBE Model drugs.

(b) *Calculation of GLOBE Model beneficiary coinsurance adjustment.* To calculate and determine if the GLOBE Model beneficiary coinsurance adjustment applies for separately payable units of GLOBE Model drugs furnished to a GLOBE Model beneficiary with respect to an applicable calendar quarter, CMS compares the payment amount as set forth in 42 CFR 427.201(b)(3) to the per unit GLOBE Model benchmark amount as set forth in 42 CFR 513.400.

(1) If the payment amount exceeds the per unit GLOBE Model benchmark amount, the GLOBE Model beneficiary coinsurance adjustment applies and the GLOBE Model beneficiary coinsurance is calculated by multiplying the per unit GLOBE Model benchmark amount by 0.20. In such case, the GLOBE Model beneficiary coinsurance is applied as a percent to the payment amount and the GLOBE Model beneficiary coinsurance percentage is calculated by dividing the GLOBE Model beneficiary coinsurance

by the payment amount and rounding to the third decimal place.

(2) If the payment amount does not exceed the per unit GLOBE Model benchmark amount, the adjustment to the beneficiary coinsurance set forth in paragraph (b)(1) of this section is not applied. In such case, the GLOBE Model beneficiary coinsurance is the coinsurance amount computed as set forth in 42 CFR 419.41(e) or 42 CFR 489.30(b)(1) as applicable.

(c) *Identification of the adjusted Medicare payment amount.* When the GLOBE Model beneficiary coinsurance adjustment applies, CMS calculates the adjusted Medicare payment amount for a GLOBE Model drug for an applicable calendar quarter as follows.

(1) *Calculation of the adjusted Medicare payment amount.* The product of the allowed amount multiplied by the GLOBE Model beneficiary coinsurance percentage is subtracted from the allowed amount. Subject to paragraph (c)(2) of this section, the result equals the adjusted Medicare payment amount.

(2) *Limitation.* The adjusted Medicare payment amount is subject to other claims adjustments and the Part B deductible.

(d) *Exclusions.* Any Part B rebatable drug that is excluded from the GLOBE Model for an applicable calendar quarter is not subject to the GLOBE Model beneficiary coinsurance adjustment set forth in paragraph (b) of this section and the adjusted Medicare payment amount set forth in paragraph (c) of this section.

Subpart D—GLOBE Model Data Sources

§ 513.300 Definitions

As used in this subpart, the following definitions apply:

Real GDP per capita means, for a country, the total gross domestic product based on purchasing power parity (PPP) divided by the total population for the same year as estimated and available in the U.S. Central Intelligence Agency (CIA) World Factbook.

Annual real GDP means, for a country, the total gross domestic product based on purchasing power parity (PPP) for a given year as estimated and available in the U.S. Central Intelligence Agency (CIA) World Factbook.

§ 513.310 Included international data.

(a) *General.* CMS uses international drug pricing information from data sources, available to CMS at least 60 business days prior to the start of an applicable calendar quarter, meeting the

requirements in paragraphs (c) and (d) of this section, for countries in the set of reference countries identified in paragraph (b) of this section.

(b) *Set of reference countries.*

(1) Subject to paragraph (b)(6) of this section, CMS uses available international drug pricing information for countries that were non-U.S. OECD member countries as of October 1, 2025 with a real GDP per capita that is at least 60 percent of the U.S. real GDP per capita and an annual real GDP of at least \$400 billion, as determined by CMS in accordance with this paragraph (b).

(2) Subject to the limitation specified in paragraph (b)(4) of this section, the real GDP per capita for a country is the most recent estimate of real GDP per capita based on purchasing power parity for that country for the year 2024 using data available in the U.S. Central Intelligence Agency (CIA) World Factbook as of October 1, 2025.

(3) Subject to the limitation specified in paragraph (b)(4) of this section, the annual real GDP for a country is the most recent estimate of annual real GDP based on purchasing power parity for that country for the year 2024 available in the U.S. Central Intelligence Agency (CIA) World Factbook as of October 1, 2025.

(4) The country's real GDP per capita and annual real GDP, and the U.S. real GDP per capita selected from the CIA World Factbook must be for the same calendar year and for the year 2024.

(5) CMS identifies countries with a real GDP per capita that is at least 60 percent of the U.S. GDP per capita by dividing the real GDP per capita for a country by the U.S. real GDP per capita and assessing the results.

(6) CMS identifies the set of reference countries for the GLOBE Model performance period prior to the start of performance year 1 using the U.S. CIA World Factbook data as available on October 1, 2025. The set of reference countries includes all of the following:

- (i) Australia.
- (ii) Austria.
- (iii) Belgium.
- (iv) Canada.
- (v) Czechia.
- (vi) Denmark.
- (vii) France.
- (viii) Germany.
- (ix) Ireland.
- (x) Israel.
- (xi) Italy.
- (xii) Japan.
- (xiii) Netherlands.
- (xiv) Norway.
- (xv) South Korea.
- (xvi) Spain.
- (xvii) Sweden.
- (xviii) Switzerland.

(xix) The United Kingdom.

(c) *Identification of available international data sources used to identify the per unit Method I GLOBE Model benchmark.*

(1) *General.* For purposes of selecting a data source for each GLOBE Model drug for an applicable calendar quarter for a reference country, CMS identifies available international drug pricing information data sources for the GLOBE Model drug, by aligning the GLOBE Model drug's assigned HCPCS Level II code long description (including dosage form) with the data sources' standardized method for identifying scientific names or nonproprietary names, dosage form, route of administration, other details within the billing and payment code long description, as applicable.

(i) CMS obtains data from one or more international drug pricing information data sources for purposes of identifying available international drug pricing information for the countries specified in paragraph (b) of this section.

(ii) The data sources must, as determined by CMS use a standardized method for identifying all of the following:

(A) Drugs across countries within that data source, such as using internationally recognized scientific and nonproprietary product names.

(B) Dosage form and route of administration across countries within the data source that at a minimum distinguishes among injectable, oral, and other forms of a drug, and other details within the billing and payment code long description, as applicable, such as using an internationally recognized nomenclature for pharmaceutical forms like the New Form Code classification

(C) Strength or concentration across countries within that data source, and they are expressed in internationally recognized measures such as milligrams or milliliters.

(D) U.S. originator drug, international originator drug, non-originator U.S. drug, and non-originator international drug using a drug's regulatory approval pathway across countries within that data source, that at a minimum distinguishes international generics and international biosimilar biological products

(iv) Contain at a minimum one of the following international drug pricing data information and utilizes a standard method across countries, including the following:

(A) List prices across countries within the data source (expressed in U.S. currency) and its corresponding volume, meaning quantity of units (for example,

number of items, packages or units sold).

(B) Sales data, which may be based on ex-manufacturer prices (sometimes called ex-factory prices) that represent actual or calculated prices paid to the manufacturer by wholesalers and other distributors across countries within the data source (expressed in U.S. currency) and its corresponding volume, meaning quantity of units (for example, number of items, packages or units sold).

(C) Retail prices that represent actual or calculated sales for retail purchasers, or prices paid by other purchasers in the distribution channels across countries within the data source (expressed in U.S. currency and its corresponding volume data, meaning quantity of units (for example, number of items, packages or units sold).

(D) List prices across countries within the data source (expressed in U.S. currency).

(E) Sales data, which may be based on ex-manufacturer prices (sometimes called ex-factory prices) that represent actual or calculated prices paid to the manufacturer by wholesalers and other distributors across countries within the data source (expressed in U.S. currency).

(F) Retail prices that represent actual or calculated sales for retail purchasers, or prices paid by other purchasers in the distribution channels across countries within the data source (expressed in U.S. currency).

(v) Have mechanisms in place to maintain, update, validate, and correct, if necessary, the information on international drug pricing in the data source on at least a quarterly basis.

(vi) Be maintained by an organization that seeks to limit the lag inherent in data to no more than 90 days from the end of the calendar quarter for which drug pricing information is compiled to the time that the organization makes updates available to users of the data source.

(2) *Selection of data source.* Subject to paragraphs (c)(1) and (c)(3) of this section, for each GLOBE Model drug for an applicable calendar quarter, CMS selects a data source using the following hierarchy and uses this data source, if available, to identify the per unit Method I GLOBE Model benchmark as described in 42 CFR 513.400(b).

(i) The data source contains drug specific sales and volume data for the applicable ASP calendar quarter from at least one country described in paragraph (b) of this section.

(ii) Except as noted in paragraph (c)(2)(iii) of this section, the data source does not have drug specific sales and volume data for the applicable ASP

calendar quarter, but contains drug specific sales and volume data for any prior ASP calendar quarter beginning on or after April 1, 2025 from at least one country described in paragraph (b) of this section. If sales and volume data from a prior ASP calendar quarter are used, CMS uses sales and volume data from the most recent ASP calendar quarter for which both sales and volume data are available.

(iii) The extracted data used by CMS to identify the most recent per unit Method I GLOBE Model benchmark available in a document posted on the GLOBE Model website, including extracted data with drug specific sales and volume data from January 1, 2024 to December 31, 2024 from at least one country described in paragraph (b) of this section.

(iv) The data source contains drug specific ex-manufacturer price data for the applicable ASP calendar quarter from at least one country described in paragraph (b) of this section.

(v) The data source contains drug specific list price data (for example, the price made available to wholesalers) for the applicable ASP calendar quarter from at least one country described in paragraph (b) of this section.

(3) If there is more than one data source for a GLOBE Model drug, CMS selects the data source at the highest level of the hierarchy that contains information from the highest number of countries described in paragraph (b) of this section and, if available, incorporates discounts, rebates, and other price concessions into its drug pricing information. CMS does not use more than one data source for a GLOBE drug across countries.

(d) *Identification of available manufacturer-submitted international net pricing information used to identify the per unit Method II GLOBE Model benchmark.*

(1) *General.* Subject to 42 CFR 513.610 and the GLOBE Model data agreement (42 CFR 513.620), for each GLOBE Model drug for an applicable calendar quarter as set forth in 42 CFR 513.20, CMS assesses manufacturer-submitted international net pricing information for the applicable ASP calendar quarter that was accepted in accordance with 42 CFR 513.610.

(2) *Determining availability of international net pricing information.* For purposes of identifying available manufacturer-submitted international drug pricing information for the countries specified in paragraph (b) of this section for a GLOBE Model drug for an applicable calendar quarter, CMS uses the following steps:

(i) CMS identifies the accepted manufacturer-submitted international net pricing information for the applicable ASP calendar quarter (as set forth in 42 CFR 513.20) that aligns with a GLOBE Model drug's HCPCS Level II code long descriptor (including scientific or nonproprietary name, dosage form, route of administration (if applicable), and other details within the billing and payment code long description), as determined by CMS.

(ii) When there is accepted international net pricing information (or, if applicable, an attestation stating that there was no reportable international net pricing information) from each eligible manufacturer of the GLOBE Model drug, using the accepted international net pricing information identified in paragraph (d)(2)(ii)(A) of this section, CMS identifies presentation level information that includes, as determined by CMS—

(A) Complete international drug product information that is consistent with the reported total quantity of drug in the pack size;

(B) International net pricing and sales data for at least one of the countries specified in paragraph (b) of this section; and

(C) The presentation level information is not for an international generic or international biosimilar biological product (as applicable for data for a country).

(iii) CMS deems the presentation level information to be complete and valid per 42 CFR 513.610.

(3) *Limitation.* If CMS determines that manufacturer-submitted international drug pricing information is not complete and valid per 42 CFR 513.610, then the presentation level information is not available for purposes of 42 CFR 513.520.

Subpart E—Determination of the Per Unit GLOBE Benchmark Amount

§ 513.400 Identification of the per unit GLOBE Model benchmark amount.

(a) *General.* The result of calculations in this subpart E are rounded to the fifth decimal place except for the calculation in paragraph (c)(4) which are rounded to the third decimal place.

(b) *Identification of the per unit GLOBE Model benchmark.* Subject to available information as determined by CMS and paragraph (b)(3), for each applicable calendar quarter, CMS identifies and designates the greater of the following as the per unit GLOBE Model benchmark:

(1) The per unit Method I GLOBE Model benchmark (as determined in 42 CFR 513.410).

(2) The per unit Method II GLOBE Model benchmark (as determined in 42 CFR 513.420), as available, as the per unit GLOBE Model benchmark for a GLOBE Model drug for the applicable calendar quarter.

(3) *Limitation.* If CMS determines that neither a per unit Method I GLOBE Model benchmark nor a per unit Method II GLOBE Model benchmark is available, CMS identifies that the per unit GLOBE Model benchmark for the GLOBE Model drug for the applicable calendar quarter is not available.

(c) *Calculation of the per unit GLOBE Model benchmark amount.* For each applicable calendar quarter, for a GLOBE Model drug, when a per unit GLOBE Model benchmark is available as set forth in paragraph (b), CMS calculates the per unit GLOBE Model benchmark amount as follows:

(1) CMS multiplies the per unit GLOBE Model benchmark by the applicable threshold percentage as set forth in 42 CFR 513.400(d).

(2) CMS calculates add-on percentage amount which is the dollar value of the add-on percentage included in the Medicare Part B payment limit for the HCPCS Level II code for the GLOBE Model drug as specified under section 1847A(b) of the Act for the applicable calendar quarter. In general, the Medicare Part B payment limit is equal to the specified amount (as defined at 42 CFR 427.302(b)).

(3) CMS sums the amounts calculated in paragraphs (c)(1) and (c)(2) of this section.

(4) CMS rounds the amount calculated in paragraph (c)(3) of this section to the third decimal place and identifies this amount as the per unit GLOBE Model benchmark amount.

(d) *Applicable threshold percentage.* When the per unit GLOBE Model benchmark is based on the per unit Method I GLOBE Model benchmark, the applicable threshold percentage is 102 percent. When the per unit GLOBE Model benchmark is based on the per unit Method II GLOBE Model benchmark, the applicable threshold percentage is 105 percent.

§ 513.410 Identification of the per unit Method I GLOBE Model benchmark.

For each GLOBE Model drug, CMS identifies the per unit Method I GLOBE Model benchmark by identifying the lowest per unit GDP (PPP) adjusted country-level price using available international drug pricing information from available data sources, in accordance with 42 CFR 513.310, as determined by CMS, and the methodology described in this section.

(a) *Per unit country-level price.* CMS identifies the per unit country-level price for each country specified in 42 CFR 513.310(b), as available, using the following steps:

(1) *Identify available international drug pricing data.* By country, using the data source selected in accordance with 42 CFR 513.310(c)(2), CMS identifies available international drug pricing data for the GLOBE Model drug, for the applicable ASP calendar quarter for the first applicable calendar quarter that the drug is a GLOBE Model drug, by aligning the GLOBE Model drug's HCPCS Level II code long description (including scientific or nonproprietary name, dosage form, route of administration (if applicable), and other details within the billing and payment code long description, as applicable) with the data sources' standardized method for identifying scientific names or nonproprietary names, dosage form, and route of administration (if applicable), as applicable. CMS extracts available drug pricing data for the countries specified in 42 CFR 513.310(b) from the selected international drug pricing information data sources that, as determined by CMS—

(i) Represent the price of a U.S. originator drug or international originator drug (as applicable for data for a country);

(ii) Have complete package size information;

(iii) Represent scientific or nonproprietary name and dosage form and include route of administration (if applicable), that could be described by the GLOBE Model drug's HCPCS Level II code descriptor; and

(iv) Have strength data.

(2) *Apply data checks.* As determined by CMS, CMS applies the following steps as applicable:

(i) Identify and discard extracted data as follows:

(A) When international drug pricing information with sales and volume data are available, CMS excludes international drug pricing data without both sales and volume data that are greater than zero.

(B) [Reserved.]

(ii) When the product information (for example, product strength or package size) is inconsistent or not verifiable with available product information such as product labeling or product approval information for the GLOBE Model drug's HCPCS Level II code descriptor.

(3) *Convert volume data to unit of measurement delineated in the HCPCS Level II Code descriptor.* CMS converts the volume data to the unit of measurement delineated in the GLOBE

Model drug's HCPCS Code Level II descriptor, as applicable.

(i) CMS adjusts the volume data, as applicable, before converting the volume data unit of measurement delineated in the GLOBE Model drug's HCPCS Level II code descriptor when the data source shows the package size or a presentation level (dosage form or route of administration (if applicable)) that is inconsistent with the manufacturer's information about that product for the GLOBE Model drug's HCPCS Level II code descriptor, as determined by CMS.

(ii) CMS limits the number of HCPCS billing units when—

(A) The available information (such as package labeling) indicates a limited quantity of drug is to be used from the presentation level; and

(B) The HCPCS dosage is per dose.

(4) *Calculate the per unit country-level price for the GLOBE Model drug by country.* Using the international drug pricing information extracted and adjusted in accordance with paragraphs (3)(i) and (3)(ii) of this section, respectively, CMS calculates the per unit country-level price for the international drug by country for each country specified in 42 CFR 513.310(b) for which international drug pricing information is available, using the calculation that is applicable.

(i) If an international drug pricing information data source with sales and volume data is used, the applicable calculation is as follows:

(A) CMS removes pricing information at the dosage form and strength level for a country that falls below 5 percent of the average price in the U.S. as set forth in paragraph (d) of this section.

(B) Using remaining data, CMS sums the adjusted volume data (as specified in paragraph (3) of this section) for the presentation levels of the applicable international analog (as specified in 42 CFR 513.600).

(C) Using remaining data, CMS sums the total sales for the presentation levels for the applicable international analog (as specified in 42 CFR 513.600) (that remain after performing the data checks).

(D) CMS divides the sum determined in paragraph (a)(4)(i)(C) of this section by the sum determined in paragraph (a)(4)(i)(B) of this section, resulting in an average price per unit, where the unit is the same unit delineated in the HCPCS Level II code descriptor.

(ii) If an international drug pricing information data source with ex-manufacturer or list prices is used, the applicable calculation is as follows:

(A) For each extracted ex-manufacturer or list price, CMS

calculates the number of HCPCS billing units in the presentation level by dividing the quantity of drug in the presentation level by the quantity of drug represented in the HCPCS dosage from the HCPCS Level II code descriptor.

(B) CMS divides the ex-manufacturer or list price, as applicable, by the number of HCPCS billing units in the presentation level (as calculated in paragraph (a)(4)(ii)(A) of this section), resulting in a price per unit where the unit is the same unit delineated in the HCPCS Level II code descriptor.

(C) CMS removes pricing information at the dosage form and strength level for a country that falls below 5 percent of the average price in the U.S. as set forth in paragraph (d) of this section.

(D) CMS calculates the sum of the price per (as calculated in paragraph (a)(4)(ii) (B) of this section) for each ex-manufacturer or list price that was identified as available as set forth in paragraph (a)(1) of this section and not removed as set forth in paragraph (a)(4)(ii)(B) of this section.

(E) CMS divides the sum calculated in paragraph (a)(4)(ii)(D) of this section by the number of ex-manufacturer or list prices that were identified as available as set forth in paragraph (a)(1) of this section and not removed as set forth in paragraph (a)(4)(ii)(C) of this section, resulting in an average price per unit where the unit is the same unit delineated in the HCPCS Level II code descriptor.

(iii) CMS performs the applicable calculation for each country specified in 42 CFR 513.310(b) for which international drug pricing information is available in the selected data source.

(b) *Per unit GDP (PPP) adjusted country-level price for the GLOBE Model drug by country.* CMS applies the applicable GDP (PPP) adjuster for the applicable ASP calendar quarter as identified 42 CFR 513.430 to each per unit country-level price identified as set forth in paragraph (a)(4) of this section to calculate the per unit GDP (PPP) adjusted country-level price by multiplying each per unit country-level price by the applicable GDP (PPP) adjuster for such country and rounds the result at the fifth decimal place.

(c) *Per unit Method I GLOBE Model benchmark.* (1) CMS identifies the lowest per unit GDP (PPP) adjusted country-level price for the international drug calculated in paragraph (b) of this section to the third decimal place and identifies the result as the per unit Method I GLOBE Model benchmark.

(2) For each Part B rebatable drug that becomes a GLOBE Model drug during the model performance period, CMS

identifies the per unit Method I GLOBE Model benchmark for the first applicable calendar quarter for which the drug is a GLOBE Model drug and this benchmark remains in place for each applicable calendar quarter thereafter until the end of the model performance period.

(d) *Average U.S. price.* (1) Subject to paragraph (d)(2), when there is international pricing information available as set forth in 42 CFR 513.410(a), CMS identifies the average U.S. drug price using the same pricing information from the selected data source used for the reference country for the applicable ASP calendar quarter.

(2) If the selected data source for the reference country does not contain available U.S. pricing information, to identify the average U.S. price CMS uses the most recently published Medicare Part B payment limit minus the add-on amount for the HCPCS Level II code for the GLOBE Model drug for the calendar quarter before the applicable ASP calendar quarter.

§ 513.420 Identification of the per unit Method II GLOBE Model benchmark.

For each applicable calendar quarter, when there is an applicable submission as set forth in 42 CFR 513.610(a) for a GLOBE Model drug, CMS identifies the per unit Method II GLOBE Model benchmark using available manufacturer-submitted international drug net pricing data for the applicable ASP calendar quarter, as identified by CMS in accordance with 42 CFR 513.20, and the methodology described in this section.

(a) *Identify available across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit in U.S. dollars.* For the GLOBE Model drug, within each applicable submission for the applicable calendar quarter, CMS identifies the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit where, using the basic data elements, the scientific or nonproprietary name, dosage form, route of administration (if applicable), and other details within the billing and payment code long description, as applicable, align with the HCPCS Level II code long descriptor for the GLOBE Model drug.

(b) *Identify the per unit Method II GLOBE Model benchmark based on number of manufacturer submissions.* Subject to paragraph (c) of this section, CMS identifies the per unit Method II GLOBE Model benchmark using the applicable steps as follows:

(1) *When there is one manufacturer submission.* CMS identifies the across

country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit data element as the per unit Method II GLOBE Model benchmark for the applicable calendar quarter.

(2) *When there is more than one manufacturer submission.* CMS calculates a volume-weighted average using data across all of the applicable submissions using the following steps:

(i) Separately, for each applicable submission, CMS multiplies the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit by the sum of the volume in billing units.

(ii) CMS sums the amounts calculated in paragraph (b)(2)(i) of this section.

(iii) CMS calculates the total volume by summing the billing units across all applicable submissions.

(iv) CMS divides the sum calculated in paragraph (b)(2)(ii) by the total volume calculated in paragraph (b)(2)(iii) of this section.

(v) The resulting volume-weighted average is rounded at the third decimal place and is identified as the per unit Method II GLOBE Model benchmark for the applicable calendar quarter.

(c) *Unavailable net pricing data.* When a manufacturer submission for an applicable calendar quarter as set forth in § 513.20 is either not accepted by CMS as set forth in § 513.610 or was not submitted by all manufacturers of the GLOBE Model drug, CMS identifies that the per unit Method II GLOBE Model benchmark is unavailable for such applicable calendar quarter.

§ 513.430 Calculation of the GDP (PPP) adjuster.

(a) *GDP (PPP) adjuster formula.* Subject to paragraphs (b), (c), and (d) of this section, for a country, CMS calculates the GDP (PPP) adjuster by dividing the U.S. GDP (PPP) per capita by the country's GDP (PPP) per capita and rounds the result at the third decimal place.

(b) *Data used.* Subject to the limitations specified in paragraphs (c) and (d) of this section, the GDP (PPP) per capita for a country is the most recent estimate of GDP per capita based on purchasing power parity for that country available in the CIA World Factbook at the start of the applicable ASP calendar quarter, as determined by CMS.

(c) *Limitations.* (1) The country's GDP (PPP) per capita and U.S. GDP (PPP) per capita must be for the same year.

(2) The GDP (PPP) per capita used must be for the same year as the data used to calculate the unadjusted per unit country-level price, if available, or the most recent earlier year available.

(d) *Maximum ratio.* In cases where the resulting ratio is less than 1.000, the GDP (PPP) adjuster is set to 1.000.

Subpart F—Determination of the total GLOBE Model Rebate Amount for GLOBE Model Drugs

§ 513.500 Calculation of the total GLOBE Model rebate amount and incremental GLOBE Model rebate amount due.

(a) *Total GLOBE Model rebate amount.* The total GLOBE Model rebate amount for a GLOBE Model drug for an applicable calendar quarter is equal to the product of the per unit GLOBE Model rebate amount of such drug, as determined under § 513.520(a), and the total number of GLOBE Model billing units, as identified by CMS as set forth in § 513.520.

(b) *Incremental GLOBE Model rebate amount.* The incremental GLOBE Model rebate amount for a GLOBE Model drug for an applicable calendar quarter is equal to the product of the incremental per unit GLOBE Model rebate amount of such drug, as determined under § 513.510(b), and the total number of GLOBE Model billing units, as identified by CMS as set forth in § 513.520.

(c) *Apportionment of the incremental GLOBE Model rebate amount.* When there is more than one manufacturer for a GLOBE Model drug for an applicable calendar quarter, CMS uses the proportion of manufacturer-reported ASP units as calculated by CMS in accordance with 42 CFR 427.301(b) or (c) and reported by CMS in the Rebate Reports specified in 42 CFR 427.501 for a manufacturer to apportion the incremental GLOBE Model rebate amount to such manufacturer.

(d) *Reducing the incremental GLOBE Model rebate amount for GLOBE Model drugs currently in shortage.* (1) For an applicable calendar quarter when the total rebate amount determined under 42 CFR 427.301(a) is reduced as specified in 42 CFR 427.401, the incremental GLOBE Model rebate amount calculated in paragraph (c) of this section, if any is owed, is reduced using the following formula: Equation 1 to Paragraph (c)(1)

Reduced incremental GLOBE Model rebate amount = the incremental GLOBE Model rebate amount multiplied by (1 *minus* “applicable percent reduction” determined under 42 CFR 427.401(b)(2) multiplied by (“percentage of time drug was currently in shortage during the applicable calendar quarter” as determined in accordance with 42 CFR 427.401(b)(3)) added to the incremental GLOBE Model rebate amount multiplied by (1 *minus* “percentage of time drug

was currently in shortage during the applicable calendar quarter” as determined in accordance with 42 CFR 427.401(b)(3)).

(2) CMS applies a reduction of the incremental GLOBE Model rebate amount determined in paragraph (d)(1) of this section to all the NDCs under the relevant billing and payment code as specified in 42 CFR 427.401(c).

(e) *Reducing the incremental GLOBE Model rebate amount for GLOBE Model biosimilar biological products when there is a severe supply chain disruption.* When CMS reduces the total rebate amount determined under 42 CFR 427.301(a), if any is owed, for a Part B rebatable biosimilar biological product that is a GLOBE Model drug for an applicable quarter, CMS reduces the incremental GLOBE Model rebate amount determined in paragraph (c) of this section for such GLOBE Model drug, if any is owed, using the same percentage reduction that CMS applied under 42 CFR 427.402 for such GLOBE Model drug for the applicable calendar quarter.

(f) *Other considerations for calculating the total GLOBE Model rebate amount and the incremental GLOBE Model rebate amount.* The amounts calculated in paragraphs (a) through (e) of this section are rounded to the third decimal place.

§ 513.510 Calculation of the per unit GLOBE Model rebate amount and incremental per unit GLOBE Model rebate amount.

(a) *Calculate the per unit GLOBE Model rebate amount.* (1) Subject to paragraph (a)(2) of this section, to calculate the per unit GLOBE Model rebate amount for a GLOBE Model drug for an applicable calendar quarter, CMS identifies the greater of the amounts specified in paragraphs (a)(1)(i) and (ii) of this section and rounds that amount to the second decimal place.

(i) The difference between the specified amount (as determined under 42 CFR 427.302(b)) and the per unit GLOBE Model benchmark amount (as determined under 42 CFR 513.400(b)); or

(ii) The difference between the specified amount (as determined under 42 CFR 427.302(b)) and the inflation-adjusted payment amount (as determined under 42 CFR 427.302(g)).

(2) Limitations.

(i) When the per unit GLOBE Model benchmark amount is not available as determined by CMS as set forth in 42 CFR 513.400(b)(3), CMS identifies the per unit GLOBE Model rebate amount by calculating the difference between the specified amount (as determined

under 42 CFR 427.302(b)) and the inflation-adjusted payment amount (as determined under 42 CFR 427.302(g)).

(ii) The per unit GLOBE Model rebate amount is set at \$0 when the amount identified as set forth in paragraph (a) of this section is less than \$0.

(b) *Calculate the incremental per unit GLOBE Model rebate amount.* (1) Subject to paragraph (b)(2) of this section, for a GLOBE drug for an applicable calendar quarter, CMS calculates the incremental per unit GLOBE Model rebate amount by subtracting the per unit Part B rebate amount calculated as set forth in 42 CFR 427.302(a) from the amount calculated as set forth in paragraph (a) of this section. The result is the incremental per unit GLOBE Model rebate amount for the GLOBE drug for an applicable calendar quarter.

(2) *Limitation.* The incremental per unit GLOBE Model rebate amount is set to \$0 when the amount calculated in paragraph (b)(1) of this section is less than \$0.

§ 513.520 Identification of the total number of GLOBE Model billing units.

(a) *General.* (1) CMS identifies the total number of billing units as set forth in 42 CFR 427.303, as determined by CMS, before identifying GLOBE Model billing units.

(b) *Identify GLOBE Model billing units.* For an applicable calendar quarter for each GLOBE Model drug, from the total number of billing units that CMS identified in accordance with 42 CFR 427.303(b), CMS identifies billing units where, on the date of service, the beneficiary was identified by CMS as a GLOBE Model eligible beneficiary and for which Medicare Part B FFS made separate payment.

(c) *Identify the total number of GLOBE Model billing units.* The sum of the billing units identified as set forth in paragraph (a) of this section equal the total number of GLOBE Model billing units for the GLOBE Model drug for the rebate quarter.

§ 513.530 Manufacturer payment responsibilities.

(a) *General.* For the purposes of the GLOBE Model, a manufacturer is defined in accordance with 42 CFR 427.20, in that the manufacturer has the meaning set forth in section 1847A(c)(6)(A) of the Act for a GLOBE Model drug as set forth in § 513.130.

(b) *Multiple manufacturers linked to a single HCPCS Level II code.* CMS apportions the total GLOBE Model rebate liability proportionally, based on each manufacturer's reported share of Medicare Part B units in that rebate quarter in accordance with § 513.500(c).

Subpart G—Manufacturer-Submitted International Net Pricing Information**§ 513.600 Definitions.**

As used in this subpart, the following definitions apply:

Authorized representative means an individual, designated by a manufacturer, as responsible for submitting international drug net pricing data, and who is also responsible for managing all communications related to such submission on behalf of the manufacturer. The authorized representative must also be legally authorized to bind the manufacturer to the terms and conditions contained within the data agreement.

Applicable international analog means a non-US analog whose scientific or nonproprietary name, dosage form, and route of administration (if applicable) align with a GLOBE Model drug and that are sold in one or more reference countries during the applicable ASP calendar quarter, excluding those identified in their respective country as a generic or biosimilar biological product according to the country's own regulations.

Average net-to-gross ratio means for a reference country, the total net sales of the set of applicable international analogs in the reference country divided by the total gross sales of the same set of drugs in the same reference country.

Gross sales amount means for each sale the manufacturer made in that reference country to a purchaser, the amount of money owed to a manufacturer by the purchasers, before subtracting any discounts, rebates, or price concessions.

Non-U.S. country regulatory approval status means information relevant for CMS to determine whether each applicable international drug's regulatory approval status (according to the applicable reference country's regulatory framework) is an international generic (international non-originator drug), international biosimilar biological product (international non-originator drug), international originator drug, or other.

Net price level, with respect to sales of applicable international analogs, means all sales of the applicable international analogs in a reference country at the same price net of price concessions during the applicable ASP calendar quarter.

Net sales amount means for each sale the manufacturer made in that reference country to a purchaser, the amount of money owed by the purchaser exclusive of any price concessions. Each net sales

amount has a corresponding sales volume in HCPCS billing units.

Price concession means the sum of the value of the following types of transactions and items whether at the time of sale or afterwards:

(1) Volume discounts: "Volume discounts" are also known as quantity discounts or bulk discounts where the price per unit is reduced when purchased in larger quantities.

(2) Prompt pay discounts: The term "prompt pay discounts", also known as early payment discounts, means any reduction in the total value of units purchased routinely offered to a purchaser when a payment is made within a specified timeframe and consistent with customary business practices for payment.

(3) Cash discounts: The term "cash discounts" refers to reductions on the price per unit when payment is made in cash. This may be facilitated through discount cards, coupons, or other agreements.

(4) Free goods include samples or other benefits provided to purchasers or patients that are contingent on any purchase requirement.

(5) Chargebacks: This term refers to retrospective payments made from manufacturers to purchasers.

(6) Rebates: This term refers to reimbursements made by a manufacturer to a wholesaler or other purchaser, for the difference between the price the wholesaler or other purchaser initially paid for the product and the lower price at which the wholesaler or other purchaser sold the product.

(7) Other price concessions that lower the amount realized by the manufacturer.

Purchaser means the entities or organizations acquiring the drug product for subsequent sale within the pharmaceutical supply chain or for administration or dispensing to a human. It may include, among others, wholesalers, distributors, hospitals, pharmacies, and other healthcare providers and practitioners.

Volume-weighted net price means exclusive of any price concessions, the volume-weighted reference country average net price in U.S. dollars where the weights are volumes in HCPCS billing units.

§ 513.610 Submission and acceptance of international net pricing information.

(a) *General.*

(1) *Timing of submission.* The submission must be received by CMS no later than 30 calendar days after the end of the applicable ASP calendar quarter for which the manufacturer is making the submission.

(2) *Scope of submission.*

Manufacturers may make a submission for one or more GLOBE Model drug(s). For each GLOBE Model drug, the submission must include all applicable international analogs with sales in the reference countries identified in § 513.310 that occur during the applicable ASP calendar quarter for which they are making the submission. Manufacturers must ensure that any allocation and calculations are done in a manner consistent with the generally acceptable accounting principles (GAAP), international financial reporting standards (IFRS), or other internationally recognized accounting approaches.

(3) *Verification of manufacturer submissions.* CMS conducts a review of all submissions for completeness and validity, upon which CMS may request additional data or information before finalizing its review and making a determination of acceptability.

(i) *Completeness.* To be verified for completeness, the submission must include all basic data elements, including presentation level information, as described in paragraph (b) of this section and all net pricing data elements as described in paragraph (c) of this section, as well as fulfill the following requirements:

(A) Proper and full execution of the data agreement.

(B) Proper and full attestation by the manufacturer's authorized representative as described in paragraph (e) of this section.

(C) The submission was done using the proper portal and all security requirements within.

(D) The submission was executed in the manner and form required by CMS.

(E) The submission includes supporting documentation that explains how each of the elements of the submission were compiled or calculated and any reasonable assumptions that were applied.

(ii) *Validity.* CMS—

(A) Verifies the submitted international sales data and calculated pricing values are greater than zero and adhere to the data format requirements;

(B) Utilizes all available data sources and information to assess the extent to which the submission reflects international drug net pricing in the reference countries; and

(C) May choose to request additional supporting information or data or both from manufacturers before completing assessment of validity of the submission.

(1) Submission of additional supporting information or data or both is limited to no more than 5 days from

the agency's request for additional supporting information or data or both.
(2) [Reserved].

(4) *Applicable submission.* CMS will determine that a submission is an applicable submission only if the submission is both complete, has all the basic data elements under paragraph (b) of this section, has all of the net pricing data elements for one of the two options under paragraph (c) of this section, and is valid as determined by CMS in order for CMS to determine that it is an applicable submission.

(b) *Basic data elements required.*

(1) A submission must include all the following basic data elements, including presentation level information:

(i) GLOBE Model drug brand name, nonproprietary name, and HCPCS Level II code.

(ii) For every reference country where at least one applicable international analog was sold during the applicable ASP calendar quarter—

(A) Reference country name;

(B) For every applicable international analog sold in that country—

(1) Scientific or nonproprietary name;

(2) Brand name, all international drug names;

(3) Names of manufacturers, marketers, or licensees;

(4) Non-U.S. country regulatory approval status (international originator drug or international non-originator drug);

(5) Dosage form and route of administration (if applicable);

(6) Strength;

(7) Volume per item (for example, 10 ml in one vial);

(8) Package type (for example, syringe, vial, ampule, etc.);

(9) Number of items per package (for example, 10 vials in a package);

(10) HCPCS dosage (CMS published data which are the quantity of drug represented in one HCPCS billing unit); and

(11) Number of HCPCS billing units.

(i) HCPCS billings unit are calculated by dividing the quantity of drug in the package by the HCPCS dosage.

(ii) [Reserved.]

(2) If for any of the basic data elements, third-party individuals and organizations were relied upon to gather, analyze, or submit data, this must be specified for each element and the third-party individual or organization identified.

(c) *Net pricing data elements required.*

(1) A submission must exclude both the following:

(i) Sales for any international biosimilar biological products and international generic products and only

have sales data for international originator drugs.

(ii) International drug price data without both sales and volume data greater than zero.

(2) A submission must include net pricing elements in complete fulfillment of one of the following net pricing data submission options:

(i) *Streamlined option.*

(A) For every reference country where at least one applicable international analog was sold during the applicable ASP calendar quarter corresponding to the submission—

(1) For every sale involving an applicable international analog aggregated at the net price level—

(i) Gross sales amount in the reference country currency and U.S. dollars rounded to 5 decimal places;

(ii) Net sales amount in the reference country currency and U.S. dollars rounded to 5 decimal places; and

(iii) Sales volume—in HCPCS billing units.

(2) Average net-to-gross ratio rounded to 5 decimal places for each reference country;

(3) The exchange rate for currency conversion from the local currency of the reference country to U.S. dollars for the applicable ASP calendar quarter corresponding to the submission—

(i) Comes from one of these exchange rate data sources and is rounded to 3 decimal places: World Bank Atlas, IMF exchange rates data, Federal Reserve Bank foreign exchange rates, or exchange rates from country-specific sources;

(ii) If the exchange rate data source uses an exchange rate frequency of less than annual, then the exchange rate is an average of exchange rates of the chosen frequency for the applicable ASP calendar quarter during which international sales occurred; and

(iii) The manufacturer applies the same exchange rate calculated in paragraph (c)(1)(i)(A)(3)(ii) of this section to all net pricing data in a reference country for the applicable ASP calendar quarter.

(iv) The manufacturer reports which exchange rate was used.

(4) Volume-weighted net price in U.S. dollars rounded to 5 decimal places for each reference country; and

(5) GDP (PPP) adjustment published by CMS at the beginning of each applicable calendar quarter.

(B) Across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit in U.S. dollars rounded to 3 decimal places across all the reference countries.

(ii) *Limited option.*

(A) For every reference country where at least one applicable international

analog was sold during the applicable ASP calendar quarter corresponding to the submission—

(1) Total gross sales amount for each reference country in the reference country currency and U.S. dollars rounded to 5 decimal places;

(2) Total net sales amount for each reference country in the reference country currency and U.S. dollars rounded to 5 decimal places;

(3) Average net-to-gross ratio for each reference country;

(4) The exchange rate for currency conversion from the local currency of the reference country to U.S. dollars for the applicable ASP calendar quarter corresponding to the submission—

(i) Comes from one of these exchange rate data sources and is rounded to 3 decimal places: World Bank Atlas, IMF exchange rates data, Federal Reserve Bank foreign exchange rates, or exchange rates from country-specific sources;

(ii) If the exchange rate data source uses an exchange rate frequency of less than annual, then the exchange rate is an average of exchange rates of the chosen frequency for the applicable ASP calendar quarter during which international sales occurred; and

(iii) The manufacturer applies the same exchange rates calculated in paragraph (c)(1)(ii)(A)(3)(ii) of this section to all net pricing data in a reference country for the applicable ASP calendar quarter.

(iv) The manufacturer reports which exchange rate was used.

(5) Total sales volume—in HCPCS billing units—meaning the corresponding volume for the total net sales amount from paragraph (c)(1)(ii)(A)(1) of this section;

(6) Volume-weighted net price in U.S. dollars rounded to 5 decimal places for each reference country; and

(7) GDP (PPP) adjustment published by CMS at the beginning of each applicable calendar quarter.

(B) Across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit in U.S. dollars rounded to 3 decimal places.

(d) *Data integrity and quality assurance.* (1) *Corrections and restatements.* Submitting manufacturers may provide corrections and restatements of applicable submissions, provided such corrections and restatements are made in accordance with the requirements in paragraphs (a) through (c) of this section and are submitted within 30 calendar days of the submission deadline, or if responding to a CMS request, within 5 business days of such request.

(1) *Attestation requirements.* (i) Each submission must include an attestation by the authorized representative certifying the completeness and accuracy of the data submission on behalf of the manufacturer and any third-party entities relied upon for gathering, analyzing, or submitting the net pricing data elements.

(ii) The attestation requires the authorized representative to do all of the following:

(A) Provide contact information.

(B) Attest that the—

(1) Submission is accurate and complete to the best of the manufacturer's knowledge;

(2) Submission is prepared in full compliance with all requirements of this section; and

(3) Authorized representative has the authority to make such attestation on behalf of the manufacturer.

(e) *Confidentiality and data protections.* CMS maintains the confidentiality of information submitted under this section to the extent permitted by law and in accordance with applicable privacy and security requirements. Under an effectuated GLOBE Model data agreement, CMS would not disclose manufacturer-submitted international net pricing information in a form which discloses the identity of a specific manufacturer and their international net pricing and sales data except as CMS determines to be necessary to carry out § 513.210 and § 513.500 (Computation of GLOBE Model beneficiary coinsurance percentage, adjusted Medicare payment for GLOBE, and GLOBE Model rebate).

(f) *Submission platform and security requirements.* (1) The authorized representative must do all of the following:

(i) Gain access to the Health Plan Management System (HPMS).

(ii) Comply with all encryption and submission requirements established by CMS.

(iii) Submit using the appropriate system and in the manner and form as determined by CMS.

(2) CMS may designate a different CMS system for submission, if necessary.

§ 513.620 GLOBE Model data agreement.

(a) General.

(1) *Voluntary submission.*

Manufacturers may elect to voluntarily submit manufacturer's international drug net pricing data, henceforth the submission, to CMS in accordance with the data requirements of paragraphs (b) in this section.

(2) *Use of the applicable submission.* CMS uses applicable submissions,

determined in accordance to paragraph (b) in this section and § 513.610(b) and (c), to determine the per unit Method II GLOBE Model benchmark per § 513.420 for the applicable ASP calendar quarter corresponding to the submission.

(3) *Requirements for a voluntary submission option of net pricing data elements.* If a manufacturer elects to voluntarily submit manufacturer's international drug net pricing data, manufacturers—

(i) Select one submission option for net pricing data elements for all applicable international analogs to a GLOBE Model drug; and

(ii) Except where paragraph (a)(3)(iii) of this section applies, a manufacturer continues to submit manufacturer's voluntary international drug net pricing data for the duration of the GLOBE model so long as sales of applicable international analogs have occurred in the reference countries identified in 42 CFR 513.310(b) for the applicable ASP calendar quarter.

(iii) If a manufacturer chooses to no longer submit voluntary international net pricing data after the data agreement per paragraph (b) of this section is effective and CMS has determined sales of the applicable international analogs have occurred in the reference countries identified in 42 CFR 513.310(b) for the applicable ASP calendar quarter, CMS may terminate the data agreement. In accordance with paragraph (b) of this section, the manufacturer may also elect to terminate the data agreement.

(B) [Reserved.]

(b) *Data requirements.*

(1) *Data agreement.* Prior to the submission, the manufacturer must execute a data agreement with CMS that establishes the terms, conditions, and requirements related to the international drug net pricing data under this section. Once the data agreement is effective, it remains applicable for the duration of the GLOBE Model unless either the manufacturer or CMS terminates the agreement.

(2) [Reserved.]

Subpart H—Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments

§ 513.700 Definitions.

[Reserved]

§ 513.710 GLOBE Model Rebate Reports and reconciliation—Incremental Approach

(a) *General.* This section applies to GLOBE Model drugs, for all applicable calendar quarters during the model performance years.

(b) *GLOBE Model Preliminary Rebate Report.* CMS provides a GLOBE Model

Preliminary Rebate report to each manufacturer of a GLOBE Model drug at least 1 month prior to the issuance of the GLOBE Model Rebate Report as set forth in paragraph (c) of this section for an applicable calendar quarter.

(1) The GLOBE Model Preliminary Rebate Report for each GLOBE Model drug includes the following information:

(i) The NDC(s) and billing and payment codes identified for the GLOBE Model drug as determined by CMS.

(ii) The total number of GLOBE Model billing units as set forth under 42 CFR 513.520.

(iii) The total number of billing units as determined under 42 CFR 427.303.

(iv) The per unit Method I GLOBE Model benchmark as identified under 42 CFR 513.410.

(v) The per unit Method II GLOBE Model benchmark, if available, as identified under 42 CFR 513.420.

(vi) The per unit GLOBE Model benchmark amount as set forth in 42 CFR 513.400.

(vii) The per unit GLOBE Model rebate amount as set forth in 42 CFR 513.520.

(viii) The incremental per unit GLOBE Model rebate amount as set forth in 42 CFR 513.520.

(ix) The applicable calendar quarter specified amount as determined under 42 CFR 427.302(b).

(x) The amount, if any, by which the specified amount as determined under 42 CFR 427.302(b) exceeds the inflation-adjusted payment amount as determined under 42 CFR 427.302(g) for the Part B rebatable drug for the applicable calendar quarter as set forth in 42 CFR 427.302.

(xi) The total GLOBE Model rebate amount as set forth in 42 CFR 513.500.

(xii) The incremental GLOBE Model rebate amount due as determined in 42 CFR 513.500(b).

(xiii) Any applied reductions as determined under 42 CFR 513 subpart F.

(xiv) The proportion of manufacturer-reported ASP units, if applicable.

(xv) The reduced incremental GLOBE Model rebate amount, if applicable.

(c) *GLOBE Model Rebate Report.* CMS provides a GLOBE Model Rebate Report to each manufacturer of a GLOBE Model drug no later than 8 months after the end of each applicable calendar quarter during a performance year.

(1) The GLOBE Model Rebate Report includes the information specified in paragraph (b) of this section, with the inclusion of any revisions to such information resulting from CMS' review of a Suggestion of Error as set forth in 42 CFR 513.730, if applicable, and any

CMS-determined recalculations from paragraph (d)(2) of this section.

(2) The GLOBE Model Rebate Report is the invoice of a manufacturer's total rebate amount due as determined under 42 CFR 513.510, if any, for a GLOBE Model drug for an applicable calendar quarter.

(3) The manufacturer's total rebate amount due is reported as a dollar amount rounded to the nearest cent.

(d) *Reconciliation of the incremental GLOBE Model rebate amount.* CMS performs reconciliation of the incremental GLOBE Model rebate amount provided in a GLOBE Model Rebate Report specified in paragraph (c) of this section for an applicable calendar quarter during a model performance year in the following circumstances:

(1) *Regular reconciliation.* CMS performs one regular reconciliation of the incremental GLOBE Model rebate amount within 12 months of the date of receipt of the GLOBE Model Rebate Report for each applicable calendar quarter to include revisions to the information used to calculate the rebate amount set forth in paragraph (c)(1) of this section.

(i) *Preliminary reconciliation.* At least 1 month prior to the issuance of a report with the reconciled incremental GLOBE Model rebate amount for an applicable calendar quarter as set forth under paragraph (d)(1)(ii) of this section, CMS conducts a preliminary reconciliation of the incremental GLOBE Model rebate amount for an applicable calendar quarter based on the information set forth in this paragraph (b)(1)(i) through (xiii) of this section and provide the information via a Preliminary GLOBE Model Reconciliation Rebate Report set forth in paragraphs (b)(1) and paragraphs (d)(1)(i)(A) through (K) of this section to the manufacturer of a GLOBE Model drug for the applicable calendar quarter, if applicable:

(A) Updated total number of GLOBE Model billing units attributed to GLOBE Model beneficiaries, as determined under 42 CFR 513.520.

(B) Updated per unit Method I GLOBE Model benchmark amount as determined under 42 CFR 513.410 if any inputs are restated within the reconciliation run-out period.

(C) Updated per unit Method II GLOBE Model benchmark amount, if any, as determined under 42 CFR 513.420 if any inputs are restated within the reconciliation run-out period.

(D) Updated per unit GLOBE Model rebate amount, if any, as set forth in 42 CFR 513.510 if any inputs are restated within the reconciliation run-out period.

(E) Applicable calendar quarter specified amount as determined under 42 CFR 427.302(b), if any inputs are restated within the reconciliation run-out period.

(F) The amount by which the specified amount as determined under 42 CFR 427.302(b) exceeds the inflation-adjusted payment amount as determined under 42 CFR 427.302(g), if any inputs are restated in the reconciliation run-out period.

(G) Reconciled total GLOBE Model rebate amount as set forth in 42 CFR 513.500, if any inputs are restated within the reconciliation run-out period.

(H) Reconciled incremental GLOBE Model rebate amount due as set forth in 42 CFR 513.500(b), if any inputs are restated within the reconciliation run-out period.

(I) Reconciled reduced incremental GLOBE Model rebate amount, if applicable.

(J) The difference between the incremental GLOBE rebate amount due as specified on the GLOBE Model Rebate Report set forth in paragraph (c) of this section and the reconciled incremental GLOBE Model rebate amount as set forth in paragraph (d)(1)(i)(I) of this section.

(ii) *GLOBE Model Reconciliation Rebate Report.* With the inclusion of any additional revisions to such information resulting from CMS' review of a Suggestion of Error as set forth in 42 CFR 513.720, if applicable, a report with the reconciled incremental GLOBE Model rebate amount is provided to each manufacturer of a GLOBE Model drug within 12 months after the issuance of the GLOBE Model Rebate Report described in paragraph (c) of this section.

(2) *CMS identification of error and manufacturer misreporting.* CMS may recalculate an incremental GLOBE Model rebate amount and provide the manufacturer of a Part B rebatable drug a GLOBE Model Reconciliation Rebate Report when—

(i) CMS identifies an agency error in the information specified in paragraphs (c) and (d)(1) of this section, including reporting system or coding errors, not later than 3 years from the date of receipt by a manufacturer of a reconciled incremental GLOBE Model rebate amount for the applicable calendar quarter; or

(ii) CMS determines at any time that the information used by CMS to calculate the incremental GLOBE Model rebate amount was inaccurate due to manufacturer misreporting.

(3) *Impact of reconciliation on the incremental GLOBE Model rebate*

amount. A reconciliation as set forth in this paragraph (d) could result in an increase, decrease, or no change to the total GLOBE Model rebate amount, as determined under 42 CFR 513.500, owed by a manufacturer for the applicable calendar quarter for the GLOBE Model drug compared to the amount described in the GLOBE Model Rebate Report described in paragraph (c) of this section or an amount described in a previous reconciliation.

(i) A GLOBE Model Reconciliation Rebate Report that is an increase to the incremental GLOBE Model rebate amount is the invoice for such additional amount due on the manufacturer's incremental GLOBE Model amount as determined under 42 CFR 513.500 for a GLOBE Model drug for an applicable calendar quarter.

(ii) [Reserved]

§ 513.720 Suggestion of error.

(a) *General.* The manufacturer of a GLOBE Model drug may submit a Suggestion of Error about the information in their GLOBE Model Preliminary Rebate Reports and the report detailing the preliminary reconciliation of the incremental GLOBE Model rebate amount to CMS, for its discretionary consideration, if the manufacturer believes that there is a mathematical error or errors to be corrected before the GLOBE Model Rebate Report, or a subsequent reconciliation of the incremental GLOBE Model rebate amount, as applicable, is finalized.

(1) Administrative and judicial review is precluded consistent with section 1847A(i)(8) and section 1115A(d)(2) of the Act.

(b) *Process of submission.* Subject to the scope and timing requirements specified in paragraphs (a) and (c) of this section, manufacturers may submit the Suggestion of Error and provide supporting documentation (if applicable) as directed by CMS.

(c) *Timing.* A manufacturer must submit its Suggestion of Error for the applicable calendar quarter within 10 calendar days from the date of receipt of a GLOBE Model Preliminary Rebate Report or a preliminary reconciliation of a total GLOBE Model rebate amount using the method and process established by CMS in paragraph (b) of this section.

(d) *Notice.* (1) CMS includes any revisions to the calculation of the total GLOBE Model rebate amount, if determined necessary by CMS based on the Suggestion of Error submitted under this section prior to issuance of the GLOBE Model Rebate Report as set forth in 42 CFR 513.720 as well as any report

of a reconciled GLOBE Model rebate amount or rebate amount as set forth in 42 CFR 513.720.

(2) CMS notifies the manufacturer whether CMS revised its calculation of the GLOBE Model rebate amount based on the Suggestion of Error.

§ 513.730 Manufacturer access to GLOBE Model rebate reports.

(a) *General.* CMS establishes a method and process for a manufacturer of a GLOBE Model drug to do all of the following:

(1) Access the manufacturer's rebate reports as set forth in 42 CFR 513.710, including any report of reconciled rebate amount.

(2) Submit a suggestion of error as set forth in 42 CFR 513.720.

(3) Pay an incremental GLOBE Model rebate amount due.

§ 513.740 Deadline and process for payment of rebate amount.

(a) *Rebate amounts owed by a manufacturer.* For an incremental GLOBE Model rebate amount owed by a manufacturer, payment is due no later than 11:59 p.m. Pacific Time (PT) on the 30th calendar day after the date of receipt of information regarding the rebate amount on—

(1) A GLOBE Model Rebate Report as set forth in 42 CFR 513.710; or

(2) A report of a reconciled incremental GLOBE Model rebate amount as set forth in 42 CFR 513.710(d).

(b) *Failure to pay an incremental GLOBE Model rebate amount.* Failure to pay an incremental GLOBE Model rebate amount due timely and in full may result in an enforcement action as described in subpart I of this part.

(c) *Refund to the manufacturer.* If a reconciled incremental GLOBE Model rebate amount for an applicable calendar quarter as set forth in 42 CFR 513.710(d) is less than what the manufacturer paid for that applicable calendar quarter, CMS will initiate the process to provide a refund equal to the excess amount paid within 60 days of the date of receipt of the report with such reconciled incremental GLOBE Model rebate amount.

Subpart I—Enforcement of Manufacturer Payment of GLOBE Model Rebate Amounts

§ 513.800 Civil money penalty notice and appeals procedures.

(a) *General.* Under section 1847A(i)(7) of the Act and section 1128A of the Act as applicable, CMS may impose a civil money penalty on a manufacturer that fails to pay the incremental GLOBE model rebate amount as set forth in 42

CFR 513.500 by the payment deadline as set forth in 42 CFR 513.740(a) for such GLOBE Model drug for such applicable calendar quarter.

(b) *Determination of the civil money penalty amount.* CMS may impose a civil money penalty for each failure by a manufacturer to pay the incremental GLOBE Model rebate amount; the civil money penalty amount is an adjusted GLOBE Model rebate amount equal to 125 percent of the incremental GLOBE Model rebate amount determined in 42 CFR 513.500.

(1) The civil money penalty is in addition to the incremental GLOBE Model rebate amount due.

(2) If a reconciled rebate amount as set forth in 42 CFR 513.720 results in an increase to the incremental GLOBE model rebate amount due, a separate civil money penalty may be imposed for the failure by a manufacturer to provide a total GLOBE Model rebate amount for the applicable calendar quarter for the increase to the incremental GLOBE rebate amount due.

(c) *Notice of imposition of civil money penalties.* If CMS makes a determination to impose a civil money penalty described in paragraph (b) of this section, CMS will send a written notice of its decision to impose a civil money penalty that includes the following:

(1) A description of the basis for the determination.

(2) The basis for the penalty.

(3) The amount of the penalty.

(4) The date the penalty is due.

(5) The manufacturer's right to a hearing as specified in paragraph (e) of this section.

(6) Information about where to file the request for a hearing.

(d) *Collection.*

(1) Subject to paragraph (d)(2) of this section, a manufacturer must pay the civil money penalty in full within 60 calendar days after the date of the notice of imposition of a civil money penalty from CMS under paragraph (c) of this section.

(2) In the event a manufacturer requests a hearing, in accordance with 42 CFR part 423 subpart T, the manufacturer must pay the amount in full within 60 calendar days after the date of a final decision by the Departmental Appeal Board, to uphold, in whole or in part, the civil money penalty.

(3) If the 60th calendar day described in paragraphs (d)(1) and (2) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(e) *Appeal procedures for civil money penalties.* Section 1128A(c)(2) of the Act provides that CMS may not collect a

civil money penalty until the affected party has had notice and the opportunity for a hearing.

(1) Manufacturers may appeal the following determinations:

(i) A CMS determination that the incremental GLOBE Model rebate amount due was not paid by the applicable payment deadline as set forth in 42 CFR 513.740.

(ii) The calculation of the amount of the civil money penalty.

(2) If CMS decides to impose a civil money penalty, CMS will provide the manufacturer with a notice in accordance with the process set forth in paragraph (c) of this section.

(3) A manufacturer has a right to a hearing following a decision by CMS to impose a civil money penalty following the administrative appeal process and procedures established in 1128A of the Act.

(f) *Bankruptcy.* In the event that a manufacturer declares bankruptcy, as described in Title 11 of the United States Code, and as a result of the bankruptcy, fails to provide either the total GLOBE Model rebate amount owed or the total sum of civil money penalties imposed, the Government reserves the right to file a proof of claim with the bankruptcy court to recover the unpaid amount of the rebates and civil money penalties owed by the manufacturer.

Subpart J—Quality Strategy, Beneficiary Protections, and Compliance Activities

§ 513.900 Quality measures.

(a) *General.* Quality measures do not adjust GLOBE Model rebates, GLOBE Model beneficiary coinsurance percentages, or Medicare payments for GLOBE Model drugs and are used for monitoring purposes.

(b) *Collection of quality measures.* (1) CMS uses existing data sources to the extent available.

(2) If CMS determines it is necessary, new surveys to a sample of manufacturers, providers and suppliers, and beneficiaries who receive a GLOBE Model drug may be conducted. A sample of non-GLOBE Model beneficiaries may also be surveyed.

§ 513.910 Beneficiary protections.

In a form and manner specified by CMS, CMS will establish procedures for collecting complaints from beneficiaries and providers about difficulties obtaining specific drugs during the GLOBE Model performance period.

Subpart K—Waivers**§ 513.1000 Waivers of Medicare program requirements for purposes of testing the GLOBE Model.**

CMS waives the Medicare program requirements in the following provisions that are necessary solely for purposes of testing the GLOBE Model:

(a) Section 1847A(i)(3) of the Act and §§ 427.302 and 427.301 of this chapter as related to calculation of rebate amounts as necessary to permit testing of an alternative rebate calculation and

coinsurance adjustment for certain units of GLOBE Model drugs.

(b) Section 1847A(i)(1) of the Act as related to the invoicing timing requirements as necessary to permit testing of an alternative invoicing procedure for GLOBE Model rebate amounts.

(c) Sections 1833(a)(1), 1833(a)(1)(S), 1833(a)(1)(EE), and 1833(t) of the Act and §§ 410.152(m), 419.41(e), 489.30(b)(1), and 489.30(b)(6) of this chapter related to beneficiary

coinsurance and the Medicare payment portion of the allowed payment amount as necessary to permit testing of an alternative beneficiary coinsurance adjustment and adjusted payment to providers of certain units of GLOBE Model drugs.

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 Part 514

Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model;
Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 514

[CMS–5546–P]

RIN 0938–AV74

Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model to test a new Medicare payment model under section 1115A of the Social Security Act. The model proposes a test of an alternative payment method for calculating inflation rebates for certain Part D drugs and biological products. The proposed GUARD Model would test whether changing the calculation of the Part D inflation rebate would reduce costs for the Medicare program while preserving or enhancing quality of care for Part D enrollees.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by February 23, 2026.

ADDRESSES: In commenting, please refer to file code CMS–5546–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–5546–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 to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5546–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:

Vinod Mitta, 667–290–8712 or GUARDmodel@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

Information Included with Pic Comments: We encourage commenters to include supporting facts, research, and evidence in their comments. When doing so, commenters are encouraged to provide citations to the published materials referenced, including active hyperlinks. Likewise, commenters who reference materials which have not been published are encouraged to upload relevant data collection instruments, data sets, and detailed findings as a part of their comment. Providing such citations and documentation will assist us in analyzing the comments.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments. The Centers for Medicare & Medicaid Services (CMS) will not post on [Regulations.gov](http://www.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/>.

I. Executive Summary

A. Background

Challenges related to the affordability of prescription drugs adversely affect taxpayers by diverting funds that could be used to improve health; such challenges also pose a direct concern for patients, with 55 percent of adults reporting that they remain concerned about medication affordability.^{1 2} High

drug costs limit access to care and treatment, which in turn, can have cascading consequences that lead to poor health for patients, increased medical spending, and potentially avoidable expenditures for all payers, including Medicare.³ Results from recent surveys show that many Americans, including Medicare beneficiaries, face significant financial burden of care that has resulted in skipping or rationing medication due to cost.⁴

Financial toxicity, or the negative impact that the monetary burden of medical care can have on patients’ well-being, fiscal security, and overall health,⁵ can be pronounced among the elderly population, most of whom are covered by Medicare, and among patients where the cost of treatment is high.⁶ One in four adults taking prescription drugs report difficulty affording their medication, including 40 percent of those with household income of less than \$40,000 per year.⁷ A separate survey conducted concluded that about four in 10 older adults with Medicare reported problems accessing health care because of its costs, and that 14 percent of Medicare beneficiaries said they skipped taking or sometimes did not fill their prescription because of the expense; this can have serious health-related consequences for Medicare beneficiaries and may result in potentially avoidable costs for Medicare.⁸

Patients and Providers. The Commonwealth Fund. <https://www.commonwealthfund.org/publications/issue-briefs/2025/feb/drug-costs-impact-care-insights-medicare-patients-providers> (Accessed: 10 December 2025).

³ Nekui, F., et al. (2021). Cost-related Medication Nonadherence and Its Risk Factors Among Medicare Beneficiaries. *Medical Care*, 59(1):13–21. <https://doi.org/10.1097/MLR.0000000000001458>.

⁴ Arnold Ventures, Commonwealth Fund, & PerryUndem. (2025). *Drug Costs and Their Impact on Care*. <https://www.arnoldventures.org/stories/drug-costs-and-their-impact-on-care> (Accessed: 10 December 2025).

⁵ Arastu A., et al. (2020). Assessment of Financial Toxicity Among Older Adults with Advanced Cancer. *JAMA Network Open*, 3(12):e2025810. <https://doi.org/10.1001/jamanetworkopen.2020.25810>.

⁶ Narang, A.K. & Nicholas, L.H. (2016). Out-of-Pocket Spending and Financial Burden Among Medicare Beneficiaries with Cancer. *JAMA Oncology*, 3(6), 757. <https://doi.org/10.1001/jamaoncol.2016.4865>.

⁷ Sparks, G., et al. (2024). *Public Opinion on Prescription Drugs and Their Prices*. KFF. <https://www.kff.org/health-costs/public-opinion-on-prescription-drugs-and-their-prices/> (Accessed: 10 December 2025).

⁸ Leonard, F., et al. (2023). *Medicare’s Affordability Problem: A Look at the Cost Burdens Faced by Older Enrollees*. The Commonwealth Fund. <https://www.commonwealthfund.org/publications/issue-briefs/2023/sep/medicare-affordability-problem-cost-burdens-biennial> (Accessed: 10 December 2025).

¹ Sparks, G., et al. (2024). *Public Opinion on Prescription Drugs and Their Prices*. KFF. <https://www.kff.org/health-costs/public-opinion-on-prescription-drugs-and-their-prices/> (Accessed: 10 December 2025).

² Jones, E. & Noda, A. (2025). *Drug Costs and Their Impact on Care: Insights from Medicare*

Medicare Part D prescription drug costs have been rising over time, with total Part D gross drug spending increasing from \$121 billion in 2014 to \$276 billion in 2023, an increase of over 100 percent, as reported by the Medicare Payment Advisory Commission (MedPAC).⁹ This translates to an approximately 66 percent increase in average gross spending for each beneficiary who used Part D drugs over that same period (\$3,267 in 2014 to \$5,429 in 2023).¹⁰ The increase in Part D gross drug spending is consistent with overall trends in U.S. drug spending. A recent analysis shows that drug spending in the United States increased from \$600 billion in 2018 to \$858 billion in 2023 for all drugs (a 43 percent increase), regardless of payer source.¹¹ Retail prescription drug prices are expected to continue to increase over time, driven by a number of factors, including increases in the use of prescription drugs as well as increases in drug prices over time.¹²

Existing research finds that the prices of drugs sold in the United States are much higher than the prices of the same drugs sold in other countries. One study finds that overall, the U.S. health care system spends substantially more on outpatient drugs for older adults with complex conditions, such as heart failure, diabetes, and chronic obstructive pulmonary disease (COPD), who are mostly covered by Medicare, than 11 other economically similar countries (including, for example, Australia, France, Germany, Canada, and the United Kingdom).¹³ The authors conclude that the United States is paying substantially higher prices for certain components of health care, including for drugs, than other countries.¹⁴ Another study finds that

prices for certain high expenditure single-source brand name prescription drugs covered under Medicare Part D in 2018 were 3 to 4 times higher in the United States, even after accounting for estimated manufacturer rebate amounts, compared to their prices in the United Kingdom, Japan, and Canada.¹⁵ Among these countries, Japan and Canada use international reference pricing to help determine drug prices within the country.¹⁶ Analyses by IQVIA show that per capita utilization of drugs is higher in certain regions and countries, specifically, in Western European countries and Japan, compared to North American countries, suggesting that utilization differences alone are not the drivers of the observed price differences.¹⁷ The data also shows that U.S. brand-name prescription drug prices exceed those found in other Organization for Economic Co-operation and Development (OECD) countries.^{18 19}

The disparity between U.S. drug prices and prices in other economically comparable countries may have several drivers, but a key component is the substantial difference in the way prescription drug prices are determined in the United States and other economically comparable countries. Although there is wide variation in the way drug prices are determined in economically comparable countries, in general, many countries take a more centralized approach to drug pricing and/or have greater involvement in

determining prices for drugs than the United States.²⁰

In the United States, prices are set by drug manufacturers for the U.S. market and the incentives and payment mechanisms embedded within the U.S. pharmaceutical drug supply chain are complex. Drug manufacturers set a Wholesale Acquisition Cost (WAC), which is the published catalog or “list price” for a drug product; this represents the amount at which wholesalers are offered the drug product.²¹ The manufacturer list price is not the ultimate net revenue realized by the manufacturer as there are multiple discounts and price concessions to stakeholders throughout the pharmaceutical drug supply chain; however, it may have influence throughout the pharmaceutical drug supply chain. Existing research shows that the list price of new brand-name drugs at launch have been increasing over time, with one study finding that from 2008 to 2021, the mean launch price increased by 13 percent per year; this increase was 11 percent per year for a subset of drugs for which the researchers were able to account for manufacturer rebates and drug characteristics.²²

There are many factors that affect the amount that is ultimately paid by stakeholders for a pharmaceutical drug after discounts, rebates, and other price concessions are excluded (referred to as the ‘net price’), including the degree to which the drug is subject to market competition. In general (though there may be exceptions), drugs that face more limited competition have higher net prices than drugs that have greater market competition.^{23 24 25} Among drugs

Health Services Research, 56(S3), 1317–1334. <https://doi.org/10.1111/1475-6773.13708>.

¹⁵ Kang, S., et al. (2019). Using External Reference Pricing in Medicare Part D to Reduce Drug Price Differentials with Other Countries. *Health Affairs*, 38(5), 804–811. <https://doi.org/10.1377/hlthaff.2018.05207>.

¹⁶ Kang, S., et al. (2019). Using External Reference Pricing in Medicare Part D to Reduce Drug Price Differentials with Other Countries. *Health Affairs*, 38(5), 804–811. <https://doi.org/10.1377/hlthaff.2018.05207>.

¹⁷ IQVIA. (2025). *The Global Use of Medicines 2025: Outlook to 2029—Global Webinar*. https://www.iqvia.com/-/media/iqvia/pdfs/events/presentation_global-meds-webinar_public.pdf (Accessed: 10 December 2025).

¹⁸ Mulcahy, A.W., et al. (2024). *International Prescription Drug Price Comparisons: Estimates Using 2022 Data*. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. <https://aspe.hhs.gov/sites/default/files/documents/277371265a705c356c968977e87446ae/international-price-comparisons.pdf> (Accessed: 10 December 2025).

¹⁹ The Organization for Economic Cooperation and Development (OECD) is a multilateral organization with 38 member countries. Comparing the United States to other OECD countries that are similar in economy, based on GDP and GDP per capita, allows for a more appropriate comparison.—*About the OECD, U.S. Mission to the Organization for Economic Co-operation and Development*, Available at <https://usoe.cd.usmission.gov/about-the-oecd/>.

²⁰ Syversen, I.D., et al. (2024). A Comparative Analysis of International Drug Price Negotiation Frameworks: An interview study of key stakeholders. *Milbank Quarterly*, 102(4), 1004–1031. <https://doi.org/10.1111/1468-0009.12714>.

²¹ Mulcahy, A.W. & Kareddy, V. (2021). *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships*. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. <https://aspe.hhs.gov/reports/prescription-drug-supply-chains> (Accessed: 10 December 2025).

²² Rome, B.N., et al. (2022). Trends in Prescription Drug Launch Prices, 2008–2021. *JAMA*, 327(21), 2145. <https://doi.org/10.1001/jama.2022.5542>.

²³ Government Accountability Office. (2023). *Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending* [GAO–23–105270]. <https://www.gao.gov/assets/gao-23-105270.pdf> (Accessed: 10 December 2025).

²⁴ Hernandez, I., et al. (2020). Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007–2018. *JAMA*, 323(9), 854. <https://doi.org/10.1001/jama.2020.1012>.

²⁵ Mulcahy, A.W., et al. (2024). *Prescription Drug Prices, Rebates, and Insurance Premiums*. RAND.

Continued

⁹ MedPAC. (2025). *Health Care Spending and the Medicare Program*. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf (Accessed: 10 December 2025).

¹⁰ MedPAC. (2025). *Health Care Spending and the Medicare Program*. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf (Accessed: 10 December 2025).

¹¹ IQVIA. (2023). *The use of medicines in the U.S. 2023*. <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2023> (Accessed: 10 December 2025).

¹² Poisal, J.A., et al. (2022). National Health Expenditure Projections, 2021–30: Growth to Moderate as COVID–19 Impacts Wane. *Health Affairs*, 41(4), 474–486. <https://doi.org/10.1377/hlthaff.2022.00113>.

¹³ Figueroa, J.F., et al. (2021). International Comparison of Health Spending and Utilization Among People with Complex Multimorbidity. *Health Services Research*, 56(S3), 1317–1334. <https://doi.org/10.1111/1475-6773.13708>.

¹⁴ Figueroa, J.F., et al. (2021). International Comparison of Health Spending and Utilization Among People with Complex Multimorbidity.

with competing therapies available, drug manufacturers have a particular incentive to compete against each other for formulary coverage by negotiating rebates with plan sponsors or their pharmacy benefit managers (PBMs). Within Part D, this generally includes drugs that are *not* in protected classes. (Centers for Medicare & Medicaid Services (CMS) protected classes are drugs for which Part D sponsors must include all or substantially all drugs within the classes on their formularies, which means that manufacturers do not have the same incentives to negotiate rebates or other price concession for these drugs.)²⁶ Ultimately, the negotiated rebates and other price concessions result in a “net” price (that is, list price net of rebates and other price concessions) for the drug that is lower than the list price.²⁷ Under the Part D program, this post point-of-sale compensation is included in Direct and Indirect Remuneration (DIR)²⁸ and is factored into CMS’s calculation of final Medicare payments to Part D plans.²⁹ This, in turn, impacts Medicare costs under the Medicare Prescription Drug Benefit program, also known as Part D, which was created under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173, 117 Stat. 2066).³⁰

Under the Part D program, drug price negotiations take place between Part D plan sponsors (or their PBMs) and

pharmaceutical manufacturers. Until recently, the federal government has not been a participant in the negotiations for drug prices.³¹ The Medicare program does not currently use international reference pricing, which broadly refers to the practice of taking pharmaceutical pricing data from other economically comparable countries into account in identifying domestic prices for drugs.³² The Inflation Reduction Act of 2022 (IRA), Public Law 117–169, included a series of provisions, including the Medicare Drug Price Negotiation Program, which authorizes the Secretary of the Department of Health and Human Services (HHS) (hereafter, “the Secretary”) to negotiate the prices of certain qualifying high expenditure single source drugs without generic or biosimilar competition with manufacturers; however, the Medicare Drug Price Negotiation Program does not consider the prices of drugs in other economically similar countries³³ in negotiating the maximum fair price (MFP).

B. Purpose

The prices of certain prescription drugs in the United States, including those covered under Part D, remain high, which contributes to increased costs under Part D. To address high spending under Part D, CMS proposes the testing of a new mandatory model under section 1115A of the Social Security Act (the Act), which authorizes the CMS’ Center for Medicare and Medicaid Innovation (hereafter, “the CMS Innovation Center”) to test innovative payment and service delivery models for the purpose of evaluating whether they will reduce Medicare, Medicaid, and Children’s Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of such programs. The IRA included the Part D Inflation Rebate Program, which requires drug manufacturers to pay a rebate if they

raise their prices for certain drugs faster than the rate of inflation. This rebate is paid to the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund and is calculated and invoiced by CMS. The CMS Innovation Center, under its statutory authority, is proposing an innovative payment model that would test an alternative approach to the IRA’s Part D Inflation Rebate Program that would change the calculation of the Part D drug inflation rebates for certain Part D drugs and biological products for the purpose of evaluating whether this approach would reduce program expenditures while maintaining or enhancing quality of care for beneficiaries. CMS proposes that the model’s period of performance would begin on January 1, 2027 and end on December 31, 2033 and the payment period for the model would begin on January 1, 2027 and end on December 31, 2035.

C. Summary of Major Provisions

The proposed Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model would test changes to the Part D Inflation Rebate Program, specifically testing whether an alternative calculation for the Part D inflation rebate calculation for certain drugs and biological products would reduce program spending for Medicare and taxpayers while preserving or enhancing the quality of care furnished to Medicare beneficiaries. The proposed model includes the following major provisions:

- The GUARD Model would include a subset of Part D rebateable drugs that are included in the Part D Inflation Rebate Program. Specifically, the GUARD Model would include sole-source drugs and sole-source biological products that are in the following specific therapeutic categories: Analgesics; Anticonvulsants; Antidepressants; Antimigraine Agents; Antineoplastics; Antipsychotics; Antivirals; Bipolar Agents; Blood Glucose Regulators; Cardiovascular Agents; Central Nervous System Agents; Gastrointestinal Agents; Genetic or Enzyme or Protein Disorder; Replacement or Modifiers or Treatment; Immunological Agents; Metabolic Bone Disease Agents; Ophthalmic Agents; and Respiratory Tract/Pulmonary Agents. The GUARD Model would exclude: (1) generics and biosimilar biological products; (2) sole-source drugs or sole-source biological products with annual application-level³⁴ total gross covered

https://www.rand.org/pubs/research_reports/RR1820-3.html (Accessed: 10 December 2025).

²⁶ See section 1860D–4(b)(3)(G) of the Social Security Act. The six protected classes are: immunosuppressant, (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic. See also, *Medicare Prescription Drug Benefit Manual Chapter 6—Part D Drugs and Formulary Requirements, Centers for Medicare & Medicaid Services* (January 15, 2016) at § 30.2.5, available at <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf> (Last accessed September 24, 2025).

²⁷ Mulcahy, A.W. & Karedy, V. (2021). *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships*. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. <https://aspe.hhs.gov/reports/prescription-drug-supply-chains> (Accessed: 10 December 2025).

²⁸ Fees, payments, or payment adjustments made after the point-of-sale that change the cost of Part D covered drugs for Part D sponsors or PBMs must be reported to CMS as Direct or Indirect Remuneration (DIR).

²⁹ Centers for Medicare & Medicaid Services. (2017). *Medicare Part D—Direct and Indirect Remuneration (DIR)*. U.S. Department of Health and Human Services. <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir> (Accessed: 10 December 2025).

³⁰ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, 117 Stat. 2066 (2003). <https://www.congress.gov/108/plaws/publ173/PLAW-108publ173.pdf> (Accessed: 10 December 2025).

³¹ The exception to this is drugs that are selected for the Medicare Drug Price Negotiation Program, implemented by the Inflation Reduction Act, which authorizes Medicare to directly negotiate drug prices for certain high expenditure, single source Medicare Part B or Part D drugs.

³² Tordrup, D., et al. (2020). *Systematic Reviews for the Update of the WHO Guideline on Country Pharmaceutical Pricing Policies*. World Health Organization (WHO). https://www.ncbi.nlm.nih.gov/books/NBK570141/pdf/Bookshelf_NBK570141.pdf (Accessed: 10 December 2025).

³³ Inflation Reduction Act of 2022, Public Law 117–169, 136 Stat 1818. The IRA is codified in multiple titles of the U.S. Code. The relevant sections of the Medicare Drug Price Negotiation Program are found at 42 U.S.C. 1320f–1 through 1320f–7.

³⁴ Application-level refers to the New Drug Application (NDA) or Biologics License application

drug costs below the GUARD minimum spend threshold; and (3) drugs that are subject to a negotiated MFP, during the price applicability period.

- Manufacturers of Part D rebatable drugs, as defined in section 1927(k)(5) of the Act and 42 CFR 428.20, that receive a Part D inflation rebate report that includes a GUARD Model drug during an applicable period that overlaps with the GUARD Model performance period would be required to participate in the GUARD Model.

- The GUARD Model would select reference countries that are economically comparable to the United States by implementing the following criteria: the country must be included as an OECD country; must have a minimum of 60 percent of the United States's purchasing power parity (PPP)-adjusted per capita gross domestic product (GDP), and must have a minimum \$400 billion (PPP)-adjusted aggregate GDP. The reference countries that meet these criteria and are therefore proposed to be selected for the model are the following: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, France, Germany, Ireland, Israel, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom.

- CMS proposes to test two approaches to calculating the GUARD Model international benchmark: the default international benchmark (also referred to as Method I) and the updated international benchmark (also referred to as Method II).

- For each GUARD Model drug for which data on international drug pricing in reference countries is available, CMS would calculate the GUARD Model default international benchmark. The GUARD Model default international benchmark for each GUARD Model drug would be identified as the lowest country-level average price among the set of average prices for each reference country, adjusted by the country-specific GDP based on PPP (hereafter, "GDP (PPP)") adjuster, where an international product that is part of

a GUARD Model drug's set of international analogs is sold.³⁵ ³⁶

- CMS would provide manufacturers with the option to submit international drug net pricing ³⁷ data for the set of reference countries where international products that are part of a GUARD Model drug's set of international analogs are sold, including the across-country average net price. This submitted across-country average net price accounts for country-specific differences using a GDP (PPP) adjuster; if the data submitted is determined to be an applicable submission, it would become the GUARD Model updated international benchmark.

- CMS would determine a GUARD Model applicable international benchmark for each GUARD Model drug that would be the greater of the GUARD Model default international benchmark and the GUARD Model updated international benchmark, unless there is only a GUARD Model default international benchmark. If there is only a GUARD Model default international benchmark, it would become the GUARD Model applicable international benchmark.

- CMS would use this information to test an alternative inflation rebate payment calculation to determine whether manufacturers owe a GUARD Model rebate payment. The alternative inflation rebate calculation tested under the GUARD Model would compare a Medicare net price against the GUARD Model applicable international benchmark.

- The GUARD Model would require manufacturers to pay a GUARD Model rebate payment if the Medicare net price is greater than the GUARD Model

³⁵ To be a part of the set of international analogs, an international product must have an active ingredient, route of administration, dosage form, and strength that aligns with that of the GUARD Model drug.

³⁶ Individual countries differ in the regulatory processes and standards governing approval of drugs and biological products. Use of international drug prices in the proposed GUARD Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved and non-U.S.-approved products.

³⁷ Where net pricing refers to drug prices exclusive of any discounts, rebates, or price concessions offered by manufacturers.

applicable international benchmark for a GUARD Model drug. The Medicare net price would be calculated by subtracting manufacturer rebates (obtained from DIR) and discounts (under the Manufacturer Discount Program) from the WAC of the GUARD Model drug.

- The total GUARD Model rebate amount would be equal to the product of the per unit GUARD Model rebate amount for a GUARD Model drug for the performance year and the total number of units of the GUARD Model drug dispensed under Part D and covered by Part D plan sponsors in the GUARD Model geographic areas for the performance year.

- When the per unit GUARD Model rebate exceeds the per unit Part D inflation rebate amount, CMS would waive the rebate amount described in section 1860D–14B(b) of the Act and instead apply the GUARD Model rebate amount. The GUARD Model rebate payment would be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

- The GUARD Model evaluation would examine the main outcome, Medicare net spending, as well as additional outcomes of the GUARD Model, including the ways in which Part D plan benefits may change for GUARD Model drugs and whether and to what extent there are impacts on beneficiary cost sharing for GUARD Model drugs.

We also propose to waive program requirements that are necessary solely for the purposes of testing the GUARD Model. We propose to issue these waivers using our waiver authority under section 1115A(d)(1) of the Act. Specifically, we propose to waive the provisions in section 1860D–14B(b)(1) of the Act, which are the Medicare Part D inflation rebate calculation provisions; and, we propose to waive the provisions in section 1860D–14B(a)(1) of the Act, which describes the timing requirements for manufacturer rebates reports issued by CMS. Each of the proposed waivers is discussed in detail in section IV.R. this proposed rule.

D. Summary of Costs and Benefits

(BLA) associated with each GUARD Model drug. This means the total gross covered prescription drug costs for all Part D rebatable NDC–9s associated with the same application (NDA or BLA) as the GUARD Model drug.

Provisions	Brief Description	Financial Impact
All of the GUARD Model provisions presented in this proposed rule.	As defined in detail throughout this proposed rule, the GUARD Model tests, for a specific subset of Part D rebatable drugs and biologic products, specific geographic locations, and specific Medicare Part D beneficiaries, the effects of replacing the Part D inflation rebate calculation with an alternative rebate calculation that takes into account international prices in economically comparable countries. CMS aims to understand whether the alternative payment calculation tested under the GUARD Model will reduce Medicare spending while preserving or enhancing beneficiary quality of care.	Over the 2028-2033 period, the GUARD Model is expected, in aggregate, to reduce Medicare spending by \$14.1 billion. This sum would be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

II. Background

Prescription drug prices in the United States have been increasing over time, and the prices of certain drugs sold in the United States are substantially higher than prices in economically comparable countries. High prescription drug prices in the United States influence Part D spending, which has also increased over time (as we discuss later in this section).

A. Prescription Drug Prices in the United States

Medicare prescription drug costs have been rising over time, with total Part D gross drug spending increasing from \$121 billion in 2014 to \$276 billion in 2023, an increase of nearly 10 percent annually.³⁸ In 2024, Part D drug spending represented a large portion (about 40 percent)³⁹ of overall gross drug spending in the United States. The increase in Part D gross drug spending is consistent with overall trends in U.S. drug spending, which are rising over time. Gross drug spending has increased from \$600 billion in 2018 to \$858 billion in 2023 for all drugs, regardless of payer source.⁴⁰ Net drug spending increased by 11.4 percent in 2024 (from \$437.1 billion in 2023 to \$487 billion in

2024), more than double the increase from the previous year (4.9 percent growth in 2023, from \$416.8 billion in 2022 to \$437.1 billion in 2023).⁴¹ These increases are driven by many factors; the way the United States pays for prescription drugs and the complex pharmaceutical drug supply chain also play a role.

Existing research shows that the prices of drugs in the United States are much higher than prices for the same drugs sold in other countries and this gap is increasing over time.^{42 43} In 2024, the United States accounted for less than 5 percent of the world’s population (4.22)⁴⁴ and about 15 percent (14.9) of the world’s real gross domestic product (GDP),⁴⁵ but U.S. gross spending on

drugs accounted for over half of the world’s gross spending on drugs (53.2 percent)⁴⁶ and only about 10 percent of the volume sold.⁴⁷ Among countries in the Organization for Economic Cooperation and Development (OECD), in 2024, the United States accounted for about 63 percent of spending on prescription drugs, but only 22 percent of the volume.⁴⁸

Research from Office of Assistant Secretary for Planning and Evaluation (ASPE) and the RAND Corporation provides comparative data on U.S. prescription drug prices relative to other OECD member countries. These studies examine prescription drug pricing patterns and present findings on how U.S. prescription drug costs compare to international benchmarks. ASPE’s

³⁸ MedPAC. (2025). *Health Care Spending and the Medicare program*. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf (Accessed: 10 December 2025).

³⁹ IQVIA. (2025). *Understanding the Use of Medicines in the U.S. 2025*. <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/understanding-the-use-of-medicines-in-the-us-2025> (Accessed: 10 December 2025).

⁴⁰ IQVIA. (2023). *The Use of Medicines in the U.S. 2023*. <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2023> (Accessed: 10 December 2025).

⁴¹ IQVIA. (2025). *Understanding the Use of Medicines in the U.S. 2025*. <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/understanding-the-use-of-medicines-in-the-us-2025> (Accessed: 10 December 2025).

⁴² Kang, S., et al. (2019). Using External Reference Pricing in Medicare Part D to Reduce Drug Price Differentials with Other Countries. *Health Affairs*, 38(5), 804–811. <https://doi.org/10.1377/hlthaff.2018.05207>.

⁴³ Mulcahy, A.W., et al. (2024). *International Prescription Drug Price Comparisons: Estimates Using 2022 Data*. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. <https://aspe.hhs.gov/sites/default/files/documents/277371265a705c356c968977e87446ae/international-price-comparisons.pdf> (Accessed: 10 December 2025).

⁴⁴ Data from the U.S. Census Bureau: the U.S. and World Population Clock (Population Clock) and the International Database (International Database). The U.S. and world population in 2024 according to the U.S. Census Bureau’s U.S. and World Population Clock was about 340 million and 8 billion which results in the U.S. population being 4.22% of the world population in 2024.

⁴⁵ Data from the CIA World Factbook’s real GDP at purchasing power parity (PPP) exchange rates (Real GDP (purchasing power parity) Comparison—The World Factbook). For 2024, the U.S. and world

GDP in real GDP at PPP (2021 U.S. dollars) according to the CIA World Factbook was 25.7 and 172.4 trillion which results in the U.S. GDP being is 14.89% of the world GDP.

⁴⁶ Mikulic, M. (2025). *Market Share of the Leading Global Pharmaceutical Markets 2024*. Statista. <https://www.statista.com/statistics/245473/market-share-of-the-leading-10-global-pharmaceutical-markets/#:~:text=The%20United%20States%20was%20the,including%20only%20the%20hospital%20market> (Accessed: 10 December 2025).

⁴⁷ Author analysis based on IQVIA MIDAS® annual volume sales data using the kilogram measure January to December 2024 reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved. The statements, findings, conclusions, views, and opinions contained and expressed in this research article are based in part on data obtained under license from the following IQVIA information service(s): IQVIA MIDAS. Copyright IQVIA. All Rights Reserved. The statements, findings, conclusions, views and opinions contained and expressed herein are not necessarily those of IQVIA or any of its affiliated or subsidiary entities.

⁴⁸ Author analysis based on IQVIA MIDAS annual sales data using the estimated sales and kilogram measures from January to December 2024 reflecting estimated of real-world activity. Copyright IQVIA. All rights reserved.

research indicated that U.S. prescription drug prices exceeded those of non-U.S. OECD countries combined in 2018. Specifically, U.S. gross prices for brand-name drugs were 344 percent of prices in non-U.S. countries.⁴⁹ The study also found that unbranded generic drugs had lower U.S. prices compared to the prices in other OECD countries. A 2024 report revealed an even larger gap, U.S. gross prices for certain drugs are higher than other countries. Specifically, for brand-name originator drugs,⁵⁰ U.S. prices are approximately 422 percent of prices in economically comparable countries or at least 322 percent if adjusted for rebates in the United States (but not in other countries).⁵¹ The same study showed the United States paid less for unbranded generic drugs; specifically, U.S. prices for these drugs represent approximately 67 percent of the OECD countries combined. This indicates that pricing patterns vary between brand-name originator drugs and generic drugs in the U.S. market. This body of research also suggests that U.S. drug prices for brand-name originator drugs are growing faster than drug prices in other countries.

The widening gap over time between U.S. drug prices and prices in other economically comparable countries for certain types of drugs exist for many reasons. However, one component is the substantial difference in the way the United States and other economically comparable countries approach prescription drug pricing. Although there is wide variation in the way economically comparable countries determine prices, in general, many countries take a more centralized approach to drug pricing and may have greater involvement in establishing prices for drugs than the United States.⁵²

The U.S. market and the incentives and payment mechanisms embedded within the U.S. pharmaceutical drug supply chain are complex. Drug manufacturers set the list price, also known as the Wholesale Acquisition Cost (WAC), which serves as the initial anchor price for a drug throughout the complex pharmaceutical drug supply chain market in the United States.⁵³ The pharmaceutical drug supply chain consists of many stakeholders, each with differing, potentially complex roles. Stakeholders include drug manufacturers, drug wholesalers, pharmacies, group purchasing organizations (GPOs), payers (that is, insurance plans, including Part D plans), and pharmacy benefit managers (PBMs).⁵⁴ When payers, including Medicare Advantage organizations offering Part D prescription drug coverage and standalone Part D plans, reimburse the pharmacy for a drug, the reimbursement is based on a negotiated payment amount for the drug plus a dispensing fee. Payers, including Part D plan sponsors, often contract with PBMs, which administer the outpatient pharmacy benefit and negotiate rebates with manufacturers. For drugs in competitive therapeutic classes, PBMs often negotiate with manufacturers to receive rebates in exchange for preferred formulary placement. These rebates, which are not typically applied at point-of-sale, ultimately reduce the net price of the drug faced by the payer. Under the Part D program, the post point-of-sale compensation is included in direct and indirect remuneration (DIR), and it is factored into the Centers for Medicare & Medicaid Services (CMS) calculation of final Medicare payments to Part D plans.⁵⁵ This, in turn, impacts Medicare costs, including premiums, under the Part D program.

B. The Medicare Prescription Drug Benefit (Medicare Part D)

The Medicare Voluntary Prescription Drug Benefit Program, also known as

Part D, is a federal prescription drug coverage program established under Title XVIII, Part D of the Social Security Act (hereafter, “the Act”) (sections 1860D–1 through 1860D–43 of the Act), as added by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA); the program provides outpatient prescription drug coverage to Medicare beneficiaries.⁵⁶ Section 1860D–15 of the Act specifies the payment methodology for Part D plan sponsors, including direct subsidy payments, reinsurance, and risk corridor payments, as well as beneficiary premiums. The program is administered by private insurers through either standalone prescription drug plans (PDPs) or Medicare Advantage prescription drug (MA–PD) plans.⁵⁷ The prices of prescription drugs covered by a Part D plan are negotiated between the plan sponsor or its PBM and pharmaceutical drug manufacturers.⁵⁸

Under the program, Medicare typically subsidizes a portion of the Part D basic benefit costs for enrollees through reinsurance and direct subsidy payments made to Part D plans, and provides additional premium and cost sharing subsidies for low-income enrollees through the low-income subsidy (LIS) program.⁵⁹ Beneficiaries who voluntarily enroll in a Part D plan typically pay a monthly premium, and depending on their specific plan and drug utilization, may have to pay an annual deductible, copayments, and coinsurance.

The Inflation Reduction Act of 2022 (IRA), Public Law 117–169, made several additions and amendments to the Act that affected the structure of the defined standard Part D drug benefit. Currently, the Part D defined standard benefit consists of three phases that enrollees go through depending on their use and cost of drugs: the deductible phase, the initial coverage phase, and the catastrophic coverage phase. Plans are responsible for setting the specific

⁴⁹ Mulcahy, A., et al. (2021). *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies*. RAND. https://www.rand.org/pubs/research_reports/RR2956.html (Accessed: 16 December 2025).

⁵⁰ The 2024 ASPE report defines brand-name originators as “the original drugs developed and licensed or approved via 351(a) or a New Drug Application (NDA) pathway.” The authors of the study are solely responsible for how brand-name originator drugs were defined for the study.

⁵¹ Mulcahy, A.W., et al. (2024). *International Prescription Drug Price Comparisons: Estimates Using 2022 Data*. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. <https://aspe.hhs.gov/sites/default/files/documents/277371265a705c356c968977e87446ae/international-price-comparisons.pdf> (Accessed: 10 December 2025).

⁵² Syversen, I.D., et al. (2024). A Comparative Analysis of International Drug Price Negotiation Frameworks: An interview study of key stakeholders. *Milbank Quarterly*, 102(4), 1004–1031. <https://doi.org/10.1111/1468-0009.12714>.

⁵³ Mulcahy, A.W. & Karedy, V. (2021). *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships*. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. <https://aspe.hhs.gov/reports/prescription-drug-supply-chains> (Accessed: 10 December 2025).

⁵⁴ Mulcahy, A.W. & Karedy, V. (2021). *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships*. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. <https://aspe.hhs.gov/reports/prescription-drug-supply-chains> (Accessed: 10 December 2025).

⁵⁵ Centers for Medicare & Medicaid Services. (2017). *Medicare Part D—Direct and Indirect Remuneration (DIR)*. U.S. Department of Health and Human Services. <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir> (Accessed: 10 December 2025).

⁵⁶ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, 117 Stat. 2066 (2003). <https://www.congress.gov/108/plaws/publ173/PLAW-108publ173.pdf> (Accessed: 10 December 2025).

⁵⁷ MA–PD plans offer both medical and prescription benefits (Medicare Part D) through Medicare Part C. Standalone PDP plans offer only Part D coverage.

⁵⁸ The exception to this is drugs that are selected for the Medicare Drug Price Negotiation Program, implemented by the Inflation Reduction Act, which authorizes Medicare to directly negotiate drug prices for certain high expenditure, single source Medicare Part B or Part D drugs.

⁵⁹ MedPAC. (2024). *Part D Payment System*. https://www.medpac.gov/wp-content/uploads/2024/10/MedPAC_Payment_Basics_24_PartD_FINAL_SEC.pdf (Accessed: 10 December 2025).

deductible, up to a maximum of \$615 in 2026.⁶⁰ In the 2026 defined standard benefit, enrollees are responsible for 25 percent of drug costs until their true out-of-pocket (TrOOP) spending reaches \$2,100, after which they enter the catastrophic coverage phase. Once enrollees reach the catastrophic coverage phase, they are not responsible for any further out-of-pocket payments for a covered Part D drug. The deductible and \$2,100 annual out-of-pocket cap in effect for 2026 will be adjusted each year based on the annual percentage increase in average expenditures for covered Part D drugs among Part D eligible individuals in the United States.⁶¹ In the defined standard benefit initial coverage phase, manufacturers are typically responsible for 10 percent of costs for certain brand drugs and biologics under the Manufacturer Discount Program and Part D plans are typically responsible for 65 percent.⁶² In the catastrophic coverage phase, Part D plans are typically responsible for 60 percent of drug costs, drug manufacturers are typically responsible for 20 percent, and Medicare pays the remaining 20 percent for brand-name drugs and biologics.⁶³

Under section 1860D–2(a)(1) of the Act, each Part D plan is required to offer either the defined standard benefit, as described previously, or an alternative coverage structure that is actuarially equivalent to the defined standard benefit. In addition, under section 1860D–2(a)(2) of the Act, Part D plan sponsors may offer enhanced or supplemental benefits. Analysis of the landscape files available on *CMS.gov* reveal that for 2026, 49 percent of standalone Part D plan offerings include enhanced benefits and 98 percent of MA–PD plans have enhanced benefits.⁶⁴ This flexibility allows Part D plans to compete for enrollees based on the

benefit design and premiums. It also leads to differences between plans' specific design (for example, whether they require a deductible and, if so, the deductible amount); coverage (for example, the specific drugs covered and tier placement of covered drugs); beneficiary cost sharing (for example, whether a drug is subject to coinsurance or copayment); and other components. Each plan maintains its own formulary, consistent with Medicare formulary requirements in 42 CFR 423.120(b)(2) and 423.272(b)(2). CMS evaluates formularies based on requirements, including sufficiency of categories and classes, tier placement, and utilization management restrictions. These requirements include, for example, that each plan must cover at least two drugs within each therapeutic category and class and generally, all drugs within the six protected classes (immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics)⁶⁵ as well as selected drugs under the Medicare Drug Price Negotiation Program for which a negotiated maximum fair price (MFP) is in effect. The Medicare Payment Advisory Commission (MedPAC) has reported that in 2023, Part D covered 54.9 million enrollees, of which about 14 million were enrolled in LIS;⁶⁶ Part D enrollees had total gross spending of about \$276 billion, which translates to about \$5,429 per Part D enrollee who used a Part D covered drug.⁶⁷ Previous research by ASPE has found that in 2019, about 5.7 million Medicare beneficiaries did not have prescription drug coverage.⁶⁸

⁶⁵ See also: Medicare Prescription Drug Benefit Manual Chapter 6—Part D Drugs and Formulary Requirements, Centers for Medicare & Medicaid Services (January 15, 2016) at § 30.2, Available at <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf> (Last accessed September 24, 2025).

⁶⁶ For eligible enrollees whose income and resources are limited, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 established Extra Help (a subsidy) for prescription drugs, which provides financial assistance for prescription drugs (premiums, deductibles, and copayments). Under the IRA, beginning in 2024, the LIS program is expanded to individuals with limited financial resources and incomes up to 150 percent of the Federal Poverty Limit (FPL).

⁶⁷ MedPAC. (2025). *Health Care Spending and the Medicare program*. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf (Accessed: 10 December 2025).

⁶⁸ Tarazi, W., et al. (2022). *Medicare Beneficiary Enrollment Trends and Demographic Characteristics*. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. <https://aspe.hhs.gov/sites/default/files/documents/b9ac26a13b4fd30c16c24e79df0c99c/medicare-beneficiary-enrollment-ib.pdf> (Accessed: 10 December 2025).

To offer the Part D benefit, under section 1860D–11(b) of the Act, each Part D plan sponsor must submit an annual bid to CMS for each plan it intends to offer, including the plan's benefit design, service area, and the sponsor's actuarial estimate of the expected cost of covering the standard benefit for an average enrollee.⁶⁹ These bids, which are due to CMS annually in June, use actuarial methods to project gross drug costs at the point of sale and subtract expected manufacturer rebates, other price concessions, and other components to estimate the net plan liability. As part of the process of bid development, Part D plan sponsors consider the price of a drug, the estimated rebate payments and price concessions from various entities, including pharmacies and drug manufacturers, and other factors. Manufacturer rebates represent the majority of these rebates received by Part D plans and substantially reduce Part D plans' net drug costs.⁷⁰ Part D plan bids are used to calculate the Part D National Average Monthly Bid Amount (NAMBA) and derive the base beneficiary premium (BBP) amount. Although the BBP does not represent the actual premiums paid by Part D enrollees, which is dependent on individual Part D plan offerings, this estimate influences the average level of enrollee premiums across the Part D plan market. Typically, Medicare subsidizes 74.5 percent of the average cost of basic benefits in the form of direct subsidies and reinsurance. However in 2025, MedPAC reports that the Medicare subsidy increased to about 83 percent of the average cost of basic benefits due to the IRA's premium cap that institutes a 6 percent cap on annual increases in the BBP.⁷¹

C. Recent Drug Pricing Policy Reforms

The IRA's amendments to Part D of Title XVIII of the Act included provisions that change the Part D benefit. As part of these changes, the IRA included several provisions that directly changed manufacturer liability under the Part D program.

⁶⁹ MedPAC. (2024). *Part D Payment System*. https://www.medpac.gov/wp-content/uploads/2024/10/MedPAC_Payment_Basics_24_PartD_FINAL_SEC.pdf (Accessed: 10 December 2025).

⁷⁰ MedPAC. (2023). *Assessing postsale rebates for prescription drugs in Medicare Part D, Report to the Congress: Medicare and the Health Care Delivery System*. https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch2_MedPAC_Report_To_Congress_SEC.pdf (Accessed: 10 December 2025).

⁷¹ MedPAC. (2025). *Chapter 4: Part D Outlook, Medicare Payment Advisory Commission*. https://www.medpac.gov/wp-content/uploads/2025/06/Jun25_Ch4_MedPAC_Report_To_Congress_SEC.pdf (Accessed: 10 December 2025).

⁶⁰ Medicare.gov. (n.d.). *Medicare Part D Costs*. Centers for Medicare and Medicaid Services (CMS), U.S. Department of Health and Human Services. <https://www.medicare.gov/health-drug-plans/part-d/basics/costs> (Accessed: 10 December 2025).

⁶¹ Centers for Medicare & Medicaid Services. (2025). *Final CY 2026 Part D Redesign Program Instructions*. U.S. Department of Health and Human Services. <https://www.cms.gov/newsroom/factsheets/final-cy-2026-part-d-redesign-program-instructions> (Accessed: 10 December 2025).

⁶² Under the Manufacturer Discount Program, there is a multi-year phase-in period for applicable discounts for certain manufacturers' applicable drugs. See section 1860D–14C(g)(4) of the Act.

⁶³ This is the Part D standard benefit for brand-name drugs and biologics. There are some differences in the Part D standard benefit for generic drugs.

⁶⁴ Centers for Medicare & Medicaid Services. (2025). *Prescription Drug Coverage (Part D)*. U.S. Department of Health and Human Services. <https://www.cms.gov/medicare/coverage/prescription-drug-coverage> (Accessed: 10 December 2025).

Section 11102(a) of the IRA added new section 1860D–14B of the Act, which establishes requirements for drug manufacturers to pay inflation rebates for certain Part D drugs. Specifically, pharmaceutical drug manufacturers that increase the price for a Part D rebatable drug faster than the rate of inflation (as measured by changes in the Consumer Price Index for all Urban Consumers, CPI–U), as described in section 1860D–14B of the Act, are required to pay Part D drug inflation rebates to the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund for each 12-month applicable period.

Under these provisions, a “Part D rebatable drug” is defined as a drug or biological described at section 1860D–14B(g)(1)(C) of the Act and is: (1) a drug approved under a New Drug Application (NDA) under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 301 *et seq.*); (2) a drug approved under an Abbreviated New Drug Application (ANDA) under section 505(j) of the FD&C Act that meets the criteria in section 1860D–14B(g)(1)(C)(ii) of the Act; or (3) a biological licensed under section 351 of the Public Health Service (PHS) Act (42 U.S.C. 201 *et seq.*). In general, the statute excludes multi-source generic drugs from the definition of a Part D rebatable drug and limits generics that may be Part D rebatable drugs to sole-source generics—that is, generic drugs for which (1) the reference listed drug approved under section 505(c) of FD&C Act, including any “authorized generic drug” (as that term is defined in section 505(t)(3) of the FD&C Act), is not being marketed, as identified in the Food and Drug Administration’s (FDA’s) National Drug Code (NDC) Directory; (2) there is no other drug approved under section 505(j) of the FD&C Act that is rated as therapeutically equivalent and that is being marketed, as identified in FDA’s NDC Directory; (3) the manufacturer is not a “first applicant” during the 180-day exclusivity period; and (4) the manufacturer is not a “first approved applicant” for a competitive generics therapy. The Part D Inflation Rebate Program also excludes drugs or biological products with an average annual total cost under Part D of less than \$100 per individual using such drug or biological product for the first applicable period; this amount is adjusted by percentage changes in the CPI–U annually thereafter.

The Part D inflation rebate calculation examines year-over-year changes to determine whether an inflation rebate is owed for a Part D rebatable drug. Specifically, the Part D inflation rebates

are calculated, as reported under section 1927(b)(3) of the Act⁷² and further clarified in a December 2023 guidance,⁷³ for each Part D rebatable drug by establishing a historical benchmark price and comparing this price against the price for an applicable 12-month period. The inflation rebate amounts are based on the difference between the drug’s volume weighted annual average manufacturer price (AnMP) in a given 12-month applicable period and the inflation-adjusted volume weighted annual average manufacturer price of the benchmark period. This means if the Part D rebatable drug’s AnMP in an applicable period exceeds the drug’s inflation adjusted payment amount, an inflation rebate amount would be due. The average manufacturer price (AMP) represents the average price paid to the manufacturer for the drug in the United States by wholesalers.

The statute defines an “applicable period” to mean a 12-month period beginning with October 1 of a year (beginning with October 1, 2022). As such, October 1, 2022 was the beginning of the first 12-month period for which drug manufacturers will be required to pay rebates to Medicare if a Part D rebatable drug’s price increases faster than the rate of inflation over the 12-month period. December 31, 2025 is the date by which CMS is required to begin invoicing pharmaceutical drug manufacturers for the Part D inflation rebates they owed Medicare for the 12-month applicable periods that began on October 1, 2022 and October 1, 2023.⁷⁴ For subsequent applicable periods, CMS must invoice pharmaceutical drug manufacturers for any Part D inflation rebates they owe Medicare by no later than 9 months after the end of the applicable period.

Section 11201 of the IRA, as codified in sections 1860D–14C and 1860D–43 of the Act, established a new Manufacturer Discount Program, which became

effective January 1, 2025. The Manufacturer Discount Program replaced the Medicare Coverage Gap Discount Program (CGDP), which was enacted into law in section 3301 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 1101 of the Health Care and Education Reconciliation Act (HCERA) of 2010 (Pub. L. 111–152) (referred to collectively as the Affordable Care Act) and codified in sections 1860D–14A and 1860D–43 of the Act. Effective January 1, 2011, the CGDP made manufacturer discounts for brand name drugs and biologic products (with biosimilars included starting in 2019) available to applicable beneficiaries at the point of sale. The CGDP provided non-low-income subsidy beneficiaries in the coverage gap phase of the Part D benefit, a 50 percent discount on the negotiated price of the drug at point of sale. For an applicable drug to be covered under Part D, the manufacturer had to sign a manufacturer agreement with the Secretary.

Section 53116 of the Bipartisan Budget Act of 2018 (BBA) (Pub. L. 115–123), changed the CGDP amount from 50 to 70 percent for applicable beneficiaries beginning in 2019. The BBA also reduced beneficiary cost sharing in the coverage gap phase to 25 percent in 2019 and subsequent years. The CGDP was sunset effective December 31, 2024, and the new Manufacturer Discount Program became effective January 1, 2025. The Manufacturer Discount Program differs from the CGDP in several important ways. First, the Manufacturer Discount Program discount is applied to applicable drugs dispensed to beneficiaries who receive a low-income subsidy as well as those who do not. Also, discounts are applied in the initial coverage and catastrophic phase of the benefit at 10 and 20 percent, respectively. The IRA outlined a method to identify certain specified manufacturers and specified small manufacturers, as defined in statute, and set forth a multiyear phase-in period to phase-in the full discount percentages for these manufacturers. Finally, unlike the CGDP, Manufacturer Discount Program discounts do not count towards a beneficiary’s TrOOP⁷⁵ costs (meaning that manufacturer payments made under the Manufacturer Discount Program will not accrue to a beneficiary’s incurred costs).

The IRA also established the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198

⁷² Social Security Act, Payment for Covered Outpatient Drugs (section 1927 of the Act, 42 U.S.C. 1396r–8). https://www.ssa.gov/OP_Home/ssact/title19/1927.htm (Accessed: 10 December 2025).

⁷³ Centers for Medicare & Medicaid Services. (2023). *Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Revised Guidance, Implementation of Section 1860D–14B of the Social Security Act*. U.S. Department of Health and Human Services. <https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-revised-guidance.pdf> (Accessed: 10 December 2025).

⁷⁴ Centers for Medicare & Medicaid Services. (2024). *Fact Sheet: Medicare Prescription Drug Inflation Rebate Program Policies in the Calendar Year 2025 Physician Fee Schedule Final Rule*. U.S. Department of Health and Human Services. <https://www.cms.gov/files/document/medicare-prescription-drug-inflation-rebate-program-final-fact-sheet.pdf> (Accessed: 10 December 2025).

⁷⁵ See sections 1860D–2(b)(4)(C)(iii) and (E) of the Social Security Act).

of the Act, which gave the Secretary authority to negotiate a MFP for certain high expenditure, single source drugs and biologics without generic or biosimilar competition with participating drug manufacturers. The program began with a set of drugs covered under Part D and expands over time to include drugs payable under Part B that meet the criteria. On August 29, 2023, CMS published the list of 10 drugs covered under Part D selected for initial price applicability year 2026; the negotiated MFPs for these drugs will go into effect on January 1, 2026.⁷⁶ The second set of 15 drugs covered under Part D that were selected for negotiation for 2027 were announced on January 17, 2025, and the MFPs, if agreed upon by the manufacturers and CMS, for these drugs are expected to go into effect on January 1, 2027.⁷⁷

D. High Drug Costs Under Part D

Although the provisions under the IRA included a series of changes to the Part D benefit, including allowing Medicare to negotiate for certain drugs, they do not fully address the issue of high drug spending in the Part D program. High drug prices affect Part D spending, particularly for certain types of drugs (for example, single-source brand-name drugs), and influence overall program spending. Moreover, enrollees may ration their prescription drugs due to cost, which can have serious health-related consequences for Medicare enrollees and may result in avoidable costs for Medicare.⁷⁸

Part D gross drug spending has risen over time (from \$348 gross drug spending per month per LIS enrollee in 2010 to \$765 gross drug spending per month per LIS enrollee in 2023 and \$163 per month per non-LIS enrollee in 2010 to \$309 per month per non-LIS

enrollee in 2023).⁷⁹ Analyses show that Part D gross spending is concentrated among certain types of drugs, particularly certain types of brand name drugs such as specialty drugs. One study examined trends in total gross drug spending under Part D between 2012 to 2021 specifically for drugs with the top 1 percent, 5 percent, and 10 percent of spending. Findings showed that gross drug costs increased by 103 percent from 2012 to 2021, driven both by increases in the number of prescriptions as well as increases in prices for existing drugs. Drugs in the top 1 percent of spending in Part D accounted for an increasing share of total gross drug costs over time, increasing from 31.4 percent to 41.1 percent from 2012 to 2021. Spending specifically for specialty drugs increased by over 500 percent over the study period and accounted for 71.1 percent of total gross drug costs in 2021, even though specialty drugs accounted for 6.2 percent of prescriptions in 2021.⁸⁰

In 2023, MedPAC reported that Medicare gross spending on brand-name drugs was about \$171.2 billion and spending on biologics was about \$60 billion, collectively representing about 84 percent of the total gross drug spending.⁸¹ Generic drugs represented the remaining 15 percent of spending.⁸² Additionally, although there were more prescriptions filled for generic drugs (about 82 percent across the top 15 therapeutic classes, including diabetic therapy, antineoplastics, anticoagulants, asthma/chronic obstructive pulmonary disease (COPD) agents, and others in 2023), the majority of gross spending (91 percent) was for brand-name products within these therapeutic classes.⁸³

Enrollee out-of-pocket costs for drugs covered under Part D vary based on several factors. Research by ASPE finds that in 2022, Part D enrollees who do not receive LIS had greater average out-

of-pocket costs than their LIS enrollee counterparts (\$464 per non-LIS enrollee vs. \$52 per LIS enrollee); these differences are particularly pronounced for enrollees who reached the catastrophic coverage phase of the Part D benefit (\$3,093 per non-LIS enrollee vs. \$87 per LIS enrollee). ASPE analysis also finds that, prior to the IRA's out-of-pocket cap going into effect, among enrollees who reached the catastrophic coverage phase of the Part D benefit, annual out-of-pocket prescription drug costs were highest for enrollees with certain health conditions (such as enrollees with cystic fibrosis, metabolic and immune disorders, certain types of cancers, and those who have undergone major organ transplant) and those who take certain types of medications. For example, enrollees who took certain brand name single source drugs used to treat cancers had significantly higher out-of-pocket costs than the average Part D enrollee.⁸⁴

The IRA caps enrollees' out-of-pocket costs for prescription drugs at \$2,100 in 2026 (and this cap is adjusted annually based on the annual percentage increase in average expenditures for covered Part D drugs in the United States for Part D eligible individuals in the previous year), which reduces the out-of-pocket costs for certain Part D enrollees who take expensive medications covered under the Part D program. However, although the provision has gone into effect, there remain concerns about the affordability of prescription drugs covered under Part D. Specifically, there is concern that Part D plan sponsors are shifting from a fixed copayment model for high-cost brand-name drugs to a coinsurance-based model, where the enrollee pays a percentage of the price at the point-of-sale in the pharmacy, potentially exposing Part D enrollees who take certain drugs to higher costs.⁸⁵ Additionally, CMS analysis of the Medicare Current Beneficiary Survey (MCBS) finds that nine percent of Medicare beneficiaries reported that they decided *not* to fill a prescription in

⁷⁶ Centers for Medicare & Medicaid Services. (2024). *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026*. U.S. Department of Health and Human Services. <https://www.cms.gov/newsroom/factsheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026> (Accessed: 10 December 2025).

⁷⁷ Centers for Medicare & Medicaid Services. (2015). *HHS Announces 15 Additional Drugs Selected for Medicare Drug Price Negotiations in Continued Effort to Lower Prescription Drug Costs for Seniors*. U.S. Department of Health and Human Services. <https://www.cms.gov/newsroom/press-releases/hhs-announces-15-additional-drugs-selected-medicare-drug-price-negotiations-continued-effort-lower> (Accessed: 10 December 2025).

⁷⁸ Leonard, F., et al. (2023). *Medicare's Affordability Problem: A Look at the Cost Burdens Faced by Older Enrollees*. The Commonwealth Fund. <https://www.commonwealthfund.org/publications/issue-briefs/2023/sep/medicare-affordability-problem-cost-burdens-biennial> (Accessed: 10 December 2025).

⁷⁹ MedPAC. (2025). *Health Care Spending and the Medicare program*. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf (Accessed: 10 December 2025).

⁸⁰ Niu, S., et al. (2024). Concentration of spending and share of specialty drug spending in Medicare Part D over a 10-year period. *Journal of Managed Care & Specialty Pharmacy*, 30(12), 1355–1363. <https://doi.org/10.18553/jmcp.2024.30.12.1355>.

⁸¹ MedPAC. (2025). *Health Care Spending and the Medicare program*. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf (Accessed: 10 December 2025).

⁸² MedPAC. (2025). *Health Care Spending and the Medicare program*. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf (Accessed: 10 December 2025).

⁸³ MedPAC. (2025). *Health Care Spending and the Medicare program*. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf (Accessed: 10 December 2025).

⁸⁴ Sayed, B.A., et al. (2024). *Inflation Reduction Act Research Series, Medicare Part D Enrollee Out-Of-Pocket Spending: Recent Trends and Projected Impacts of the Inflation Reduction Act*. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. <https://aspe.hhs.gov/reports/medicare-part-d-enrollee-out-pocket-spending> (Accessed: 10 December 2025).

⁸⁵ Trish, E. & Blaylock, B. (2025). *Shifting Cost-Sharing Burden to Beneficiaries in Medicare Part D*. U.S.C. Schaeffer Center White Paper Series. White Paper No. 2025–06. <https://schaeffer.usc.edu/research/cost-sharing-burden-medicare-part-d/> (Accessed: 10 December 2025).

2025 due to cost.⁸⁶ All of this suggests that Part D enrollees with certain health conditions and particularly those who take certain brand-name drugs or biologics may still experience high out-of-pocket spending.

In addition to out-of-pocket costs for their prescription drugs, enrollees also pay monthly premiums for their Part D coverage, which may impact whether a Medicare beneficiary elects to enroll in a Part D plan. Previous ASPE research finds that in 2019, about 5.7 million Medicare beneficiaries did not have any prescription drug coverage.⁸⁷ From 2024 to 2025, MedPAC found a decrease in the average premiums paid by enrollees, from \$27 to \$23. This decline is largely attributed to the IRA's 6 percent cap on base beneficiary premiums, which remains in effect through 2029 and to the voluntary Part D Premium Stabilization Demonstration. This demonstration, which began in 2024 for calendar year 2025, is testing an approach to stabilize the year-over-year changes in premiums for standalone PDPs during the implementation of the Part D redesign.⁸⁸ MedPAC analysis shows that average monthly premiums are higher for standalone PDPs than MA-PD plans. This is driven in part by the additional tools and flexibilities available to MA-PD plans (for example, MA-PD sponsors that submit MA bids that are below the applicable benchmark can use MA rebates to reduce Part D premiums) compared to PDPs.⁸⁹

E. Rationale and Need for GUARD Model Test

Within the United States, the prices of certain types of drugs have been increasing over time, which impacts spending in Part D and affordability of Part D coverage for Medicare beneficiaries. Brand-name drugs and

biologics, in particular, represent a large portion of Part D spending in spite of the fact that generic drugs have a higher volume of use.^{90 91} The IRA addresses certain high drug costs under Part D. However, the IRA provisions—specifically the Drug Price Negotiation Program—focuses on a small set of drugs and only after they are available in the market for a period of time. The current Part D Inflation Rebate Program requires manufacturers to pay a rebate for certain drugs based on price changes over time within the United States. While this approach is useful for curbing post-launch increases in drug prices, the Part D Inflation Rebate Program does not address the high launch prices of drugs, which continue to increase over time and contribute to high Medicare drug spending. One way to address high Part D spending is to test a change in the IRA's Part D inflation rebate calculation by using a benchmark that takes into account drug pricing information from economically comparable countries. The benchmark could then be subtracted from a net price that uses the manufacturer's starting point for negotiations (for example, the publicly available list price); manufacturer rebates and discounts could be netted from this figure (to give credit to manufacturers for rebates that have been paid). This approach is different from the current Part D Inflation Rebate Program, which compares each applicable drug's current year price (based on the applicability period as described previously in this Section of the proposed rule) to the inflation adjusted benchmark period price, and in so doing, evaluates changes in prices *within* the United States over time.⁹²

Under the CMS Innovation Center's statutory authority under section 1115A of the Act, we propose to address this key issue of persistent high domestic Medicare drug spending for certain drugs and biologics through the GUARD Model, which tests changes to the Part D inflation rebate provision by

implementing an innovative alternative payment method for the purpose of reducing Medicare drug spending and preserving or improving quality of care for Part D enrollees.

III. Summary Provisions Proposed in the Guard Model

The proposed GUARD Model would test changes to the Part D Inflation Rebate Program, specifically testing whether an alternative for the Part D inflation rebate calculation for certain drugs and biological products would reduce program spending for Medicare and taxpayers while preserving or enhancing the quality of care furnished to Medicare beneficiaries. The proposed model includes the following major provisions:

- The GUARD Model would include a subset of Part D rebatable drugs that are included in the Part D Inflation Rebate Program. Specifically, the GUARD Model would include sole-source drugs and sole-source biological products that are in the following specific therapeutic categories: Analgesics; Anticonvulsants; Antidepressants; Antimigraine Agents; Antineoplastics; Antipsychotics; Antivirals; Bipolar Agents; Blood Glucose Regulators; Cardiovascular Agents; Central Nervous System Agents; Gastrointestinal Agents; Genetic or Enzyme or Protein Disorder; Replacement or Modifiers or Treatment; Immunological Agents; Metabolic Bone Disease Agents; Ophthalmic Agents; and Respiratory Tract/Pulmonary Agents. The GUARD Model would exclude (1) generics and biosimilar biological products; (2) sole-source drugs or sole-source biological products with annual application-level⁹³ total gross covered drug costs below the GUARD minimum spend threshold; and (3) drugs that are subject to a maximum fair price (MFP), during the price applicability period. For a more detailed discussion, see section IV.B. of this proposed rule.

- The Centers for Medicare & Medicaid Services (CMS) proposes in section IV.D. of this proposed rule that manufacturers of "Part D rebatable drugs," as defined in section 1927(k)(5) of the Act and 42 CFR 428.20, that receive a Part D inflation rebate report that includes a GUARD Model drug for an applicable period that overlaps with the GUARD Model performance period

⁸⁶ Internal CMS analysis of Medicare Current Beneficiary Survey data collected May–July 2025 (Office of Enterprise Data and Analytics).

⁸⁷ Tarazi, W., et al. (2022). *Medicare Beneficiary Enrollment Trends and Demographic Characteristics*. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. <https://aspe.hhs.gov/sites/default/files/documents/b9ac26a13b4df30c16c24e79df0c99c/medicare-beneficiary-enrollment-ib.pdf> (Accessed: 10 December 2025).

⁸⁸ Centers for Medicare & Medicaid Services. (2025). *2026 Medicare Part D Bid Information and Part D Premium Stabilization Demonstration Parameters*. U.S. Department of Health and Human Services. <https://www.cms.gov/newsroom/fact-sheets/2026-medicare-part-d-bid-information-and-part-d-premium-stabilization-demonstration-parameters> (Accessed: 10 December 2025).

⁸⁹ Suzuki, S., et al. (2025). *Structural differences between the Part D PDP and MA-PD markets*. MedPAC. <https://www.medpac.gov/wp-content/uploads/2025/04/Tab-D-Structural-differences-in-Part-D-April-2025.pdf> (Accessed: 10 December 2025).

⁹⁰ Trish, E. & Blaylock, B. (2025). *Shifting Cost-Sharing Burden to Beneficiaries in Medicare Part D*. U.S.C. Schaeffer Center White Paper Series. White Paper No. 2025–06. <https://schaeffer.usc.edu/research/cost-sharing-burden-medicare-part-d/> (Accessed: 10 December 2025).

⁹¹ MedPAC. (2025). *Health Care Spending and the Medicare program*. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf (Accessed: 10 December 2025).

⁹² In addition, unlike the Medicare Drug Price Negotiation Program, which has requirements for the number of years a drug has been on the market before it is eligible to be selected for negotiation, under the GUARD Model, if a drug meets the criteria, it would be included and potentially be subject to a rebate regardless of how long it has been on the market.

⁹³ Application-level refers to the New Drug Application (NDA) or Biologics License application (BLA) associated with each GUARD Model drug. This means the total gross covered prescription drug costs for all Part D rebatable NDC–9s associated with the same application (NDA or BLA) as the GUARD Model drug.

would be required to participate in the GUARD Model.

- CMS proposes in section IV.E. of this proposed rule that the GUARD Model would select reference countries that are economically comparable to the United States. Reference countries must meet the following criteria: they must be a part of the Organization for Economic Cooperation and Development (OECD), have a minimum of 60 percent of the United States's purchasing power parity (PPP)-adjusted per capita gross domestic product (GDP), and a minimum \$400 billion (PPP)-adjusted aggregate GDP. The reference countries that meet these criteria and are therefore proposed to be selected for the model are the following: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, France, Germany, Ireland, Israel, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom.

- As part of the GUARD Model, CMS proposes to test two approaches to calculating the GUARD Model international benchmark: the default international benchmark (also referred to as the Method I benchmark) and the updated international benchmark (also referred to as the Method II benchmark).

- For each GUARD Model drug for which data on international drug pricing in reference countries are available, CMS would calculate the GUARD Model default international benchmark. The GUARD Model default international benchmark for each GUARD Model drug would be identified as the lowest country-level average price among the set of average prices for each reference country, adjusted by the country-specific GDP based on PPP (hereafter, "GDP (PPP)") adjuster, where an international product that is part of a GUARD Model drug's set of international analogs⁹⁴ is sold. Please see section IV.G. of the proposed rule.

- CMS would provide manufacturers with the option to submit international drug net pricing data for the set of reference countries where international products that are part of a GUARD Model drug's set of international analogs are sold, including the across-country average net price. This submitted across-country average net price accounts for country-specific differences using a GDP (PPP) adjuster; if the data submitted is determined to be an applicable submission, it would become the GUARD Model updated

international benchmark. Please see section IV.F. of this proposed rule.

- CMS would determine a GUARD Model applicable international benchmark for each GUARD Model drug that would be the greater of the GUARD Model default international benchmark and the GUARD Model updated international benchmark, unless there is only a GUARD Model default international benchmark. If there is only a GUARD Model default international benchmark, it would become the applicable international benchmark. Please see section IV.G. of this proposed rule.

- CMS would use this information to test an alternative inflation rebate payment calculation to determine whether manufacturers owe a GUARD Model rebate payment. The alternative inflation rebate calculation tested under the GUARD Model would compare a Medicare net price against the applicable international benchmark. Please see section IV.H. of this proposed rule.

- The GUARD Model would require manufacturers to pay a GUARD Model rebate payment if the Medicare net price is greater than the GUARD Model applicable international benchmark for a GUARD Model drug. The Medicare net price would be calculated by subtracting manufacturer rebates (obtained from direct and indirect remuneration (DIR)) and discounts (under the Manufacturer Discount Program) from the wholesale acquisition cost (WAC) of the GUARD Model drug. Please see section IV.H. of this proposed rule.

- The total GUARD Model rebate amount would be equal to the product of the per unit GUARD Model rebate amount for such GUARD Model drug for the performance year and the total number of units of the GUARD Model drug dispensed under Part D and covered by Part D plan sponsors in the GUARD Model geographic areas for the performance year. Please see section IV.H. of this proposed rule.

- When the per unit GUARD Model rebate exceeds the per unit Part D inflation rebate amount, CMS would waive the rebate amount described in section 1860D–14B(b) of the Act and instead apply the GUARD Model rebate amount. The GUARD Model rebate payment would be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

- The evaluation would examine the main outcome, Medicare net spending, as well as additional outcomes of the GUARD Model, including the ways in which Part D plan benefits may change for GUARD Model drugs and whether

and to what extent there are impacts on beneficiary cost sharing for GUARD Model drugs.

IV. Detailed Description of Provisions in the Proposed Guard Model

In this Section, CMS proposes our policies for testing and implementing the GUARD Model, including model-specific definitions and the general framework for implementation of the GUARD Model. The proposed model-specific terms are described in applicable Sections of this proposed rule. We propose to codify these model-specific terms at proposed 42 CFR part 514. In addition, for purposes of this proposed rule and the proposed GUARD Model, we propose that the following terms would have the same meaning as set forth in 42 CFR 428.20: "applicable period"; "Consumer Price Index for All Urban Consumers" (CPI-U); "applicable threshold"; "average manufacturer price" (AMP); "manufacturer"; "national drug code" (NDC); "Part D rebatable drug"; and "unit." We also propose that "covered Part D drug" has the same meaning as set forth in 42 CFR 423.100, and "line extension" has the same meaning as set forth in 42 CFR 428.200.

The remaining sections of this proposed rule are organized as follows: In section IV.A. of this proposed rule, we describe the proposed model performance and test period. In section IV.B. of this proposed rule, we present the Part D covered drugs that would be included in the GUARD Model. In section IV.C. of this proposed rule, we present the model test design, geographic selection, and beneficiary population that would be included in the GUARD Model. In section IV.D. of this proposed rule, we present the GUARD Model participants, including the requirement that participation is mandatory as well as requirements for participants during the GUARD Model performance period and after the ending of the performance period. In section IV.E. of this proposed rule, we present the existing international drug pricing data that CMS proposes to use to generate the GUARD Model default international benchmark as well as CMS' proposed data sources and methods to identify the reference countries for the GUARD Model. In section IV.F. of this proposed rule, we present the option for manufacturers to submit international drug net pricing data, if they choose to do so; the requirements for such data submission; and the process to elect this option if preferred for the purpose of determining the updated international benchmark. In section IV.G. of this proposed rule, we

⁹⁴ To be a part of the set of international analogs, an international product must have an active ingredient, route of administration, dosage form, and strength that aligns with that of the GUARD Model drug.

present the proposal to determine the GUARD Model applicable international benchmark based on the set of reference countries, including the default international benchmark and the updated international benchmark (which only applies if the manufacturer elects to submit international drug net pricing data, and it is deemed applicable by CMS). In section IV.H. of this proposed rule, we propose the methods to determine the GUARD Model rebate payment, including the data inputs and the calculation steps for the GUARD rebate payment amount. Section IV.I. of this proposed rule presents the proposals for reports of rebate amounts and timing of reports for GUARD Model participants. In section IV.J. of this proposed rule, we present the proposed reconciliation process for a GUARD rebate payment and the suggestion of error process. In section IV.K. of this proposed rule, we present the enforcement mechanisms that would be used to ensure manufacturer payment of rebates are paid in a timely manner. Section IV.L. of this proposed rule presents the proposed quality and monitoring strategy for the GUARD Model, and section IV.M. of this proposed rule presents the proposed beneficiary protections and compliance related activities that CMS would require under the GUARD Model. Section IV.N. of this proposed rule presents the GUARD Model's interaction and coordination with other models and programs and CMS' approach for taking these into account. Section IV.O. of this proposed rule presents the proposed evaluation approach for the GUARD Model, including the key outcomes that would be examined. Section IV.P. of this proposed rule presents information on the limitations on review that apply to CMS Innovation Center Models, including the GUARD Model. Section IV.Q. of this proposed rule presents program waivers that CMS proposes to apply to the GUARD Model. Section IV.R. of this proposed rule denotes that the GUARD Model and its provisions are severable from other CMS programs. Section IV.S. of this proposed rule presents information on the termination of the GUARD Model. Section IV.T. of this proposed rule presents the process for response to comments on this proposed rule.

A. Proposed Model Performance and Test Period

CMS is proposing in § 514.1(c) that the GUARD Model would have a 7-year overall test period, which would consist of 5 performance years, during which GUARD Model rebate payments would

apply, and 7 payment years during which CMS calculates, invoices, collects, and reconciles the GUARD Model rebates for a performance year, unless the model is terminated sooner, in accordance with proposed § 514.910(a).

In § 514.5, we propose to define “payment year” as a 12-month period beginning on January 1 and ending on December 31 during the GUARD Model test period. As such, we propose to define “GUARD Model payment period” as the 7-year period beginning on January 1, 2027 through December 31, 2033, as specified in § 514.1(c). We propose a 7-year payment period to allow for sufficient time for payments to be invoiced and collected after the end of the 5 performance years of the GUARD Model.

In § 514.5, we propose to define the “GUARD Model performance period” as the 5-year period, beginning on January 1, 2027, through December 31, 2031, as specified in § 514.1(c). We propose to define at § 514.5, the “performance year” (PY) as the 12-month period beginning on January 1st and ending on December 31st during the GUARD Model performance period, and in alignment with the GUARD Model duration as specified in § 514.1(c). We propose to utilize a 5-year performance period because it would allow for sufficient time and duration to test an alternative to the Part D inflation rebate calculation under the Medicare Part D Inflation Rebate Program, using the applicable international benchmark price, as described in section IV.G. of this proposed rule, and for the purpose of understanding the impacts of the GUARD Model. A 5-year performance period would allow CMS to examine whether the Model reduces expenditures under Part D and maintains or improves quality of care for Part D enrollees; that is, whether the GUARD Model—(1) maintains spending while improving quality; (2) maintains quality while reducing spending; or (3) reduces spending and improves quality. We believe this is sufficient time to evaluate the way the GUARD Model impacts Medicare net spending for the GUARD Model drugs. Within this time horizon, we would also be able to observe short-, intermediate-, and some long-term impacts of the GUARD Model, such as manufacturer and other stakeholder responses as well as changes in cost sharing for beneficiaries. See section IV.L. of this proposed rule for the quality and monitoring approach and section IV.O. of this proposed rule for the evaluation strategy of the GUARD Model.

CMS proposes in § 514.110(c) that it would be necessary to continue GUARD Model processes for payment beyond the end of the GUARD Model performance period and reconciliation activities beyond the GUARD Model payment period. CMS believes the reconciliation activities beyond the end of the GUARD Model payment period would pose minimal burden to manufacturers. Examples of reconciliation activities that could take place after the end of the GUARD Model payment period are responses to reconciliation reports, suggestion of error processes, and payment of any reconciled rebate amounts due or owed.

B. GUARD Model Drugs

1. Proposed Identification of GUARD Model Drugs

From among the Part D rebatable drugs included in the Part D Inflation Rebate Program, as defined in 42 CFR 428.20 and identified in 42 CFR 428.101, CMS proposes at § 514.120(a) that GUARD Model drugs would be defined as sole-source drugs and biological products identified at the NDC-9 level, except those that meet certain exclusions, as described in section III.B.2. of this proposed rule. This means that for every performance year, only sole-source drugs and sole-source biological products included in the Part D Inflation Rebate Program would be considered for the GUARD Model.

CMS proposes at § 514.120(a) that identification of drugs and biological products would be at the NDC-9 level because this is the same unique prescription drug product number that is used to identify a Part D rebatable drug in accordance with 42 CFR 428.20 and 428.101. We would use the NDC-9 level at which to identify the drugs in the Medicare Part D Prescription Drug Event (PDE) data. At § 514.5 CMS defines “PDE data” to mean records submitted by a Part D plan to CMS each time a beneficiary fills a prescription under Medicare Part D. A PDE record is data summarizing the final adjudication of a Part D dispensing event that is reported to CMS by the Part D sponsor using a CMS-defined file layout.

We propose at § 514.100 that for the purposes of the GUARD Model test, a “sole-source drug” will be defined as a drug approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) under section 505 of the Food Drug and Cosmetics Act (FD&C Act) for which there are no

generic(s),⁹⁵ as defined at § 514.5, rated as therapeutically equivalent (under the FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations"). The generic rated as therapeutically equivalent to the drug must be recognized as a therapeutic equivalent in the FDA's Orange Book and be identified as marketed in the FDA's NDC Directory. From this definition, it follows that a multi-source drug, which is a drug with at least one therapeutically equivalent generic approved and marketed, is not a GUARD Model drug.

We propose at § 514.100 that a "sole-source biological product," for purposes of the GUARD Model test, will be defined as a biological product licensed by the FDA under a Biologics License Application (BLA) under section 351(a) of the Public Health Service (PHS) Act that is not the reference biological product, as defined at 42 U.S.C. 262(i)(4), for a biosimilar biological product licensed by FDA in a BLA under section 351(k) of the PHS Act. The biosimilar biological product⁹⁶ must have the biological product as its reference product as defined at 42 U.S.C. 262(i)(4) in the FDA's Purple Book and be identified as marketed in the FDA's NDC Directory. From this definition, it follows that a multi-source biological product, which is a biological product with at least one biosimilar biological product licensed and marketed that has said biological product as their reference product, is not a GUARD Model drug.

At the time of evaluating inclusion of a drug into the GUARD Model (based on being sole-source drugs or biological products) for each performance year, CMS would use the FDA's NDC Directory, including historical information from NDC Directory files such as discontinued, delisted, and expired listings, provided by the FDA or published on the FDA website to identify whether the generic or biosimilar biological products are being sold or marketed for purposes of the GUARD Model. Additionally, CMS proposes at § 514.120(a) that should a sole-source drug or sole-source biological product become multi-source at any point during a performance year, it would only be subject to the GUARD

Model for the period of the performance year during which it was sole-source.

CMS recognizes that based on the definitions of sole-source previously described, authorized generics and unbranded biological products could potentially be GUARD Model drugs. Authorized generics are drugs sold without their brand name by the original manufacturer or a third party under the NDA of the original drug. Unbranded biological products are biological products sold without their brand name by the original manufacturer or a third party licensed by the BLA 351(a) of the original biological product.⁹⁷ Since both authorized generics and unbranded biological products are, directly or indirectly, sponsored by the original pharmaceutical drug manufacturer, CMS believes that if their NDC-9 is included in the Part D Inflation Rebate Program, then subject to the exclusions described in section III.B.2. of this proposed rule, they would be included in the GUARD Model.

Under the proposed policies, the GUARD Model drugs would consist of a subset of Part D rebatable drugs. CMS believes that focusing the GUARD Model test on a subset of the Part D rebatable drugs, rather than all Part D rebatable drugs, would allow CMS to understand the GUARD Model's impacts with a smaller set of drugs. For example, testing the GUARD Model on a select subset of drugs would allow CMS to understand how the Part D plan market would respond to the alternative rebate payment methodology tested under the GUARD Model. In § 514.120(a), we propose sole-source drugs and sole-source biological products for inclusion in the GUARD Model because generally, these drugs face similar market dynamics. By including only sole-source drugs and sole-source biological products in the GUARD Model, we expect that learnings from the test would not be influenced by the very different market dynamics that exist for other types of drugs included in the Part D Inflation Rebate program.

When determining the scope of drugs included in our proposal for the GUARD Model, we considered two key characteristics related to market dynamics for sole-source drugs and

sole-source biological products. First, sole-source drugs and sole-source biological products experience different competitive forces than multi-source drugs and multi-source biological products. The entry of a generic drug, which changes a sole-source drug into a multi-source one, has been shown to shift utilization from the original drug to the generic by 75 percent within a year,⁹⁸ with prices falling on average by more than half for the sole-source drug.⁹⁹ 100 Biosimilar biological product entry, which changes a sole-source biological product into a multi-source biological product, has been shown to shift utilization from the original biological product to the biosimilar biological product by 40 percent within a year, with prices falling by up to 25 percent.¹⁰¹ These shifts and prices in multi-source drug¹⁰² and multi-source biological product¹⁰³ markets varies by market size, product form, therapeutic area, distribution channel, and other idiosyncratic characteristics. Therefore, by only including sole-source drugs and sole-source biological products, the GUARD Model test can focus on understanding the impacts on these types of drugs without having to account for confounding factors that may arise due to the entry of generics or biosimilars, which fundamentally alters market dynamics.¹⁰⁴

Second, pharmaceutical drug manufacturer rebates and discounts are significantly different for sole-source

⁹⁸ Grabowski, H., et al. (2016). Updated Trends in US Brand-name and Generic Drug Competition. *Journal of Medical Economics*, 19(9), 836–844. <https://doi.org/10.1080/13696998.2016.1176578>.

⁹⁹ Darling P., et al. (2024) *Economic Considerations Related to Biosimilar Market Entry*. American Bar Association. https://www.americanbar.org/groups/antitrust_law/resources/newsletters/economic-considerations-biosimilar-market-entry/ (Accessed: 10 December 2025).

¹⁰⁰ Aitken, M. (2016). *Price Declines after Branded Medicines Lose Exclusivity in the U.S.* IQVIA. <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-medicines-lose-exclusivity-in-the-us.pdf> (Accessed: 10 December 2025).

¹⁰¹ Maini L. et al. (2021). Biosimilar Entry and the Pricing of Biologic Drugs. *SSRN*. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3760213.

¹⁰² Frank, R.G., et al. (2021). The Evolution of Supply and Demand in Markets for Generic Drugs. *The Milbank quarterly*, 99(3), 828–852. <https://doi.org/10.1111/1468-0009.12517>.

¹⁰³ McGeeney, J.D., et al. (2025). Measuring the First Mover Advantage in US Biosimilar Markets. *Value Health*. <https://doi.org/10.1016/j.jval.2025.07.011>.

¹⁰⁴ Bosworth, A., et al. (2023). *Changes in the List Prices of Prescription Drugs, 2017–2023*. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. <https://www.aspe.hhs.gov/reports/changes-list-prices-prescription-drugs> (Accessed: 10 December 2025).

⁹⁵ At § 514.5 we define "generic" to mean, for the United States, a marketed drug submitted in an ANDA and approved under an ANDA under section 505(j) of the FD&C Act.

⁹⁶ At § 514.5 we define "biosimilar biological product" to mean, for the United States, a marketed biological product submitted in a BLA under section 351(k) of the PHS Act.

⁹⁷ It is possible for there to be an unbranded biological product derived from a biosimilar biological product, which would have been licensed under section 351(k) of the PHS Act. Given that at § 514.120 CMS proposes to exclude generics and biosimilar biological products and that biosimilar biological products are defined at § 514.5 as those licensed under section 351(k), it follows that these specific unbranded biological products would be excluded from the GUARD Model.

and multi-source drugs and biological products. Although there are many factors that influence the net price of a drug, which is exclusive of rebates, discounts, and other price concessions, in general (though there are exceptions), drugs that face more limited competition (such as sole-source drugs and sole-source biological products) maintain higher net prices than drugs that have market competition (such as multi-source drugs and multi-source biological products).^{105 106 107} This occurs for multiple reasons, but one reason is due to the specific features of the sole-source drug market. Part D plan sponsors or their pharmacy benefit managers (PBMs) negotiate with pharmaceutical drug manufacturers for rebates in exchange for favorable formulary placement, which includes assigning drugs into tiers with different cost sharing requirements (for example, coinsurance vs. copayment); prior authorization requirements; utilization management approaches, and other aspects. Although Part D plan sponsors or their PBMs negotiate with pharmaceutical drug manufacturers for formulary placement for both sole-source drugs and sole-source biological products as well as multi-source drugs and biological products, negotiation is fundamentally different due to the different characteristics of these types of drugs.

These two key differences illustrate how market dynamics vary between sole-source drugs and biological products and multi-source drugs and biological products, and the way these differences directly impact their pricing dynamics. CMS believes that the focus of the GUARD Model on sole-source drugs and sole-source biological products mitigates the potential confounding factors that would arise if the full set of Part D rebatable drugs were included in the GUARD Model test.

Further, CMS proposes in § 514.120(a) to limit the subset of sole-source drugs and sole-source biological products to those classified by the United States Pharmacopeia (USP) Drug Classification as belonging to certain categories selected by CMS. The categories

selected by CMS, hereinafter referred to as “USP selected categories” are proposed at § 514.120(e) and include the specific categories from the USP Drug Classification that correspond to all of the Part D protected classes and additional categories based on several considerations. The primary reasons for selection of these categories are that Medicare beneficiaries taking these drugs have conditions for which deficits in care exist and they represent a meaningful amount of spending under Part D.

a. Approach for Selecting Categories From the United States Pharmacopeia

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, 117 Stat. 2066 (2003), section 1860D–4(b)(3)(C)(ii) of the Act, the USP is required to develop and revise the Medicare Model Guidelines, which is a classification system used for the purpose of supporting Part D formulary development and submission. The Medicare Model Guidelines include a list of categories and classes that may be used by prescription drug plans; USP revises them on a continuous basis based on changes in therapeutic uses of covered Part D drugs and the additions of new covered Part D drugs.¹⁰⁸

CMS proposes at § 514.120(d) to use the ‘category’ field of the USP Drug Classification because CMS believes this field is sufficient to identify drugs and biological products for conditions where Medicare beneficiaries may experience deficits of care, while allowing for differences in mechanism of action and molecular or biological targets for products that treat the same therapeutic area. We recognize that a drug or biological product may be listed in more than one USP category. We propose at § 514.120(d) that as long as one of the categories selected for inclusion in the GUARD Model applies to the drug or biological product, it will be considered to have met this criterion and would be included in the GUARD Model.

CMS proposes at § 514.120(d) to identify the Part D rebatable drugs classified as belonging to one of the categories listed later in this Section of this proposed rule using their RxNorm¹⁰⁹ Concept Unique

identifier,¹¹⁰ active ingredient(s), NDC–9, or the FDA approved indication.

Using the current guidelines, the USP Medicare Model Guidelines v9.0,¹¹¹ CMS proposes at § 514.120(a) that a drug or biological product whose listed USP categories include at least one of the following USP selected categories (as defined at § 514.120(e)) would be included in the GUARD Model if they meet all other inclusion criteria and limited to the exclusion criteria proposed at § 514.120(c): Analgesics; Anticonvulsants; Antidepressants; Antimigraine Agents; Antineoplastics; Antipsychotics; Antivirals; Bipolar Agents; Blood Glucose Regulators; Cardiovascular Agents; Central Nervous System Agents; Gastrointestinal Agents; Genetic or Enzyme or Protein Disorder; Replacement or Modifiers or Treatment; Immunological Agents; Metabolic Bone Disease Agents; Ophthalmic Agents; and Respiratory Tract/Pulmonary Agents.

The proposed list of USP categories includes categories that correspond to the six Medicare Protected Classes (anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants) identified by CMS as those for which “all or substantially all” drugs must be covered by Part D plans.¹¹² The USP categories that correspond to the Medicare Protected Classes are Anticonvulsants, Antidepressants, Antineoplastics, Antipsychotics, Antivirals, Bipolar Agents, and Immunological Agents, as defined at § 514.5. The Bipolar Agents USP category has significant overlap with the Medicare Protected Classes of antidepressants and antipsychotics; thus, CMS considers Bipolar Agents to correspond with the Medicare protected classes and this category would be included in the GUARD Model. These USP categories that correspond to the protected classes are included because of their relevance for vulnerable

www.nlm.nih.gov/research/umls/rxnorm/index.html.

¹¹⁰ An RXCUI is a machine-readable code or identifier that points to the common meaning shared by the various source names grouped and assigned to a particular concept. A concept is a fundamental unit of meaning in RxNorm. <https://www.nlm.nih.gov/research/umls/rxnorm/overview.html>.

¹¹¹ The current guidelines can be found here: <https://www.usp.org/health-quality-safety/usp-medicare-model-guidelines>.

¹¹² Centers for Medicare & Medicaid Services. (2016). *Medicare Prescription Drug Benefit Manual: Chapter 6—Part D drugs and formulary requirements* (Rev. 18, Issued Jan. 15, 2016). U.S. Department of Health and Human Services. <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf> (Accessed: 10 December 2025).

¹⁰⁵ Government Accountability Office. (2023). *Medicare Part D: CMS should monitor effects of rebates on plan formularies and beneficiary spending* (GAO–23–105270). <https://www.gao.gov/assets/gao-23-105270.pdf>.

¹⁰⁶ Hernandez, I., et al. (2020). Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007–2018. *JAMA*, 323(9), 854–862. <https://doi.org/10.1001/jama.2020.1012>.

¹⁰⁷ Mulcahy, A.W., et al. (2024). *Prescription Drug Prices, Rebates, and Insurance Premiums*. RAND. https://www.rand.org/pubs/research_reports/RR1820-3.html (Accessed: 10 December 2025).

¹⁰⁸ Historically, every 3 years, the USP publishes an updated version of the Medicare Model Guidelines. The current guidelines can be found following this link <https://www.usp.org/health-quality-safety/usp-medicare-model-guidelines>.

¹⁰⁹ The National Library of Medicine (NLM) produces RxNorm. RxNorm provides normalized names and unique identifiers for medicines and drugs. The goal of RxNorm is to allow computer systems to communicate drug-related information efficiently and unambiguously. See <https://>

beneficiaries that depend on these drugs for serious conditions. Except for Anticonvulsants, among the Part D rebatable sole-source drugs and sole-source biological products, all of the USP selected categories that correspond to Medicare protected classes have 2024 total covered gross drug costs above \$1 billion.¹¹³ The top three spending categories that correspond to Medicare Protected Classes in 2024 are Immunological Agents, Antineoplastics, and Antivirals; for these categories, among Part D rebatable sole-source drugs and sole-source biological products, the total covered drug costs are \$32, \$30, and \$10 billion, respectively.

The proposed list also includes additional categories that correspond to drugs that are used for conditions for which Medicare beneficiaries experience deficits of care and that are within the top spending categories for the Part D Inflation Rebate Program based on previous spending trends. The additional USP selected categories (as defined at § 514.120(e)) are Analgesics; Antimigraine Agents; Blood Glucose Regulators; Cardiovascular Agents; Central Nervous System Agents; Gastrointestinal Agents; Genetic or Enzyme or Protein Disorder; Replacement or Modifiers or Treatment; Metabolic Bone Disease Agents; Ophthalmic Agents; and Respiratory Tract/Pulmonary Agents. Among the Part D rebatable sole-source drugs and sole-source biological products, in 2024, all of these USP selected categories have total covered gross drug costs above \$1 billion.¹¹⁴ The top two spending categories in 2024 were Blood Glucose Regulators and Respiratory Tract/Pulmonary Agents.

CMS proposes at § 514.120(d) that once CMS has identified the drug or biological product's category, it should remain in that category for the entire GUARD Model performance period. Accordingly, drugs or biological products will retain their category, while newly added drugs or biological products will retain the category assigned at the time of their identification, based on the USP Medicare Model Guidelines available at the time. Additionally, as defined at § 514.5, any change to the definition of Medicare Protected Classes in Chapter 6 section 30.2.5 from the Medicare Prescription Drug Benefit Manual would be carried over.

b. Addressing Deficits of Care Among Part D Enrollees

We propose these categories partly because Part D enrollees who take these drugs have conditions for which deficits of care are documented. For example, Part D beneficiaries who have immunological diseases (and therefore may take immunological agents), endocrine diseases (and therefore may take blood glucose regulators and metabolic bone disease agents), neurological diseases (and therefore may take analgesics, anticonvulsants, antimigraine agents, central nervous system agents) and chronic diseases (and therefore may take cardiovascular agents, gastrointestinal agents, respiratory tract and pulmonary agents), may experience affordability challenges related to their treatment.^{115 116 117} There is evidence that patients with autoimmune diseases such as rheumatoid arthritis and systemic lupus erythematosus, neurological disease such as multiple sclerosis and myasthenia gravis, and endocrine diseases such as diabetes mellitus, continue to experience financial burden.^{118 119 120}

Additionally, CMS analysis of the Medicare Current Beneficiary Survey (MCBS) finds that nine percent of Medicare beneficiaries reported that they decided *not* to fill a prescription in 2025 due to cost.¹²¹ Financial distress

associated with cost coping behaviors, such as rationing or skipping medicines or delaying care that could worsen health outcomes continues to raise concerns for providers treating a range of conditions. This includes, for example, providers treating autoimmune diseases such as systemic lupus erythematosus¹²² and neuromyelitis optical spectrum disorder,¹²³ endocrine diseases such as diabetes mellitus,¹²⁴ neurological diseases such as multiple sclerosis^{125 126} and myasthenia gravis,¹²⁷ and chronic diseases such as cardiovascular diseases^{128 129} and inflammatory bowel disease.¹³⁰

Although the GUARD Model does not directly impact Part D enrollees' out-of-pocket costs for these drugs, we believe the GUARD Model has the capacity to address deficits of care experienced by the populations who take the drugs that fall within these categories. The GUARD Model test requires a GUARD Model

¹²² Sandoval-Heglund, D., et al. (2024). Economic Insecurities and Patient-Reported Outcomes in Patients with Systemic Lupus Erythematosus in the USA: a cross-sectional analysis of data from the California Lupus Epidemiology Study. *Lancet Rheumatology*, 6(2), e105–e114. [https://doi.org/10.1016/S2665-9913\(23\)00296-5](https://doi.org/10.1016/S2665-9913(23)00296-5).

¹²³ Wingerchuk, D.M., et al. (2022). Aligning Payer and Provider Strategies with the Latest Evidence to Optimize Clinical Outcomes for Patients with Neuromyelitis Optica Spectrum Disorder. *Journal of managed care & specialty pharmacy*, 28(12–a Suppl), S3–S27. <https://doi.org/10.18553/jmcp.2022.28.12-a.s1>.

¹²⁴ Patel, M.R., et al. (2022). Measurement and Validation of the Comprehensive Score for Financial Toxicity (COST) in a Population with Diabetes. *Diabetes Care*, 45(11), 2535–2543. <https://doi.org/10.2337/dc22-0494>.

¹²⁵ Singer, B.A., et al. (2024). Early Use of High-Efficacy Therapies in Multiple Sclerosis in the United States: benefits, barriers, and strategies for encouraging adoption. *Journal of Neurology*, 271(6), 3116–3130. <https://doi.org/10.1007/s00415-024-12305-4>.

¹²⁶ Mizell, R. (2024). The Impact of Insurance Restrictions in Newly Diagnosed Individuals with Multiple Sclerosis. *International Journal of MS Care*, 26(1), 17–21. <https://doi.org/10.7224/1537-2073.2022-069>.

¹²⁷ Choi, S.A., et al. (2025). Health Care Costs and Resource Utilization Among Patients with Myasthenia Gravis in the United States. *Journal of Managed Care & Specialty Pharmacy*, 31(5), 472–481. <https://doi.org/10.18553/jmcp.2025.31.5.472>.

¹²⁸ Sukumar, S., et al. (2023). Financial Toxicity of Medical Management of Heart Failure: JACC Review Topic of the Week. *Journal of the American College of Cardiology*, 81(20), 2043–2055. <https://doi.org/10.1016/j.jacc.2023.03.402>.

¹²⁹ Wang, S.Y., et al. (2021). Out-of-Pocket Annual Health Expenditures and Financial Toxicity from Healthcare Costs in Patients with Heart Failure in the United States. *Journal of the American Heart Association*, 10(14), e022164. <https://doi.org/10.1161/JAHA.121.022164>.

¹³⁰ Nguyen, N.H., et al. (2021). National Estimates of Financial Hardship from Medical Bills and Cost-related Medication Nonadherence in Patients with Inflammatory Bowel Diseases in the United States. *Inflammatory Bowel Diseases*, 27(7), 1068–1078. <https://doi.org/10.1093/ibd/izaa266>.

¹¹³ CMS analysis using preliminary list of Part D rebatable drugs for 2024 and PDE data as of October 1, 2025.

¹¹⁴ CMS analysis using preliminary list of Part D rebatable drugs for 2024 and PDE data as of October 1, 2025.

¹¹⁵ Dusetzina, S.B., et al. (2022). Many Medicare Beneficiaries Do Not Fill High-Price Specialty Drug Prescriptions. *Health Affairs*, 41(4), 487–496. <https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2021.01742>.

¹¹⁶ San-Juan-Rodriguez, A., et al. (2019). Trends in Prices, Market Share, and Spending on Self-administered Disease-Modifying Therapies for Multiple Sclerosis in Medicare Part D. *JAMA Neurology*, 76(11), 1386–1390. <https://doi.org/10.1001/jamaneurol.2019.2711>.

¹¹⁷ Tarazi, W., et al. (2022). *Prescription Drug Affordability among Medicare Beneficiaries*. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. <https://aspe.hhs.gov/sites/default/files/documents/1e2879846aa54939c56feec9c6f96f0/prescription-drug-affordability.pdf> (Accessed: 15 December 2025).

¹¹⁸ Sandoval-Heglund, D., et al. (2024). Economic Insecurities and Patient-Reported Outcomes in Patients with Systemic Lupus Erythematosus in the USA: a cross-sectional analysis of data from the California Lupus Epidemiology Study. *Lancet Rheumatology*, 6(2), e105–e114. [https://doi.org/10.1016/S2665-9913\(23\)00296-5](https://doi.org/10.1016/S2665-9913(23)00296-5).

¹¹⁹ Weinstein, D.R., et al. (2022). Multiple Sclerosis: Systemic Challenges to Cost-Effective Care. *American Health & Drug Benefits*, 15(1), 13–20. <https://pubmed.ncbi.nlm.nih.gov/35586614/>.

¹²⁰ Khan, S., et al. (2025). Insulin Rationing Persists Despite Policy Changes: Repeated Cross-Sectional Studies, 2017 vs 2024. *Journal of General Internal Medicine*, 10.1007/s11606-025-09886-9. Advance online publication. <https://doi.org/10.1007/s11606-025-09886-9>.

¹²¹ Internal CMS analysis of Medicare Current Beneficiary Survey data collected May–July 2025 (Office of Enterprise Data and Analytics).

rebate payment, as described in Section IV.H. of this proposed rule, if a GUARD Model drug's Medicare net price is greater than an international benchmark. It is possible that in response to the alternative payment strategy tested under the model, manufacturers reduce their net price for a given drug, for instance by reducing launch prices for drugs that are likely to become GUARD Model drugs. If manufacturers decrease launch prices for GUARD Model drugs for the purpose of reducing their liability under the GUARD Model, it may have cascading effects. For example, such a response may benefit Part D plans, who may then change their benefit design and offerings for Part D plan enrollees and potentially reduce cost sharing for the drugs included in the GUARD Model.

It is also possible manufacturers respond to the GUARD Model by reducing the list prices of the drugs included in the model. A reduction of list prices would reduce a manufacturer's rebate liability under the GUARD Model. Given that the list price of drugs is used as a starting point for negotiations in the pharmaceutical drug supply chain, it is possible that a reduction in list prices may lead to a reduction in the out-of-pocket costs paid by Part D enrollees who take these drugs, particularly if the out-of-pocket cost is based on coinsurance instead of a flat copayment.

In sum, CMS proposes at § 514.5 that "GUARD Model drug" means, subject to the exclusions set forth in § 514.120(c), a Part D rebatable drug, as set forth in section 1860D–14B(g)(1) of the Act and defined in 42 CFR 428.20 and determined in 42 CFR 428.101, that is a sole-source drug or sole-source biological product as defined in § 514.100, has a USP category classification that includes at least one of the USP selected categories, as defined in § 514.120(e), and is identifiable by a unique NDC–9 for which a payment was made under Medicare Part D. This means that CMS proposes to limit the GUARD Model test to the subset of sole-source drug and sole-source biological products belonging to USP selected categories among the Part D rebatable drugs, with some exclusions. Focusing the GUARD Model test on sole-source drugs and source biological products allows the GUARD Model test to identify the impact of the model without having to consider and potentially adjust for the very different market dynamics between these different types of drugs. Additionally, selecting drugs in specific USP categories with deficits of care and high costs means the GUARD Model

focuses on drugs with the greatest potential for savings for the Medicare program and Part D enrollees. Moreover, the proposed approach allows for testing of the GUARD Model on a smaller subset of Part D rebatable drugs, which would generate learnings and insights that can help CMS understand how stakeholders may respond, even for drugs that are not included in the GUARD Model.

2. Proposed Exclusion of Certain Part D Rebatable Drugs

CMS proposes in § 514.120(a) to test the GUARD Model with a subset of Part D rebatable drugs, specifically, sole-source drugs and sole-source biological products belonging to the proposed selected therapeutic USP categories.¹³¹ CMS proposes to exclude from the GUARD Model, generics and biosimilar biological products. At § 514.5 we propose "generic" to mean, for the United States, a drug approved and marketed under an Abbreviated New Drug Application (ANDA) under section 505(j) of the FD&C Act; and "biosimilar biological product" to mean, for the United States, a biological product approved and licensed under a BLA under section 351(k) of the PHS Act. Given that the only generics that are Part D rebatable are sole-source generics, another way of stating the exclusion is that sole-source generics and any (sole- or multi-source) biosimilar biological products are excluded from the GUARD Model.

CMS proposes this exclusion because sole-source generics and biosimilar biological products experience very different market dynamics than sole-source drugs (the original drug product approved under an NDA)¹³² and sole-source biological products (the original biological product licensed under section 351(a) of the PHS Act).¹³³ This

¹³¹ From the USP Medicare Model Guidelines v9.0: Analgesics, Anticonvulsants, Antidepressants, Antimigraine Agents, Antineoplastics, Antipsychotics, Antivirals, Bipolar Agents, Blood Glucose Regulators, Cardiovascular Agents, Central Nervous System Agents, Gastrointestinal Agents, Genetic or Enzyme or Protein Disorder: Replacement or Modifiers or Treatment, Immunological Agents, Metabolic Bone Disease Agents, Ophthalmic Agents, and Respiratory Tract/Pulmonary Agents.

¹³² Could also be referred to as the reference listed drug to the generic, where "reference listed drug" means the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its ANDA according to 21 U.S.C. 314.3(b).

¹³³ Could also be referred to as the reference product to the biosimilar biological product, where "reference product" means the single biological product licensed under section 351(a) against which a biological product is evaluated in an application submitted under section 351(k) according to 42 U.S.C. 262(i)(4).

is consistent with our proposed policy to only include sole-source drugs (which excludes multi-source drugs due to them having generics) and sole-source biological products (which excludes multi-source biological products due to them having biosimilar biological products).

As explained in this Section previously, sole-source generics experience different market dynamics than sole-source original drugs. Specifically, their existence necessitates that patent protections on the original drugs have expired; their original counterparts may have ceased to be marketed (usually discontinued due to business reasons); they are typically at higher risk for disruptions in their supply; and they tend to be older drugs.^{134 135} For instance, sole-source generics have been singled out by FDA via the Competitive Generic Therapies pathway (created under the FDA Reauthorization Act of 2017); this pathway seeks to facilitate approval of sole-source generics with the goal being to impact their market dynamics via increased competition. CMS believes that it does not strengthen the GUARD Model test to include sole-source generics in the model because of their specific market dynamics.

Biosimilar biological products also experience different market dynamics compared to the original biological product. As stated earlier in this Section of this proposed rule, the entry of a biosimilar biological product results in a multi-source biological product market which results in competitive forces that shift consumption patterns, prices, and overall utilization of both the original biological product and other biosimilars (if they exist). As such, CMS proposes at § 514.120(c) that biosimilar biological products would be excluded from the GUARD Model. For sole-source biosimilar biological products, this would mean that the original biological product would have to no longer be marketed according to the FDA's NDC Directory. At time of this writing, there is no clear case of a sole-source biosimilar biological product in the United States; however, there is also no reason to believe that sole-source biosimilar biological products would behave any differently from sole-source

¹³⁴ McGeeney, J.D., et al. (2025) *Drug Shortages, 2018–2023*. Eastern Research Group, Inc. & Office of the Assistant Secretary of Planning and Evaluation, U.S. Department of Health and Human Services. <https://aspe.hhs.gov/reports/drug-shortages-2018-2023> (Accessed: 10 December 2025).

¹³⁵ Food and Drug Administration. (2019). *Drug Shortages: Root Causes and Potential Solutions*. U.S. Department of Health and Human Services. <https://www.fda.gov/media/131130/download> (Accessed: 10 December 2025).

generics in the market. For a sole-source biosimilar biological product to exist, patent protections on the original product would have to have expired; their original biologic products may have been discontinued; and we would expect them to be older drugs. As such, CMS believes that inclusion of sole-source biosimilar biological products would not strengthen the GUARD Model test.

CMS proposes at § 514.120(c) that the second exclusion would be based on whether a sole-source drug or biological product's application-level total gross covered prescription drug costs are below the GUARD Model minimum spend threshold, as discussed below in this Section of this proposed rule. "Application-level total gross covered prescription drug costs" is defined at § 514.100 as the sum of total gross covered prescription drug costs, as defined in 42 CFR 428.100, from Medicare Part D PDE data for all rebatable Part D drugs belonging to the same FDA application.

CMS believes that by using an application-level total gross covered prescription drug costs, the risk of gaming to keep a specific Part D rebatable drug below the threshold by, for example, applying for a new NDC–9 to reduce the total gross covered prescription drug spend of the original NDC–9 or by shifting formulary placement, is mitigated. At the same time, the approach considers total spending incurred by the Medicare Program on a GUARD Model drug by a manufacturer.¹³⁶

CMS proposes at § 514.100 that the "GUARD minimum spend threshold" means for the performance year beginning on January 1, 2027, an amount equal to \$69 million and for subsequent performance years, the minimum spend threshold is equal to the GUARD Model minimum spend threshold for the prior performance year increased by the percentage increase in the CPI–U¹³⁷ for the 12-month period beginning with January of the previous performance year, where a "subsequent performance year" means every performance year after the first. There are four, starting January 1 and ending on December 31 of 2028, 2029, 2030, and 2031, as defined at § 514.5. This

means that for each subsequent performance year, the GUARD minimum spend threshold would increase with inflation. CMS would use PDE data to check whether a potential GUARD Model drug is excluded from the GUARD Model due to the minimum spend threshold. CMS proposes at § 514.120(c) to examine PDE data for the application-level total gross covered prescription drug costs for the corresponding performance year. CMS proposes at § 514.120(c) that once a GUARD Model drug has exceeded the GUARD Model minimum spend threshold for a performance year during the GUARD Model performance period, they would no longer be subject to this exclusion for subsequent performance years. This means that a GUARD Model drug's minimum spend would *not* be checked annually.

CMS believes that setting a GUARD minimum spend threshold and comparing application-level total gross covered prescription drug costs against it reduces the risk of access-related challenges associated with the drug. In our analysis, we find that on average, across the 2024 Part D rebatable drugs that would be included in the GUARD Model if the model had been implemented in 2024¹³⁸ (using an application-level total gross covered drug cost above \$69 million), the included drugs would be associated with approximately \$188 million per drug in Part D spending.¹³⁹ Therefore, we believe applying a threshold of \$69 million that is adjusted for inflation annually thereafter means that manufacturers of GUARD Model drugs would have significant revenue from the Medicare Program and thus would likely remain in the Medicare program during the GUARD Model test.

CMS also believes that a threshold of \$69 million in the first performance year of the GUARD Model that is adjusted for inflation annually thereafter allows us to evaluate impacts to drugs above and below the threshold as part of the GUARD Model test. Specifically, applying the \$69 million GUARD minimum threshold to 2024 Part D rebatable drugs that would be included if the model had been implemented in

2024¹⁴⁰ results in 38 percent¹⁴¹ of sole-source drugs and sole-source biological products included in the GUARD Model test. Among the 2024 Part D rebatable drugs¹⁴² with an application-level total gross covered drug cost above \$69 million, each drug that would be included in the GUARD Model is associated with an average wholesale acquisition cost (WAC) of approximately \$47; and each drug excluded is associated with an average WAC of approximately \$14.¹⁴³ This analysis suggests that the GUARD minimum threshold, as applied to 2024 Part D rebatable drugs, results in the GUARD Model test directed towards more expensive drugs and biological products whose average gross covered prescription drug costs are significantly higher than the GUARD minimum threshold.

CMS believes that this threshold, in addition to the Part D Inflation Rebate Program applicable threshold¹⁴⁴ defined in 42 CFR 428.101, minimizes risk of disrupting access to drugs for several reasons. The GUARD minimum threshold supports the goal of having sufficient inclusion to adequately test the alternate payment strategy on a set of specific type of drugs (sole-source, high-expenditure drugs in specific USP selected categories). The Part D Inflation Rebate Program applicable threshold ensures that drugs with low per beneficiary gross drug costs which—given the low volume or price—could be affected disproportionately with a

¹⁴⁰ 2024 Part D rebatable sole-source drugs and sole-source biological products whose USP category is a USP selected category excluding generics, biosimilar biological products, and those subject to an MFP during the price applicability period.

¹⁴¹ CMS analysis using 2024 total gross drug costs and preliminary list of Part D rebatable NDC–9s (as of October 1, 2025). According to the GUARD Model drug definition and in alignment with the Part D Inflation Rebate Program, drugs are defined at the NDC–9 level, thus the percentage represents the number of NDC–9s included in the GUARD Model.

¹⁴² 2024 Part D rebatable sole-source drugs and sole-source biological products whose USP category is a USP selected category excluding generics, biosimilar biological products, and those subject to an MFP during the price applicability period.

¹⁴³ CMS analysis using 2024 total gross drug costs and preliminary list of Part D rebatable NDC–9s (as of October 1, 2025). The averages are a weighted average using total quantity dispensed as weights at the NDC–9 level.

¹⁴⁴ For the applicable period beginning October 1, 2022, the applicable threshold is equal to \$100. For the applicable period beginning October 1, 2023, the applicable threshold is equal to \$100 increased by the percentage increase in CPI–U for the 12-month period beginning October 1, 2023. For subsequent applicable periods, the applicable threshold is equal to the applicable threshold for the prior applicable period increased by the percentage increase in the CPI–U for the 12-month period beginning with October of the previous period.

¹³⁶ While it is possible for an application to change sponsor, during or after approval, there is one responsible party (the sponsor) for an application at a time. Any shifts in application ownership are notified to FDA, thus reflected in Orange or Purple Book, and would require a new NDC–9 and NDC codes are manufacturer-specific.

¹³⁷ If for a subsequent performance year, the resulting amount is not a multiple of \$10, CMS rounds that amount to the nearest multiple of \$10.

¹³⁸ 2024 Part D rebatable sole-source drugs and sole-source biological products whose USP category is a USP selected category excluding generics, biosimilar biological products, and those subject to an MFP during the price applicability period.

¹³⁹ CMS analysis using 2024 total gross drug costs and preliminary list of Part D rebatable NDC–9s (as of October 1, 2025).

change in payment strategy, are excluded from the GUARD Model because they are not Part D rebatable drugs.

In § 514.120(c), CMS proposes, as a third exclusion, that when the Part D payment is based on a maximum fair price (MFP) (as defined in section 1191(c)(3) of the Act), the Part D rebatable drug would be excluded from the GUARD Model. This means that drugs that are selected for the Medicare Drug Price Negotiation program (under Part E of Title XI of the Act (sections 1191 through 1198)) would be excluded from the GUARD Model when the negotiated MFP is in effect. Specifically, this proposal would mean that a GUARD Model drug that is selected for negotiation of an MFP would be removed from the GUARD Model on the date that the MFP goes into effect. For example, because the prices of the drugs selected for initial price applicability year 2028 go into effect on January 1, 2028, these set of drugs would not be included as GUARD Model drugs as of January 1, 2028.

Should a drug no longer have a negotiated MFP in effect, but still be covered under Medicare, and to the extent it continues to fulfill the GUARD Model inclusion requirements, the drug would be included in the GUARD Model. CMS believes that excluding drugs when the Medicare Part D payment is based on a negotiated MFP is appropriate because these drugs are subject to different market dynamics within the United States, and we believe that including them could confound the GUARD Model test. As such, we do not propose a waiver under this model related to the Medicare Drug Price Negotiation Program.

To maintain consistency with the definition of a Part D rebatable drug at 42 CFR part 428, we propose at § 514.120(e) that any changes to the definition of Part D rebatable drug at 42 CFR part 428 would be automatically carried over to the definition of a GUARD Model drug at Part 514.

In summary, for the purposes of the GUARD Model, CMS is defining a GUARD Model drug as proposed at § 514.120(a) as a Part D rebatable sole-source drug or biological product identified based on the Part D Inflation Rebate Program and whose assigned USP categories are within one of the USP selected categories listed previously in this Section of the proposed rule with some exclusions. The proposed exclusions are: (1) sole-source generics and any biosimilar biological products; (2) sole-source drugs or sole-source biological products whose annual application-level total

gross covered prescription drug costs are below the GUARD minimum spend threshold; and (3) sole-source drugs or sole-source biological products that are subject to an MFP during the price applicability period when the MFP is in effect. CMS believes that the proposed identification approach, along with the proposed exclusions covered in this Section of this proposed rule, would result in the inclusion of drugs and biological products that are used to treat a variety of conditions in the Part D enrollee population and are frequently sold at retail pharmacies, mail order pharmacies, and long-term care pharmacies.

We invite public comment on our proposed approach for defining a GUARD Model drug as discussed in this proposed rule. We are seeking comment on the inclusion and exclusion criteria for GUARD Model drugs, including the GUARD minimum spend threshold and the proposal to include drugs in the GUARD Model if they are included in one of the USP selected categories included in the GUARD Model.

3. Alternatives Considered

CMS considered including multi-source drugs and biological products, sole-source generic drugs, and biosimilar biological products in the GUARD Model. However, CMS believes that their market dynamics and pricing behaviors, as discussed previously, would generate variability that would hinder precision in the evaluation of the alternate payment strategy tested under the GUARD Model.

CMS also considered including additional USP categories beyond the ones proposed. Specifically, we considered including some additional categories based on their 2024 Part D total gross drug costs. For instance, CMS considered including the following additional USP categories due to each category having 2024 total covered gross drug costs for Part D rebatable sole-source drugs and sole-source biological products above \$1 billion: Blood Products and Modifiers, Dermatological Agents, Antibacterials, Electrolytes/Minerals/Metals/Vitamins, and Genitourinary Agents.¹⁴⁵ We also considered including all USP categories with Part D rebatable sole-source drugs and sole-source biological products that had any amount of Medicare Part D gross covered drug spending in 2024. This would result in the additional inclusion, besides the five USP categories already mentioned, of the

following USP categories: Antiparasitics, Dental and Oral Agents, Otic Agents, Antimycobacterials, Contraceptives, and Antispasmodic Agents. These additional six USP categories only amount to 1.6 percent of spending among Part D sole-source rebatable drugs and sole-source biological products. Finally, CMS also considered including in the USP selected categories list others such as Antidementia Agents, Inflammatory Bowel Disease Agents, and Skeletal Muscle Relaxants; and even considered not limiting inclusion for the GUARD Model by USP category and including all Part D rebatable drugs regardless of their USP category. However, CMS believes prioritizing the USP selected categories proposed at § 514.120(a)(2) is necessary because these categories represent drugs with high Part D gross drug spending and they treat conditions for populations that experience care deficits. We also considered excluding some of the proposed USP selected categories from the GUARD Model. For example, we considered excluding categories that correspond to the Medicare Protected Classes such as Anticonvulsants, or other categories such as Antimigraine Agents, Gastrointestinal Agents, and Metabolic Bone Disease Agents. However, we decided inclusion better serves the GUARD Model as the drugs in these categories are taken by populations that experience deficits of care. CMS seeks feedback on our approach, including whether additional categories should be included (and if so, which ones) or if there are any categories proposed that should be excluded. We also seek feedback on whether there are other approaches to identify the categories that we should consider.

CMS considered using the total gross covered prescription drug costs for an NDC-9 instead of the application-level total gross covered prescription drug costs to identify the GUARD minimum spend threshold. However, we decided not to propose any thresholds at the NDC-9 level due to concerns regarding gaming, particularly the possibility of a new NDC-9 being introduced without a significant change in the drug. CMS also considered basing the minimum spend threshold on the total gross covered drug costs accrued over a calendar year for all Part D rebatable drugs with the same combination of certain characteristics. These characteristics could include all or some of active ingredient, route of administration, and dosage form. However, this would mean the total summed covered gross drug costs would not necessarily all

¹⁴⁵ CMS analysis using preliminary list of Part D rebatable drugs for 2024 and PDE data as of October 1, 2025.

correspond to the same manufacturer. Therefore, CMS does not believe this is the best approach for identifying the GUARD minimum spend threshold.

Additionally, CMS considered determining the application-level or other aggregate levels of total covered gross costs for comparison with the GUARD minimum spend threshold using all Part D drugs not just those that qualify for the Part D Inflation Rebate Program. However, CMS believes that, given that the GUARD Model is testing an alternative calculation for the Part D inflation rebate calculation, it is appropriate to use the total covered gross costs from Part D rebatable drugs.

CMS also considered evaluating whether a GUARD Model drug's application-level total covered gross costs exceeds the GUARD Model minimum spend threshold for every performance year instead of only for the first performance year that the drug is being considered for inclusion as a GUARD Model drug. However, in the interest of stability and transparency regarding which drugs or biological products are GUARD Model drugs and given the modest 5-year duration of the GUARD Model performance period, CMS decided against this. CMS welcomes comments on the proposed approach and the alternatives considered.

In proposing the GUARD minimum spend threshold, CMS considered all amounts between \$24.4 and \$127 million since these amounts would result in 50 and 30 percent of Part D rebatable sole-source drugs and sole-source biological products after GUARD Model exclusions being included.¹⁴⁶ A GUARD minimum spend threshold lower than \$24.4 million would result in the set of drugs and biological products included being too broad and CMS believes that it benefits the GUARD Model to focus the model test on a narrower set of drugs for conditions with observed deficits of care and those with higher costs. A GUARD minimum spend threshold higher than \$127 million would result in a set of drugs included too narrow; CMS believes this is an insufficient number of drugs and biological products for the GUARD Model test to be informative.

CMS also considered not inflation adjusting the \$69 million GUARD

minimum threshold for each subsequent performance year after the first performance year; however, we believe that given the specific characteristics of the Part D program, inflation adjustment is necessary.

Additionally, CMS considered beginning the GUARD Model with a limited set of drugs, ranging from only a set number of top spending drugs or starting with a small subset of drugs and phasing drugs in over time. Concerns around administrative burden, competitive disadvantages, operational complexity, and insufficient sample for evaluation of the model contributed to our decision not to employ these alternative approaches. CMS believes that beginning the GUARD Model with a subset of Part D rebatable drugs that allows for exclusions is a transparent, consistent, and clear approach that would provide sufficient opportunity for CMS to observe a wide range of manufacturer behavior with respect to drug pricing, increasing the generalizability of the evaluation findings.

We believe the benefits of including a subset of Part D rebatable drugs in the GUARD Model with some exclusions, as discussed in this Section of this proposed rule, outweigh the benefits of initiating the GUARD Model with greater or fewer Part D rebatable drugs. We seek comments on our proposed approach, including the inclusion of only sole-source drugs and biological products from selected therapeutic areas;¹⁴⁷ the exclusion of sole-source generics and biosimilar biological products; the exclusion of drugs whose annual application-level total gross covered prescription drug cost are below the GUARD minimum spend threshold; and the exclusion of drugs subject to an MFP during the price applicability period.

4. GUARD Model Drug Units

We propose at § 514.125(a) that the GUARD Model include every GUARD Model drug unit, with some exceptions, as defined at 514.5 and described in this section of the proposed rule, dispensed based on Part D PDE records for GUARD Model drugs that are furnished to Part D enrollees who reside in "GUARD Model geographic areas" as defined by

§ 514.5, which means the geographic areas, defined by Zonal Improvement Plan Code Tabulation Areas (hereinafter ZCTAs; see Section IV.C. of this proposed rule for details), selected for participation in the GUARD Model in accordance with § 514.110(d), and who are part of the GUARD Model beneficiary population (as described in section IV.C. of this proposed rule). We propose to use the PDE data to identify GUARD Model drug and drug units because it is the prescription drug cost and payment data that enables CMS to administer the Part D benefit and records all prescription drug events for drugs covered under the Part D program.

We propose at § 514.125(b) that the following drug units would be excluded from the GUARD Model: drug units for which payment is subject to an agreement under 340B.

C. Proposed Model Test Design, Geographic Selection, and Beneficiary Population

Section 1115A(b) of the Act gives the Secretary discretion in the design of models, including the geographic reach of models. Section 1115A(a)(5) of the Act states that the Secretary may elect to limit testing of a model to certain geographic areas. In this section, we describe the proposed model test design, including the geographic selection approach, and the defined beneficiary population that would be included in the GUARD Model.

1. Proposed Model Test Design and Identification of Geographic Areas

At § 514.110(d), we propose a randomized design in which the GUARD Model geographic approach will be determined by selection of geographic areas where GUARD Model beneficiaries reside, as determined by CMS. Model test geographic areas would be randomly selected to balance the Part D population and Medicare expenditures nationwide. Later in this Section of the proposed rule, we propose the process by which CMS would identify the model cohort and propose that, prior to the model start, CMS would randomly identify the model geographic areas. We also propose at § 514.130(e) that the identification of included beneficiaries and the timing of such identification, as well as the identification of a comparison group, would be performed by CMS and would not be subject to administrative or judicial review.

CMS proposes to establish the unit of geography for evaluation of GUARD Model impacts based on identifying existing well-defined geographic units that are sufficiently numerous to

¹⁴⁶ CMS analysis using 2024 total gross drug costs and preliminary list of Part D rebatable NDC-9s (as of October 1, 2025). Part D rebatable sole-source drugs and sole-source biological products whose USP category is a USP selected category excluding generics, biosimilar biological products, and those subject to an MFP during the price applicability period. Drugs and biological products analyzed at the NDC-9 level.

¹⁴⁷ From the USP Medicare Model Guidelines v9.0: Analgesics, Anticonvulsants, Antidepressants, Antimigraine Agents, Antineoplastics, Antipsychotics, Antivirals, Bipolar Agents, Blood Glucose Regulators, Cardiovascular Agents, Central Nervous System Agents, Gastrointestinal Agents, Genetic or Enzyme or Protein Disorder: Replacement or Modifiers or Treatment, Immunological Agents, Metabolic Bone Disease Agents, Ophthalmic Agents, and Respiratory Tract/ Pulmonary Agents.

support statistical analysis. Based on CMS' review of existing defined geographic units that are suitable for statistical purposes, CMS, after consideration of alternatives, proposes at § 514.110(d) that ZCTAs would be an appropriate geographic unit to randomly select geographic areas included in the GUARD Model. At § 514.100, CMS defines "ZCTAs" to mean approximate area representations of U.S. Postal Service 5-digit Zonal Improvement Plan (ZIP) Code service routes that the U.S. Census Bureau creates using whole blocks to present statistical data from censuses and surveys, where "ZIP Code" means a trademark of the USPS created to coordinate mail handling and delivery. The USPS assigns ZIP Code ranges to regional post offices, which in turn assign ZIP Codes to delivery routes. ZCTA's are a geographic product of the U.S. Census Bureau, created to allow mapping, display, and geographic analyses. They are both numerous and small in size. ZCTAs are generalized and real representations of the geographic extent and distribution of the U.S. Postal Service 5-digit ZIP Code service routes that the U.S. Census Bureau creates using whole blocks to present statistical data from censuses and surveys. The ZIP Code used for beneficiary enrollment in Medicare can be linked to ZCTAs.

CMS believes that because of their small size and large numbers, the random assignment of ZCTAs to define the GUARD Model geographic area and the associated GUARD Model beneficiaries would enable CMS to achieve the desired balance in the counts of beneficiaries, Part D spending, and prescription drug utilization between the intervention and comparison arms of the GUARD Model within the country, within the Part D Plan regions, and within Part D plans. In addition, ZCTAs are small enough to allow CMS to randomly select the GUARD geographic area and the associated GUARD Model beneficiaries to ensure balance in the number of beneficiaries included in the GUARD Model for each Part D plan.

The proposed design of the model would reduce the potential for unintended interactions resulting from the geographic selection approach. Under this proposed design, the beneficiary is assigned to the GUARD geographic area based upon the ZCTA linked to their enrollment data and not where the beneficiary would fill their prescription, limiting beneficiary incentives to switch pharmacies. For example, when a beneficiary is assigned to a non-GUARD Model geographic area, their prescription fill, even if for a

GUARD rebatable drug at a pharmacy located in a GUARD Model geographic area, would not be subject to the intervention. Also, because beneficiary assignment to a GUARD Model geographic area or non-GUARD Model geographic area would not change with a change in residence, the measurement of outcomes to be evaluated in the proposed model would not be dependent upon the size of the geographic area. Therefore, randomizing a geographic area that is small and numerous, such as a ZCTA, would enable balance of measured and unmeasured characteristics of the geography, the associated resident population, and pharmacies and other dispensing entities that may be associated with this model.

CMS has considered the variation in GUARD Model drugs with respect to cost and use in the Medicare population and proposed at § 514.110(d) that the ideal allocation between GUARD Model and non-GUARD Model regions for operational fairness is to allocate based on a 1:3 ratio. That is, the GUARD Model should be tested with approximately 25 percent of Medicare beneficiaries. A simple random selection of 25 percent of ZCTAs would result in the selection of approximately 25 percent of Medicare Part D enrollees representing approximately 25 percent of Medicare Part D spending. The geographic area would be varied, and a representative selection of urban and rural areas are expected to be included. CMS proposes this policy because a simple random selection at the ZCTA level would enable about a quarter of nearly every Part D plan sponsors' beneficiaries to be in the GUARD Model and three-quarters would be in the comparison group (and therefore, not subject to the GUARD Model test).

2. Proposed Unit of Analysis and Defined Population

In designing the proposed GUARD Model, CMS determined that conducting the proposed GUARD Model test in the population of beneficiaries residing in GUARD Model geographic areas would provide the best means for testing the alternative rebate mechanism.

CMS proposes in § 514.130(a) to identify a GUARD Model beneficiary as a Part D enrollee who "*resides within the GUARD Model geographic area*", which means according to § 514.100, that the beneficiary's home address as recorded in CMS' Medicare Enrollment Database [or CMS' Medicare Beneficiary Database (MDB) System] is within the set of ZIP Codes linked to ZCTAs selected for the GUARD Model

geographic areas in the U.S., excluding U.S. territories as identified in § 514.110. In § 514.5, CMS proposes to define a "GUARD Model beneficiary" as an individual who is enrolled in a Part D plan, either in a standalone prescription drug plan (PDP) or Medicare Advantage prescription drug (MA-PD) plan, but not in an Employer Group Waiver Plan (EGWP), and who resides in a GUARD Model geographic area as determined by the beneficiary's address of record with Medicare. CMS proposes at § 514.130(a) that Part D enrollees who do not have Medicare as their primary payer or are enrolled in EGWPs would be excluded from the GUARD Model. Therefore, the "GUARD Model beneficiary population" is defined in this proposed rule at § 514.5, to include all Part D enrollees (with the exception of those who are enrolled in an EGWP) who are furnished with a GUARD Model drug as identified in Medicare Part D PDE data within the GUARD Model performance period and who reside within a GUARD Model geographic area.

CMS proposes in § 514.130(b) that 30 calendar days prior to the start of the model, CMS would identify a beneficiary as a GUARD Model beneficiary. Periodically thereafter, but no more than weekly, CMS would identify eligible GUARD Model beneficiaries who would be subsequently aligned to the model. GUARD Model beneficiaries would be aligned to the model until the model ends, or the beneficiary is no longer enrolled in Part D. If a GUARD Model beneficiary's address as recorded in CMS' MBD changes (that is, they no longer reside within the GUARD Model geographic areas) they would continue to be aligned to the model, as proposed in § 514.110(d). Beneficiaries who become newly enrolled in Medicare Part D plans and are identified by CMS as GUARD Model beneficiaries (because all criteria are met) would be aligned to the GUARD Model; these beneficiaries (and any relevant drug units) would be included in the GUARD Model rebate payment calculations from the time that they newly enroll in Medicare Part D, if all criteria are met. Beneficiaries for whom Medicare switches from being a secondary payer to being the primary payer and are identified by CMS as a GUARD Model beneficiary (because all criteria are met) would be aligned to the model cohort at the time that they switch, according to § 514.130(c). No other beneficiaries would be aligned to the GUARD Model after the model starts. For example, the following changes would not enable beneficiary

alignment to the GUARD Model after the model starts: (1) beneficiaries who were enrolled in Medicare at the time CMS identifies the initial cohort prior to the start of the model and had an MBD address in a non-GUARD Model geographic area then had an address change to a GUARD Model geographic area; and (2) newly enrolled Medicare Part D beneficiaries with an address with a new ZIP Code that did not exist at the time that the GUARD Model geographic areas were identified.

Defining the population broadly and in a manner that fosters a stable and consistent model cohort would allow CMS to observe the implications of an alternative approach to determining the GUARD Model rebate payment for GUARD Model drugs across a broad set of manufacturers and beneficiaries. If this proposed rule is finalized, the GUARD Model geographic areas would be identified in a table that lists the model test areas, total number of Medicare beneficiaries at the time of analysis, and any other relevant information no later than 60 calendar days in advance of the beginning of the GUARD Model performance period. This table would be shared on the GUARD Model website. Defining the population in this manner would allow CMS to assess if the GUARD Model payment test reduced Medicare costs while preserving or enhancing quality of care, in line with section 1115A(b)(2) of the Act, across a broad set of pharmacies and other dispensing entities and Part D enrollees, as well as a large set of manufacturers. Lessons learned from the GUARD Model would inform CMS and other interested parties about the effect of applying the proposed alternative rebate approach to a broader set of drugs on Part D enrollees and to the Medicare program.

3. Alternatives Considered

CMS considered initiating the model with a greater number of geographic areas to include up to approximately 50 percent of Part D beneficiaries in the model beneficiary cohort instead of our proposal to test the model with approximately 25 percent of Part D beneficiaries. We also considered an approach of initially testing the model with approximately 25 percent of Part D beneficiaries and then after initial monitoring observations are assessed, increasing the model beneficiary cohort to include up to approximately 50 percent of Part D beneficiaries. We note that these alternatives would likely necessitate selection of the initial and potentially additional geographic areas at the same point, prior to model start. These approaches would have the

benefit of enhancing the model evaluation as a random selection of approximately 50 percent of the Medicare Part D population would enable a 1:1 allocation of treatment to comparison. We also considered approaches that CMS could follow to identify when and how the included geographic areas and beneficiary cohort could be increased to include up to 50 percent of Part D beneficiaries. One option is that CMS could increase the beneficiary cohort at different points throughout the model, depending on observed data. For example, based on the first 6 months of data, if new patient access or supply chain constraints do not appear or do not appear to be attributed to the GUARD Model, CMS could increase the size of the model cohort later in the model test period. CMS could continue to periodically monitor available data and consider whether to increase the geographic areas included in the model. However, we decided against these approaches because we believe testing the GUARD Model with 25 percent of Medicare Part D enrollees across randomly selected geographic areas is sufficient for CMS to glean learnings on the impacts of the model. We seek feedback on this approach.

We also considered the following geographic areas as the geographic unit from which beneficiaries would be included in the model requirements: (1) ZIP Codes; (2) counties; (3) states; (4) Census-defined Core Based Statistical Areas (CBSAs) or Combined Statistical Areas (CSAs); and (5) Part D Plan regions. ZIP Codes were considered because they are the basis for determining beneficiary residence. However, ZIP Codes, unlike ZCTAs are not technically geographic areas, but delivery routes for the U.S. Postal Service, and they are not Census-designated regions. Counties, states and CBSAs were determined to be too heterogeneous in their size and population to achieve the desired balance between intervention and comparison groups for the proposed design. Part D Plan regions were considered to reduce operational complexity but also were determined to be too large and heterogeneous. CMS determined that these candidates would likely fail to achieve the desired balance in the counts of beneficiaries, Part D spending, and prescription drug utilization between the intervention and comparison arms of the GUARD Model within the country, within the Part D Plan regions, and within Part D plans. We welcome comment on this proposal and the alternatives considered.

We considered including the ZCTAs of U.S. territories among the geographic regions from which the randomly selected model geographic area would be selected. However, due to operational considerations, we decided to exclude U.S. territories. We seek feedback on this exclusion.

We also considered randomly selecting plans as the unit from which Part D drugs would be subject to the model requirements. This would enable plans to have a uniform consideration of how rebates would apply across all their beneficiaries. This, however, could reduce operational fairness across plans nationally so we decided against this approach. We welcome comment on our proposal to select ZCTAs as our geographic unit of analysis.

In addition, we considered whether to include beneficiaries who are enrolled in an EGWP. We decided against this, however, because there are differences in the data that is available for these enrollees compared to beneficiaries enrolled in standalone PDPs and MA-PDs and because we believe this group could serve as an important counterfactual for subgroup analysis in the evaluation. We seek feedback on this proposed policy.

We welcome comment on all of our policy proposals presented here, including proposals to test the model in geographic areas to cover 25 percent of Part D beneficiaries in the GUARD Model beneficiary population and whether CMS should test the model with an alternative approach that would include additional geographic areas, different geographic selection units, U.S. territories, and additional beneficiaries in the model.

D. GUARD Model Participants

1. Proposed Participants

At § 514.110(a), CMS proposes that manufacturers would be the participants of the GUARD Model. CMS proposes at § 514.5 that “manufacturer” would have the same meaning as that term is defined and used in § 428.20 and section 1927(k)(5) of the Act. We note that this is consistent with how CMS defines manufacturer for the purposes of the Part D Inflation Rebate Program. We propose to define at § 514.5 “GUARD Model participant” as a manufacturer of a GUARD Model drug that receives a Part D inflation rebate report for an applicable period that overlaps with the GUARD Model performance period.

At § 514.110(a), CMS proposes that all manufacturers that receive a Part D inflation rebate report including a GUARD Model drug for an applicable period that overlaps with the GUARD

Model performance period would be required to participate in the GUARD Model. There would be no specific enrollment activities for GUARD Model participants; rather, their participation will be effectuated through the requirements under the Part D Inflation Rebate Program, and where applicable, the application of the proposed GUARD Model rebate payment, as described in section IV.H. of this proposed rule.

CMS believes that this proposal to require participation of manufacturers is necessary to conduct the GUARD Model test and comprehensively understand the potential impacts of the model. Mandatory participation can enhance the generalizability of model results, as mandatory model participants may be more broadly representative of all organization types that could be affected by a model. With a mandatory participation policy, CMS would be able to observe the experience of manufacturers with a diverse range of characteristics—including, for example, large and small manufacturers—as well as manufacturers with varying corporation structures; difference in penetration within the United States and global markets; differences in global pricing approaches; and differences in marketing strategies. Additionally, CMS believes that despite the potential opportunity under the GUARD Model to lower the Part D program's financial liability and potentially reduce Part D enrollees' financial barriers to access GUARD Model drugs, which could, in turn, increase U.S. sales of such drugs, manufacturers of the proposed GUARD Model drugs would likely not volunteer to participate in the GUARD Model, which would threaten the model test. Therefore, CMS believes that mandatory participation of manufacturers is essential to carrying out the GUARD Model test.

CMS invites comment on our proposal for mandatory participation in the GUARD Model by manufacturers of GUARD Model drugs. We also seek feedback on whether manufacturers of proposed GUARD Model drugs would voluntarily participate in the proposed GUARD Model absent a mandatory participation requirement while still allowing for a robust test and evaluation during performance year 1 and thereafter.

2. Mandatory Participation Requirements

CMS proposes that model participation would be mandatory for all manufacturers that receive a Part D inflation rebate report including a GUARD Model drug during an applicable period that overlaps with the

GUARD Model performance period. In § 514.110(b) and (c), we propose the GUARD Model participant requirements during and after the GUARD Model performance period and payment years.

During the GUARD Model performance period and payment years, CMS proposes that GUARD Model participants must—

- Adhere to the proposed GUARD Model rebate invoicing and payment instructions as proposed in § 514.610 and established by CMS and its contractors responsible for providing GUARD Model rebate reports and invoices and processing GUARD Model rebates, including without limitation those described in proposed § 514.640 to ensure appropriate and accurate GUARD Model rebate payments.

- Participate in GUARD Model monitoring and evaluation activities in accordance with 42 CFR 403.1110(b), including collecting and reporting of information as the Secretary determines is necessary to monitor and evaluate the GUARD Model.

- If voluntarily electing to submit manufacturer reported international drug net pricing data, adhere to the requirements set forth in § 514.310 and the GUARD Model data agreement set forth in § 514.310(b)(1).

After the GUARD Model performance period and payment years, we propose that GUARD Model participants must—

- Adhere to the proposed GUARD Model rebate invoicing and payment instructions as proposed in proposed § 514.610 and established by CMS and its contractors responsible for providing GUARD Model rebate reports, processing GUARD Model rebates, including without limitation those described in proposed § 514.640 to ensure appropriate and accurate GUARD Model rebate payments.

- Participate in GUARD Model monitoring and evaluation activities in accordance with 42 CFR 403.1110(b), including collecting and reporting of information as the Secretary determines is necessary to monitor and evaluate the GUARD Model.

- If electing to submit international net drug pricing data, adhere to the requirements set forth in § 514.310 and the GUARD Model data agreement set forth in § 514.310(b)(1).

- Continue GUARD Model rebate payment reconciliation activities as proposed in § 514.640.

We seek comment on our proposal for model participation requirements for GUARD Model participants.

E. Proposed Existing International Drug Pricing Data and Reference Countries

Under the GUARD Model, as described in section IV.G. of this proposed rule, CMS will test two approaches to calculating the GUARD Model international benchmark: Method I referred to as the GUARD Model default international benchmark, and Method II, referred to as the GUARD Model updated international benchmark. This Section of this proposed rule discusses the existing sources for international drug pricing data and the selection process of an international drug pricing data source that CMS proposes to use, if available, to calculate the GUARD Model default international benchmark for each GUARD Model drug. We also describe our proposals to identify the set of reference countries that would be used to identify the GUARD Model international benchmark, both for the default and the updated international benchmarks.

1. Existing Data Sources for International Drug Pricing Data

CMS proposes that the selected data source for a specific GUARD Model drug must contain international drug pricing data for that specific GUARD Model drug's set of international analogs. We propose, at § 514.5, to define “set of international analogs” to mean, for each GUARD Model drug, the set of international products sold in all reference countries, identified in § 514.220(d) and as discussed later in this Section of this proposed rule; and, we define “international product” to mean a drug or biological product, sold in a reference country (where “reference country” means the countries identified in § 514.220(d) and discussed later in this Section of this proposed rule), that is aligned across its identifying characteristics with a GUARD Model drug. The identifying characteristics are specific to each GUARD Model drug (which in accordance with § 514.120(a), is identified at the NDC-9 level) and include active ingredient(s), route of administration, dosage form, and strength. Alignment across identifying characteristics, according to § 514.410 and as discussed in section IV.G. of the proposed rule, allows for adjustments that do not materially modify the nature of the drug but account for country-specific differences, such as differences due to language, units of measurement, labeling standards, or differences in dosage form or strength. The international drug pricing data for international analogs would then be used to determine, for each GUARD

Model drug, the GUARD Model default international benchmark, as described in section IV.G. of this proposed rule, which would be used to calculate the GUARD Model rebate payment, which is described in section IV.H. of this proposed rule.

To calculate the GUARD Model default international benchmark as described in section IV.G. of this proposed rule and proposed at § 514.410, CMS proposes to use existing data sources as proposed in § 514.210 available to CMS that contain international drug pricing data, including coordinated prices and volume data, coordinated sales and volume data, or only prices.

Within the available data sources with international drug pricing data that CMS proposes to use, sales may be based on ex-manufacturer prices (sometimes referred to as ex-factory price) that represent actual or calculated prices paid to the manufacturer by wholesalers and other distributors, retail prices, prices for other distribution channels, or a combination thereof. Confidential manufacturer rebates to payers and other off-invoice payments would not likely be accounted for within this data as this data does not typically represent net prices. Therefore, existing sources for international drug sales data may differ from net prices realized by manufacturers. However, CMS believes the existing data sources are adequate for purposes of identifying country-level average prices. At § 514.5, “country-level average price” is defined for a reference country identified in § 514.220(d), as the average or weighted-average unitary price for the international products sold in the specific reference country that are part of a GUARD Model drug’s set of international analogs, where the unit is the lowest dispensable amount of the GUARD Model drug expressed in terms of National Council for Prescription Drug Program (NCPDP) units.¹⁴⁸ If the selected data source (according to the requirements and selection criteria proposed at § 514.210(b) and (c)) includes international drug pricing information on volume, then the country-level average price is a weighted-average where the weights are the corresponding volume for a price expressed in the terms of the NCPDP

unit corresponding to the GUARD Model drug. The country-level average prices would serve as the basis for the GUARD Model default international benchmark, as described in section IV.G. of this proposed rule, and CMS would select, among these, the lowest country-level price, as described in section IV.G. of this proposed rule. In addition, manufacturers would have the option to voluntarily submit international drug net pricing data to CMS that would potentially be used to identify the GUARD Model updated international benchmark, as described in sections IV.F and IV.G. of this proposed rule.

We identified and assessed several existing data sources to confirm the availability and sufficiency of international drug pricing data for the implementation of the GUARD Model. Specifically, we reviewed proprietary global drug pricing data sources that include drug pricing data for a large diverse set of pharmaceutical products, including the types of pharmaceutical products that could be covered under Part D, for more than 30 countries. These data sources vary with respect to the scope (such as products, manufacturer level, market level data, countries), and periodicity of updates (such as daily, monthly, quarterly).

One existing data source evaluated by CMS was IQVIA’s MIDAS[®],¹⁴⁹ which is an IQVIA proprietary information service which integrates IQVIA’s national audits into a globally consistent view of the pharmaceutical market, and provides estimated product volumes of registered medicines, trends and market share through retail and non-retail channels. IQVIA MIDAS¹⁵⁰ includes detailed drug product information such as brand name, molecule, strength, dosage form, pack characteristics, manufacturer, regulatory approval, and intellectual property protection statuses. For each of the drug products, it also has sales and volume amounts by country, distribution channel (for example, retail or hospital), and calendar quarter. IQVIA’s MIDAS is updated monthly and retains extensive historical data for over 90 countries.

¹⁴⁹ The statements, findings, conclusions, views, and opinions contained and expressed in this research article are based in part on data obtained under license from the following IQVIA information service(s): IQVIA MIDAS[®]. Copyright IQVIA. All rights reserved. The statements, findings, conclusions, views and opinions contained and expressed herein are not necessarily those of IQVIA or any of its affiliated or subsidiary entities.

¹⁵⁰ IQVIA. (n.d.) *IQVIA MIDAS Overview*. <https://www.iqvia.com/solutions/commercialization/data-and-information-management/midas> (Accessed: 10 December 2025).

Another potential data source we assessed is Global Data Pharmaceutical Prices (POLI)¹⁵¹ data which includes prices for at least 80 countries at the pack level (pharmaceutical name, generic name, dosage form, strength, and number of units). POLI includes drug product information (such as drug descriptor, molecule type, dosage form, strength, and classification as brand or generic) and market information (such as therapeutic area and geography). POLI is updated monthly and provides historic data since 2016. Eversana NAVLIN’s Price & Access database,¹⁵² includes pricing data for more than 100 countries, as well as tools to compare international pricing (specifically, pricing across countries), and is another potential data source.

CMS believes any of these three data sources would provide adequate information in a timely way to inform CMS’ determination of the GUARD Model default international benchmark for the vast majority of proposed GUARD Model drugs. Therefore, CMS has confirmed the availability and sufficiency of at least three international drug pricing data sources for the implementation of the GUARD Model and we acknowledge that it is possible for other international drug pricing data sources to be utilized for the determination of the GUARD Model default international benchmark.

CMS proposes at § 514.210(a) to identify data sources of international drug pricing data for each GUARD Model drug’s set of international analogs that are sold in the reference countries identified in § 514.220(d) for purposes of calculating the GUARD Model default international benchmark, prior to the GUARD Model rebate payment calculation for the first performance year. During subsequent performance years, for any GUARD Model drug that was not a GUARD Model drug in any of the previous performance years, CMS proposes to identify data sources of international drug pricing data for each of these GUARD Model drug’s set of international analogs that are sold in the reference countries identified in § 514.220(d) for purposes of calculating the GUARD Model default international benchmark, prior to the GUARD Model rebate payment calculation for the corresponding subsequent performance year.

¹⁵¹ Global Data. (n.d.) *Data Lake—Pharmaceutical Prices (POLI)*. <https://marketaccess.globaldata.com/product-solutions/data-lake-pharmaceutical-prices-poli/> (Accessed: 10 December 2025).

¹⁵² NAVLIN by Eversana. (n.d.). *Navlin*. <https://www.navlin.com/> (Accessed: 10 December 2025).

¹⁴⁸ To assist in consistent and accurate billing of pharmaceutical products, NCPDP developed the Billing Unit Standard (BUS). The standard contains three billing units: EA, ML and GM. CMS also requires reporting of unit type for purposes of rebates in the Medicaid Drug Rebate Program. When possible, the NCPDP billing unit and CMS unit type should be aligned. https://standards.ncdpd.org/Standards/media/pdf/BUS_fact_sheet.pdf.

CMS proposes in § 514.210(c), for each GUARD Model drug, to select a data source that CMS has access to, has international drug pricing information and fulfills the following five criteria (proposed at § 514.210(b)).

First, the data source(s) must incorporate and apply standardized approaches within and between countries to consistently define drug products in terms of their active ingredient(s), route of administration, dosage forms, and strengths. This criterion means a data source must have the following elements.

- A standardized active ingredient naming scheme, such as using an internationally recognized set of scientific (nonproprietary) names (for example, International Nonproprietary Names¹⁵³ (INN) names).
- A standardized method to differentiate between dosage forms (including route of administration) of drug products such as using an internationally recognized nomenclature for pharmaceutical dosage forms like the New Form Code classification.
- A standardized method for differentiating between different dosage strengths of drug products in terms of different strength units that can reliably be converted to and expressed in terms of NCPDP units—the units used in Part D.

This first criterion is necessary because the process that CMS proposes to calculate the GUARD Model default international benchmark, as discussed in section IV.G. of this proposed rule, requires international drug pricing data to be aligned with each GUARD Model drug across active ingredient, route of administration, dosage form, and strength.

Second, the data source(s) must use and apply a standardized approach based on country-specific regulatory approval pathways that, at a minimum, distinguishes international generics and international biosimilar biological products¹⁵⁴ At § 514.5 CMS proposes “international generic” to mean, for a reference country identified in § 514.220(d), a drug approved and marketed in a reference country under

that reference country’s regulatory framework under a pathway similar to section 505(j) of the FD&C Act in the United States; and “international biosimilar biological product” to mean, for a reference country identified in § 514.220(d), a biological product approved and licensed in a reference country under that reference country’s regulatory framework under a pathway similar to section 351(k) of the PHS Act in the United States. If the data source does not directly differentiate approval pathways but has other factors that can allow for this differentiation to be implemented, CMS will evaluate the specific case and may consider the criterion fulfilled. For instance, it is possible that the data source includes a standardized approach based on country-specific regulations to identify products with or without brand names, with or without intellectual property protection (for example, patents), or as single-source or multi-source products depending on the extent of competition in each market.

Third, the data source(s) must contain either: (1) coordinated international drug price data and volume data; (2) coordinated international drug sales and volume data that can be used to calculate prices; or (3) drug price data. Such data must be expressed in a standardized manner (for example, with appropriate and clearly defined volume and monetary units). For volume data, this means the quantity of units where the lowest dispensable amount is or can be converted into NCPDP units. For price or sales data, this means a price or sales amount corresponding to a volume that is recorded in a standardized currency across countries within that data source. Such data must also be accompanied by written or other structured descriptions of the methods underlying the generation of the data, including conversion and projection factors.

Fourth, the data source must have a process for data cleaning and validation, including but not limited to checking errors, identifying outliers, and where possible, comparing with other relevant information as part of the validation process.

Fifth, the data source(s) must be maintained by organizations that seek to limit the lag inherent in data to no more than 90 calendar days from the end of the period for which drug pricing data is compiled to the time that the organization makes such updates available to users of the data source. We believe the limit of no more than 90 calendar days provides sufficient time for organizations to collect data, perform data quality checks, and update their

data sources, and for CMS to obtain and use the data available.

In addition, we propose at § 514.210(c) to use international drug pricing information for international products that are part of the set of international analogs for each GUARD Model drug in reference countries from no earlier than January 1, 2024 to increase the likelihood that GUARD Model drugs are included in international drug pricing data sources, as well as to mitigate incentives to limit the availability of international drug pricing data during the GUARD Model performance period.

We seek feedback on our approach to existing sources for international drug pricing data.

2. Proposed Hierarchy for Using Existing Data Sources

For each GUARD Model drug, CMS would apply the approach proposed in § 514.210(c) to determine the international drug pricing data source that would be used to obtain international drug pricing data for a specific GUARD Model drug’s set of international analogs. The data source that is selected would then be used to calculate the GUARD Model default international benchmark, as discussed in section IV.G. of this proposed rule.

Among the existing international drug pricing data sources that CMS is able to access, for the GUARD Model’s first performance year, we propose a hierarchy in § 514.210(c) for identifying and selecting which international drug pricing data source to use in obtaining international drug pricing data for each GUARD Model drug’s set of international analogs. CMS would select the data source at the highest level of the following hierarchy:

- First level: The data source with coordinated sales and volume data for the set of international analogs in the highest number of reference countries, identified in § 514.220(d), for any duration of the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year. If data for the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year is not available, data for any duration of the most recently available prior 12-month period beginning on or after January 1, 2024, would be used.
- Second level: The data source with coordinated prices and volume data for the set of international analogs in the highest number of reference countries, identified in § 514.220(d), for any duration of the 12-month period corresponding to the 12-month calendar

¹⁵³ World Health Organization. (n.d.). *International Nonproprietary Names (INN)*. <https://www.who.int/teams/health-product-and-policy-standards/inn> (Accessed: 10 December 2025).

¹⁵⁴ Individual countries differ in the regulatory processes and standards governing approval of drugs and biological products. Use of international drug pricing information in the proposed GUARD Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved or licensed and non-U.S.-approved or licensed products.

year prior to the start of the first performance year. If data for the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year is not available, data for any duration of the most recently available prior 12-month period beginning on or after January 1, 2024, would be used.

- Third level: The data source with price data for the set of international analogs in the highest number of reference countries, identified in § 514.220(d), for any duration of the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year. If data for the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year is not available, data for any duration of the most recently available prior 12-month period beginning on or after January 1, 2024, would be used.

CMS believes using a 12-month period is appropriate because this mirrors the duration of the performance year and gives sufficient time for an international product to accrue transactions that are captured by the selected data source. Regardless of the period of time used by the selected data source to measure pricing information, CMS proposes at 514.410(c)(3) to aggregate data to the 12-month period,

regardless of the duration of time for which observations are available within the 12-month period. For instance, if the data source has pricing information reported on a monthly basis and there is data for 7 of the 12 months, the 7 monthly data points would be used.

In cases when there is more than one data source meeting the requirements proposed in § 514.210(b) and they are all equal on the level of the hierarchy noted previously, CMS proposes to select a single data source based on an assessment of the relative reliability and generalizability of the data from each available data source. This assessment and CMS’ resulting decision will be based on the technical characteristics of the data source rather than on the relative magnitude of prices from one source or another. CMS’ assessment may consider, among others, the following factors: the share of national reference country markets reflected in the data source, the specificity of price information to specific international analog products, the number of data points available, methods to identify and address any errors, and data validation processes.

For the GUARD Model’s subsequent performance years, we propose in § 514.210(c) that the same hierarchy approach as the one noted previously would apply, except that instead of first

performance year it would apply to the subsequent performance year.

Under this proposal, for each GUARD Model drug, CMS would use an existing data source with international drug pricing data that CMS can access to calculate the GUARD Model default international benchmark, as described in section IV.G. of this proposed rule, once during the GUARD Model performance period. This means that the GUARD Model default international benchmark would not be revised over time with more recent international pricing data. Table B1 illustrates this proposal. We propose this policy to limit the possibility that a data source that meets CMS’ criteria would experience challenges in collecting data about GUARD Model drugs in the future. We considered the possibility of using the most recent international pricing data to update the GUARD Model default international benchmark annually to correspond to each performance year. However, we believe that doing so increases the risk that a drug (for which a GUARD Model default international benchmark had been previously identified) would not have the available data to construct a benchmark in future years. We welcome comments on this policy proposal.

TABLE B1: ILLUSTRATION OF CMS’ PROPOSED TIMEFRAME FOR INTERNATIONAL PRICING DATA SOURCE SELECTION FOR A GUARD MODEL DRUG’S SET OF INTERNATIONAL ANALOGS

	GUARD Model PY 1	GUARD Model PY 2	GUARD Model PY 3	GUARD Model PY 4	GUARD Model PY 5
Timeframe for international pricing data source selection for New GUARD Model drugs (or those that do not yet have a default international benchmark)	12 months prior to PY1 which corresponds to January – December 2026; Or, if not available, any preceding 12-month period after January 1, 2024.	12 months prior, which corresponds to January – December 2027; Or, if not available, any preceding 12-month period after January 1, 2024.	12 months prior, which corresponds to January – December 2028; Or if not available, any preceding 12-month period after January 1, 2024.	12 months prior, which corresponds to January – December 2029; Or if not available, any preceding 12-month period after January 1, 2024.	12 months prior, which corresponds to January – December 2030; Or if not available, any preceding 12-month period after January 1, 2024.
Timeframe of Data for Existing GUARD Model drugs	Not applicable.	No update or change to the GUARD Model default international benchmark.	No update or change to the GUARD Model default international benchmark.	No update or change to the GUARD Model default international benchmark.	No update or change to the GUARD Model default international benchmark.

Notes: PY stands for performance year, as defined at § 514.5. This proposed timeframe applies to each GUARD Model drug. These data would be used to calculate the GUARD Model default international benchmark for a GUARD Model drug. As discussed in this Section of this proposed rule, the 12-month periods referred to in this table require pricing data for any duration of the 12-month period to qualify as the selected data source.

An example of how the proposed selection process would apply is presented in Table B2 It illustrates how the hierarchy would function. Table B2 also illustrates that for data sources within the same proposed level of

hierarchy (having the same pricing data available), selection would be made in the following way: first, by choosing the data source with the highest number of reference countries and second, by choosing the data source with the most

recent 12-month period with respect to the start of the first performance year (January 1, 2027). We seek feedback on our proposed selection process.

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TABLE B2: ILLUSTRATION OF CMS' PROPOSED HIERARCHY FOR SELECTION OF AN INTERNATIONAL PRICING DATA SOURCE FOR A GUARD MODEL DRUG

For GUARD Model drug X in PY 1 (begins January 1, 2027)									
Data Source	A	B	C	D	E	F	G	H	I
Pricing data	Sales and volume*	Sales and volume*	Sales and volume*	Price and volume*	Price and volume*	Price and volume*	Prices	Prices	Prices
Number of reference countries	10	5	10	10	5	10	8	5	8
Timeframe	Jan-Dec 2026	Jan-Dec 2026	Jan-Dec 2025	Jan-Dec 2026	Jan-Dec 2026	Jan-Dec 2025	Jan-Dec 2026	Jan-Dec 2026	Jan-Dec 2025
Proposed hierarchy level	1	1	1	2	2	2	3	3	3
Selection preference within the same proposed hierarchy level	1	3	2	1	3	2	1	3	2

Notes: Jan stands for January; Dec stands for December; PY stands for performance year, as defined at § 514.5. *The pricing information must be coordinated (sales and volume or price and volume). Proposed hierarchy refers to the hierarchy for data source selection proposed in § 514.210.

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3. Proposed Criteria and Process for Identifying the Set of Reference Countries

In this Section of this proposed rule, we propose the criteria and process that CMS would use to identify the non-U.S. countries that would be included in the set of reference countries for the GUARD Model for purposes of calculating the GUARD Model default international benchmark, as described in section IV.G. of this proposed rule.

Our proposed approach aims to select a large set of countries that are economically similar, have reasonably comparable purchasing power to the United States, and generally have existing international drug pricing information available. In § 514.220(b), CMS proposes to identify a set of reference countries that are non-U.S. Organization for Economic Cooperation and Development (OECD) members as of October 1, 2025 with: (1) purchasing power parity (PPP)-adjusted per capita gross domestic product (GDP) that is at least 60 percent of the corresponding U.S. level, as estimated and available in the Central Intelligence Agency (CIA) World Factbook; and (2) annual (PPP)-adjusted aggregate GDP that is at least \$400 billion (as measured in U.S. dollars) as estimated and available in the CIA World Factbook.

For each country, CMS proposes at § 514.220(b) to use (PPP)-adjusted per capita GDP and (PPP)-adjusted aggregate GDP, as estimated and available in the CIA World Factbook, to identify the reference countries. We note that while the CIA online World Factbook is updated daily, the underlying data such as GDP and PPP are reported no more frequently than annually, based on a July 1 mid-point. Therefore, our proposal is to identify the set of reference countries using data available

as of October 1, 2025, in the CIA World Factbook. There are other existing sources for GDP per capita data besides the CIA World Factbook, including the World Bank, and the International Monetary Fund. Upon examining these sources, we found that the GDP data across these sources are highly associated with one another, and include data for countries that are economically comparable to the United States. We propose using the CIA World Factbook as our source for GDP data as it is issued by a U.S. government agency.¹⁵⁵

We believe that applying a minimum of 60 percent of the United States's (PPP)-adjusted per capita GDP and a minimum \$400 billion (PPP)-adjusted aggregate GDP strikes a balance between having too low (PPP)-adjusted per capita GDP and (PPP)-adjusted aggregate GDP thresholds and including data from countries with economies that are substantially different from the United States, while also not having such high (PPP)-adjusted per capita GDP and (PPP)-adjusted aggregate GDP thresholds that the set of reference countries would be very small. Therefore, we believe that our proposed approach is appropriate and would result in a set of reference countries that are economically similar, have reasonably comparable purchasing power to the United States, and generally have existing international drug pricing data that is available.

We propose that CMS would identify the set of reference countries using CIA World Factbook data that is available to CMS as of October 1, 2025. We propose that the identified set of reference countries would remain the same throughout the GUARD Model performance period, even if a country would not meet the criteria for the set

of reference countries during any performance year of the model. Considering the relatively short duration of the performance period (5-years), CMS believes that this approach yields increased stability for the GUARD Model test, affords manufacturers stability, and reduces substantial administrative burden for manufacturers.

4. Set of Reference Countries for the GUARD Model Identified Using the Proposed Methodology

Using the criteria to identify the set of reference countries for the GUARD Model that CMS proposes in § 514.220(b), CMS identified the set of reference countries by applying our proposed criteria to non-U.S. OECD-member countries using CIA World Factbook data that was available on October 1, 2025; this results in the following set of reference countries: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, France, Germany, Ireland, Israel, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom. All 19 countries are economically comparable to the United States with (PPP)-adjusted per capita GDP in 2024 (the most recent data available) falling between 61 and 153 percent of U.S (PPP)-adjusted per capita GDP in 2024 and have an aggregate (PPP)-adjusted GDP in 2024 exceeding \$400 billion. We propose that the set of reference countries listed previously would be the GUARD Model's reference countries and remain the same throughout the 5 years of the model's performance period. Table B3 presents the (PPP)-adjusted per capita GDP, (PPP)-adjusted aggregate GDP, and GDP (PPP) adjuster for the United States and the proposed reference countries.

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¹⁵⁵ Central Intelligence Agency. (2025). *The World Factbook*. <https://www.cia.gov/the-world-factbook/> (Accessed: 10 December 2025).

TABLE B3: GDP RELATED INDICATORS FOR THE UNITED STATES AND THE SET OF REFERENCE COUNTRIES IDENTIFIED AS ECONOMICALLY COMPARABLE TO THE UNITED STATES FOR THE GUARD MODEL

OECD Member Country	2024 Aggregate (PPP)-Adjusted GDP (billion)	2024 (PPP)-Adjusted Per Capita GDP	Percent of U.S. (PPP)-Adjusted Per Capita GDP	GDP (PPP) Adjuster
United States	\$25,676	\$75,500	100%	1.000
Canada	\$2,341	\$56,700	75%	1.332
France	\$3,732	\$54,500	72%	1.385
Germany	\$5,247	\$62,800	83%	1.202
Italy	\$3,133	\$53,100	70%	1.422
Japan	\$5,715	\$46,100	61%	1.638
United Kingdom	\$3,636	\$52,500	70%	1.438
Australia	\$1,635	\$60,100	80%	1.256
Korea, South	\$2,607	\$50,400	67%	1.498
Netherlands	\$1,276	\$70,900	94%	1.065
Spain	\$2,361	\$48,400	64%	1.560
Austria	\$581	\$63,300	84%	1.193
Belgium	\$749	\$63,100	84%	1.197
Czechia	\$522	\$48,000	64%	1.573
Ireland	\$621	\$115,300	153%	1.000*
Norway	\$508	\$91,100	121%	1.000*
Sweden	\$669	\$63,300	84%	1.193
Switzerland	\$741	\$82,000	109%	1.000*
Denmark	\$441	\$73,700	98%	1.024
Israel	\$472	\$47,300	63%	1.596

Notes: OECD stands for Organization for Economic Co-operation and Development; PPP stands for purchasing power parity; GDP stands for gross domestic product, as defined at § 514.5. The GDP (PPP) adjuster is necessary to account for differences in the economic capacity between the countries. In this case the GDP (PPP) adjuster accounts for differences between the reference countries' (PPP)-adjusted per capita GDP and the U.S. (PPP)-adjusted per capita GDP. The GDP (PPP) adjuster is obtained by dividing the 2024 (PPP)-adjusted per capita GDP of the United States by the reference country's 2024 (PPP)-adjusted per capita GDP. In cases marked with a *, where the reference country has a greater (PPP)-adjusted per capita GDP than the United States, the adjusted is kept at one (not allowed to go below one).

Source: CIA World Factbook.¹⁵⁶

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We seek comment on whether there are any inclusion or exclusion policies we should consider after identifying the set of reference countries using the proposed criteria. CMS also welcomes comments on any of the proposed policies in this Section of this proposed rule.

5. Alternatives Considered

For the policy proposals presented in this Section of this proposed rule, CMS considered a number of alternatives, including alternatives related to the proposed existing data sources and the proposed hierarchy as well as the proposed criteria and process for identifying the set of reference countries.

a. Alternatives Related to Data Sources and the Proposed Hierarchy

In cases when there is more than one data source meeting the requirements for a GUARD Model drug and using the hierarchy proposed in § 514.210(c), CMS considered using the data source at the highest level of the hierarchy with the lowest country-level average price. However, CMS believes that selecting based on the relative reliability and quality of the data from each available data source better serves the model test.

Other hierarchy arrangements were also considered. One proposal CMS considered was to not differentiate between data sources based on the number of reference countries for which they have data. This would mean that a

data source with one reference country would be considered at the same hierarchy level as a data source with multiple reference countries if they had the same timeframe and pricing data available. Under this option, ties between data sources would be resolved by selecting the data source with the lowest country-level average price, in absolute terms, regardless of the number of reference countries contained in the data source. We also considered a hierarchy arrangement that prioritized recency of timeframe for the data over the type of pricing information available. For this potential proposal, a data source that contained only prices, but with data for a more recent timeframe, would be selected over a data source with sales and volume data with a less recent timeframe. However, CMS believes that by prioritizing the data source according to: (1) type of

¹⁵⁶ Central Intelligence Agency. (2025). *The World Factbook, Real GDP (Purchasing Power Parity)—Country Comparison*. <https://www.cia.gov/>

[the-world-factbook/field/real-gdp-purchasing-power-parity/country-comparison/](https://the-world-factbook.com/field/real-gdp-purchasing-power-parity/country-comparison/) (Accessed: 10 December 2025).

pricing data; (2) number of reference countries with data;¹⁵⁷ and (3) recency of data, the selected data source is the best possible in terms of completeness, quality, and recency. Therefore, CMS believes that the proposed approach is appropriate for determining the GUARD Model default international benchmark.

CMS also considered an even broader approach. Under this potential proposal, CMS would allow each GUARD Model drug to have more than one data source contribute to its corresponding international drug pricing information. CMS would make no adjustments for differences between the data sources. This means that for one GUARD Model drug, international drug pricing information could be from data source A for three reference countries, data source B for two different reference countries, data source C for four other different reference countries, and so on; the reference country-level average prices obtained for each of those reference countries would be compared to select the lowest without any data source specific adjustment. This broad approach would allow for more reference countries to be included in the calculation of the GUARD Model default international benchmark. However, the potential drawback of this approach is that there would be differences with respect to the type of international pricing information between the data sources for the same GUARD Model drug. For instance, one data source could have a price that incorporates retail and non-retail prices; another data source has only in-patient prices; and another has only government prices. There would be no clear standard way of adjusting the prices to make them directly comparable, thus CMS would have proposed making no adjustments. While this approach would have maximized the number of reference countries available to select the lowest country-level average price, CMS believes that the drawbacks outweigh the benefits and so we did not propose this policy.

CMS also considered adding a hierarchy level at the end that would allow CMS to consider pricing data in the form of prices made public in any other source even if they do not comply with the data source requirements outlined in § 514.210(b) when there is no compliant and available data source. However, CMS believes it unlikely that this approach would yield sufficient detail for alignment of international analogs to the GUARD Model drug.

¹⁵⁷ Pricing information may be coordinated sales and volume, coordinated prices and volume, or just prices.

Therefore, we did not propose this policy.

We also considered using all the available data sources for a GUARD Model drug and calculating the average of the pricing information available across all the data sources. Because this alternative approach could result in cases where different types of pricing information for a drug from a reference country would be combined, we are not proposing this at this time and may reconsider the potential value of this approach based on feedback from interested parties and further information gathering.

We are interested in better understanding the existing data sources for international drug pricing data that may be available and steps we could follow to best use such data sources for the GUARD Model. CMS solicits feedback on the proposed policies as well as alternative proposals for the hierarchy of data sources that would be used in calculating the GUARD Model default international benchmark. CMS welcomes comments on the methods or processes that we should consider when more than one existing data source is available at the highest level of the hierarchy for the purpose of determining which data source to use when there are multiple potential sources available. We also seek comments on how CMS might refine the hierarchy for potential use of more than one data source for a GUARD Model drug or for ways in which we might be able to incorporate new data sources that may become available during the GUARD Model performance period. We also welcome comments on how CMS should weigh data sources that include fewer reference countries, but which incorporate discounts, rebates, or other price concessions.

b. Alternatives Related to Identifying the Set of Reference Countries

We considered different criteria to identify a country's economy size based on minimum percentages of U.S. (PPP)-adjusted per capita GDP. For example, a (PPP)-adjusted per capita GDP threshold of 80 percent of the corresponding U.S. level would result in the set of reference countries only including eight countries (Austria, Belgium, Germany, Ireland, the Netherlands, Norway, Sweden, and Switzerland), all of which are in Western Europe. We also considered different criteria to identify economy size based on different (PPP)-adjusted aggregate GDP. For example, \$300 billion, \$1 and \$2 trillion. Again, this resulted in either including countries significantly different from the United

States or too few countries. For instance, an aggregate (PPP)-adjusted GDP level of \$2 trillion results in only three non-U.S. OECD member countries—Canada, Germany, and Japan—being included. We welcome feedback on our proposals to include only OECD reference countries that have a (PPP)-adjusted per capita GDP of 60 percent and an annual (PPP)-adjusted aggregate GDP of at least \$400 billion.

We also considered alternative approaches to our proposed criteria for identifying the set of reference countries. Specifically, we considered including all non-U.S. OECD member countries or including countries based on factors such as having a national regulatory authority recognized as a Stringent Regulatory Authority by the World Health Organization (WHO) (to be replaced by the WHO-listed authority or WLA)^{158 159} and intellectual property protections. We also considered including only countries that may represent large markets for drug manufacturers such as all countries in the European Union, Canada, Japan, and United Kingdom. However, we do not believe that these approaches would be as optimal for purposes of identifying the GUARD Model default international benchmark because they would result in either too few countries or countries with economies too different from the United States being included as reference countries for the GUARD Model.

We also considered alternatives that would phase-in countries or would adjust the set of reference countries over time based on a defined set of characteristics, such as GDP per capita or average drug prices. However, we believe that phasing in countries over time or adjusting the set of reference countries periodically would create instability within the GUARD Model test and could confound implementation, monitoring, and evaluation activities as well as cause potential negative impacts on GUARD Model participants (for example, creating confusion regarding voluntary data submission). In addition, if we adopted a phase-in of countries or an adjustment to the set of countries during the GUARD Model performance period, it would mean that we would also need

¹⁵⁸ World Health Organization. (2025). *List of WHO Listed Authorities (WLAs)*. <https://www.who.int/publications/m/item/list-of-who-listed-authorities-wlas> and https://cdn.who.int/media/docs/default-source/medicines/regulatory-systems/wla/list_of_wla.pdf (Accessed: 10 December 2025).

¹⁵⁹ World Health Organization. (n.d.). *WHO Listed Authority (WLA)*. <https://www.who.int/initiatives/who-listed-authority-reg-authorities> (Accessed: 10 December 2025).

to consider whether to change our proposal to maintain the GUARD Model default international benchmark for the duration of the model test if we determine that the phase-in would apply to all GUARD Model drugs, regardless of when they became a GUARD Model drug, which creates additional complexity. For all these reasons, we propose to maintain a stable set of reference countries for the duration of the GUARD Model.

Although we have concerns about the potential negative impacts that could occur if the set of reference countries is not held constant during the 5-year GUARD Model performance period, as discussed in this Section of this proposed rule, we welcome comment on the potential benefits and drawbacks of establishing a threshold for adding or removing a country from the set of reference countries at certain points during the model performance period. Specifically, we seek comment on whether a country should be removed from the set of reference countries if the CIA World Factbook data for a calendar year after 2024 shows that, for 2 consecutive calendar years, the country does not meet the criteria for inclusion in the set of reference countries that are finalized in a final rule that establishes the GUARD Model. We also welcome comment on the processes and timing that would be necessary to operationalize a change to the set of reference countries that would minimize impacts on the model test. For example, to allow time for model operations and manufacturer activities to adjust, it may be necessary or prudent to establish a specified period when CMS would review available CIA World Factbook data for a calendar year and a minimum amount of time between CMS' identification that a country no longer meets the criteria for inclusion in the set of reference countries and when the set of reference countries would be revised. We also welcome comment on the potential benefits and drawbacks of setting a threshold for removal at 2 consecutive years and whether a different length of time would be sufficient to justify a change to the set of reference countries.

F. Proposed Submission of International Drug Net Pricing Data

In this Section of this proposed rule, we describe the process for submission of international drug net pricing data that manufacturers may choose to exercise for GUARD Model drugs. CMS is proposing at § 514.310(a) that, subject to certain conditions, manufacturers of GUARD Model drugs would have the option to voluntarily submit to CMS, the

international drug net pricing data that corresponds with a manufacturer's GUARD Model drug, which could then be used to determine the GUARD Model updated international benchmark for that specific GUARD Model drug, as described in section IV.G. of this proposed rule. The international drug net pricing data would need to correspond to net pricing information for a GUARD Model drug's set of international analogs, as defined in section IV.E. of this proposed rule.

At § 514.310(b), CMS proposes to assess each data "submission," which we define at § 514.5 to mean manufacturer international drug net pricing data voluntarily submitted to CMS to consider for use for the performance year for which it was submitted. In other words, each submission is only used by CMS for the specific corresponding performance year, and any subsequent performance year would need a separate submission. CMS proposes at § 514.310(b) that a submission is determined to be an applicable submission if it fulfils the data requirements which include verification of the submission for completeness and validity by CMS. As such, CMS defines at § 514.5 that "applicable submission" means a voluntary manufacturer submission that CMS determines fulfils the data requirements, which include verification of the submission for completeness and validity, and therefore is suitable for determination of the GUARD Model updated international benchmark per § 514.410(d). Only submissions determined to be applicable by CMS are suitable for determination of the GUARD Model updated international benchmark, as explained in section IV.G. of this proposed rule.

1. Proposed Voluntary Submission of International Drug Net Pricing Data

Under the GUARD Model, if a manufacturer elects to submit international drug net pricing data for a GUARD Model drug, CMS proposes that the manufacturer would be required to execute a data agreement at least 90 calendar days prior to submission. The "data agreement" would establish terms, conditions, and requirements, including data completeness and validity requirements; compliance responsibilities; CMS confidentiality obligations; and other ongoing requirements. In § 514.310(b), CMS proposes a one-year data agreement duration aligned with annual submission cycles. Manufacturers may make a submission for one or more GUARD Model drugs. For each GUARD

Model drug, the submission would include the set of international analogs with sales in the reference countries identified in § 514.220(d) that occur during the performance year for which the submission applies.

CMS proposes that manufacturers who elect the option to submit international drug net pricing data for a GUARD Model drug must include data that corresponds to the same timeframe as the performance year for which it will be used to determine the GUARD Model updated international benchmark. Submission of the data must occur within 180 calendar days of the end of the performance year. For example, for the first performance year ending on December 31, 2027, CMS must receive manufacturer net pricing data by June 29, 2028, for it to be considered for the GUARD Model updated international benchmark determination, if deemed applicable, and this submission must include data for the entire first performance year (January 1, 2027 to December 31, 2027). This would mean manufacturers would have to establish a data agreement by March 31, 2028, at the latest.

CMS recognizes that 180 calendar days after the end of the performance year would mean that the published list of Part D rebatable drugs would only account for nine months of said performance year. This is due to the different timelines between the Part D Inflation Rebate Program (an applicable period begins in October and lasts 12 months) and the GUARD Model (a performance year begins in January and lasts 12 months). However, CMS believes that manufacturers are able to identify whether a drug is a Part D inflation rebatable drug and a GUARD Model drug by applying the inclusion and exclusion criteria. Therefore, CMS believes the 180 calendar days are sufficient for manufacturers to know with reasonable certainty if their drug is a Part D rebatable drug and whether it meets criteria for a GUARD Model drug.

CMS considered shortening this period, specifically considering whether a submission should occur within 90 calendar days of the end of the performance year. However, CMS believes that given the data lags, providing sufficient time for manufacturers to process data is necessary. Therefore, a longer period is preferable. CMS also considered an even longer period than the current proposal, specifically considering whether a submission should occur within 10 calendar quarters after the end of the performance year to allow for time for the list of Part D rebatable drugs to be published. However, this would extend

the time for rebate payment calculations, invoicing, reconciliation, and due dates of payments and reconciliation amounts, if a manufacturer chooses to submit international drug net pricing data. One potential way of doing this would be using the GUARD Model default international benchmark for the GUARD Model drug up until the time when the manufacturer submits international drug net pricing data, if they choose to do so. Assuming the submission is deemed an applicable submission by CMS, the payment amount would be updated and reconciled based on the GUARD Model updated international benchmark. However, this approach would be more complex and potentially create unpredictability for both CMS and manufacturers. CMS believes that manufacturers are able to identify GUARD Model drugs by applying the criteria under the Part D Inflation Rebate Program and the GUARD Model as proposed at § 514.120; therefore, we do not believe these alternative approaches are preferable. CMS welcomes comments on this proposal and the alternatives considered.

Upon submission of the data, CMS proposes to conduct a verification review to determine whether the submission meets the submission requirements as proposed in § 514.310(b), which is necessary for CMS to determine whether the submission represents an applicable submission for use in determining the GUARD Model updated international benchmark. We describe the verification review process in more detail later in this Section of this proposed rule.

For CMS to determine that the submission is an applicable submission, CMS proposes in § 514.310(c) and (d) that the data must include all the basic data elements required by CMS for the set of international analogs that corresponds to a GUARD Model drug, as described later in this Section of the proposed rule, as well as all the net pricing data elements required under one of the two options manufacturers can select to submit net pricing data, in addition to all other requirements. CMS proposes at § 514.310(g) that if, for any of the basic or net pricing data elements, third-party individuals and organizations were relied upon to gather, analyze, or submit the data, the manufacturer must note its reliance on a third party with respect to each of the type of activities (gather, analyze, or submit the data) engaged in by the third party, and the third-party individual or organization identified.

In addition, CMS proposes in § 514.310(b) that the submission is verified for completeness, which includes the executed data agreement; attestation (as described later in this Section of this proposed rule); submission using the proper portal in the manner and form requested by CMS; and all basic data elements and net pricing data elements. CMS also proposes that the submission is verified for validity as part of the verification review process, and to do so, CMS may utilize all available existing data sources and information to assess the extent to which the submission reflects international drug net pricing in the reference countries. Additionally, CMS may choose to request additional supporting information and/or data before completing the assessment of validity of the submission and finalizing review. We describe this process in more detail later in this Section of this proposed rule.

2. Basic Data Requirements

The basic data requirements, as proposed at § 514.310(c), consist of data elements that manufacturers would be required to submit in order for CMS to corroborate that the set of international analogs which are included in the submission are aligned with the GUARD Model drug. Identification of international analogs based on alignment of the international analog's identifying characteristics with the GUARD Model drug's characteristics should be consistent with the alignment approach to identify the set of international analogs proposed at § 514.410(c). CMS would issue supplementary guidance with more information.

CMS proposes that these data elements would be required for the set of international analogs that correspond to a GUARD Model drug. This means that if, for a GUARD Model drug, there are multiple reference countries that sell some or all the international products that are part of the set of international analogs, the manufacturer submission should include the basic data elements for all the international products sold in each reference country. That is, the basic data requirements necessitate submitting the data elements separately for each reference country; and within each reference country, the data submission must include all the international products that are part of the set of international analogs that are sold in the reference country. This is necessary to allow CMS to verify, by reference country the international

products sold that are part of the set of international analogs for the GUARD Model drug.

The required basic data elements are the GUARD Model drug brand name, nonproprietary name, and NDC-9; and then for every reference country where some or all of the international products that are part of the set of international analogs for the GUARD Model drug are sold during the submission performance year, a list of every international product sold in that reference country. In other words, there must be a list for every reference country where at least one international product of the set of international analogs are sold. This list of international products (that are part of the set of international analogs for the GUARD Model drug) must have the following details for each international product:

- Scientific name and active ingredient(s).
- Brand name(s) (all variations if there are multiple in the reference country) and nonproprietary name.
- Names of manufacturers, marketers, distributors, licensees, or other entities responsible for selling the international product in the reference country.
- International regulatory approval status.¹⁶⁰
- Route of administration and dosage form as they are expressed in the reference country and in equivalent terms to what is expressed in the NDC directory for the GUARD Model drug.
- Dosage strength and dosing unit as they are expressed in the reference country and in NCPDP equivalent units according to the GUARD Model drug's NCPDP unit.
- All package forms and sizes available.

Refer to Table B4 for an illustrative example of the basic data elements.

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¹⁶⁰ As defined at proposed § 514.300 “international regulatory approval status” means any information relevant and sufficient for CMS to determine whether each international product's approval or licensing status according to the reference country's regulatory framework would make it an international generic, international biosimilar biological product, or neither. Individual countries differ in the regulatory processes and standards governing approval of drugs and biological products. Use of international drug pricing information in the proposed GUARD Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved or licensed and non-U.S.-approved or licensed products.

TABLE B4: ILLUSTRATIVE EXAMPLE OF BASIC DATA ELEMENTS

Basic Data Elements are: (1) GUARD Model drug elements for identification: brand name, nonproprietary name, and NDC-9. (2) For every reference country where at least one international product of the GUARD Model drug’s set of international analog drugs are sold during the submission performance year, a list of international products sold in that reference country must have the following details for each international product:									
Example Country A:									
Intl. Product*	Scientific Name and Active Ingredient(s)	Brand Name(s) and Nonproprietary Name **	Manufacturer(s), Marketer(s), Licensee(s), and Other Entities	Intl. Regulatory Approval Status	Route of Admin. and Dosage Form	Dosage Strength	Dosing Unit	NCPDP Equivalent	Package(s)***
Product 1									
Product 2									
Product ...									
Product n									
Notes: Intl. stands for international; Ref. Country stands for reference country; Admin. stands for administration; NDC stands for National Drug Code; NCPDP stands for National Council for Prescription Drug Program, as defined at § 514.5. Route of admin., dosage form, dosage strength, dosing unit, and NCPDP equivalent would match the GUARD Model drug’s NDC-9. *All international products sold in Ref. Country A. **For example, brand name, non-proprietary name. ***That is, all package forms and sizes.									

supplementary guidance with information regarding the definitions of the data elements, the manner and form in which they must be submitted, guidelines to facilitate identification of the international products that are part of the set of international analogs for the corresponding GUARD Model drug, guidelines on currency conversion, reasonable assumptions that may be necessary for any of the data elements, instructions for the submission process, and any other relevant topic related to the voluntary submission of international drug net pricing data.

CMS will review the basic data elements reported in each submission to determine if the appropriate set of international analogs for the GUARD Model drug have been submitted. CMS may use existing data sources of international drug pricing data, such as IQVIA MIDAS or POLI data, as well as publicly available information on the drugs sold in reference countries, to determine if the full set of international analogs that are sold in the reference countries have been submitted for a GUARD Model drug. The full set of international analogs includes all international products sold in each of the reference countries whose identifying characteristics (active ingredient, route of administration, dosage form, and strength) are in alignment with the GUARD Model drug's identifying characteristics. If the full set of international analogs are not reported for the GUARD Model drug, CMS proposes that the submission is not acceptable and thus it would not be an applicable submission, unless additional information is provided and CMS approves the use of the data. Specifically, CMS recognizes that given the requirement that international products be aligned according to all their identifying characteristics with the GUARD Model drug, it is possible that manufacturers would need flexibility in reporting for various reasons. For example, data processing and lags in compiling information (given the number of reference countries involved and the level of granularity at which the data must be submitted—NDC-9 level) and administrative lags in receiving data on manufacturer discounts and rebates (or lags associated with coordinating with third-parties that may be involved in the sales of the international products that are part of the GUARD Model drug's set of international analogs) may all pose challenges for submission of the international net pricing data at the NDC-9 level. Thus, CMS proposes at § 514.310(f) that manufacturers who cannot provide the full set of

international analogs for all reference countries where they are sold provide a detailed explanation of why this is not possible. CMS will consider this information as part of the verification review process.

CMS also proposes at § 514.310(b) that during the verification process CMS may choose to request additional supporting information from manufacturers before completing its assessment of a submission's validity. In this situation, the manufacturer would be required to respond to CMS within 15 days; and if responses are acceptable to CMS, CMS will confirm the validity of the submission and proceed to use the subset of international products for which the manufacturer has submitted data, as long as it meets all other requirements, to represent the set of international analogs and thus be used to determine the GUARD Model updated international benchmark.

CMS considered the possibility of accepting a submission without explanation even if the full set of international analogs are not included in the submission and using the data that is submitted along with existing international drug pricing information to calculate an updated international benchmark. However, we decided against this approach because of concerns about combining different data sources and whether it would be logical to do so with some adjustments. We seek feedback on this potential option.

CMS also considered providing manufacturers the set of international analogs for which they must submit the international net pricing data. However, we believe that manufacturers have this information and it would not be burdensome to identify the set of international analogs that are sold in the reference countries. CMS also considered not accepting, even with appropriate explanation, any submission that does not include the full set of international analogs for the GUARD Model drug. However, we decided against this because we believe there may be legitimate reasons for a manufacturer to be unable to submit this information for certain drugs, particularly because CMS is requesting data at a granular level—the NDC-9 level—which is necessary because Part D drugs are identified by NDC-9 and the Part D Inflation Rebate Program is based on the same. CMS recognizes that this level of granularity may result in exceptional situations and circumstances where the data for a particular NDC-9 is not yet available. Therefore, under our proposed policy, CMS allows for manufacturers to share an explanation that CMS will assess for

acceptability. CMS seeks feedback on our proposed policy as well as the alternatives presented, including whether CMS should provide the set of international analogs for which data should be submitted for each corresponding GUARD Model drug.

CMS recognizes the complexities inherent in international pharmaceutical markets, including variations in dosage strengths, formulations, and routes of administration; packaging differences; and diverse relationships between U.S. and international entities responsible for product marketing and distribution. For these reasons, we also considered only requesting this data for the set of international analogs that correspond to a GUARD Model drug that are sold directly by the manufacturer and not by any other subsidiary or company in the reference countries. We also considered an option where manufacturers would only submit the data for the set of international analogs that they directly sell in the reference countries. However, we believe that manufacturers have relationships with subsidiaries, wholesalers, and other businesses involved in selling the set of international analogs in the reference countries and can obtain the data that is requested under this option. CMS welcomes feedback on our policy and the alternatives presented.

CMS seeks comments on whether the proposed voluntary framework, which includes basic required data elements to ensure alignment of GUARD Model drugs and international products, adequately addresses these market complexities. CMS also seeks comments on whether additional basic data elements should be required or if any of the proposed elements present significant data collection, analysis, or submission challenges.

3. Options for Submission of Net Pricing Data Elements

CMS proposes in § 514.310(d) that manufacturers who elect to submit international drug net pricing data must submit all of the data elements required for one of the two options described later in this Section of this proposed rule, in addition to the basic data elements that are presented in this Section of this proposed rule. Manufacturers would select which option to follow. For each of the two options, manufacturers must report data elements for the international products that comprise the set of international analogs that are sold in the set of reference countries that correspond to the GUARD Model drug and which they

have included in the basic data elements.

a. Streamlined Option

Under this option, manufacturers would be required to report a set of data elements at the net price level, reference country level, and at an across-country level. Beginning with the “net price level”, CMS proposes at § 514.300 this to mean, with respect to sales of international products, all sales of an international product in a reference country at the same price and price concession, where “price concession,” also defined at § 514.300, means any discounts, rebates, or other concessions offered by the manufacturer that lowers the amount paid for purchase of an international product in a reference country. Thus, a single international product may have multiple net price levels in a reference country as it may be sold at different prices to different purchasers and each purchaser may receive different concessions from the manufacturer. However, if an international product is sold at the same price to multiple purchasers and each of them receives the same concession, then it has only one net price level.

The three data elements that CMS proposes at § 514.310(d) must be reported at the net price level are gross sales amount, net sales amount, and volume in NCPDP units. “Gross sales amount,” defined at § 514.300, means the amount of money paid, inclusive of any price concessions, for the purchase of an international product in a reference country. In contrast, “net sales amount,” defined at § 514.300, means the amount of money paid, exclusive of any price concessions, for the purchase of an international product in a reference country. The net sales amount is not a list price (for example, the equivalent of WAC in the United States); rather, it is based on the net price of the international products sold in the reference countries.

Both gross and net sales amounts must be reported in local country currency and in U.S. dollars (details on the exchange rate for currency conversion are discussed later in this Section of this proposed rule). Both of these values for an international product at the net price level are expected to correspond to each other, and will have a corresponding volume of the international product that was purchased. When reporting the volume, it must be expressed in NCPDP units or converted into NCPDP units that correspond to the GUARD Model drug’s NCPDP unit.

Under our proposal, CMS would expect the manufacturer to obtain every

sale that is made directly to health care entities, distributors, wholesalers, or other international purchasers and aggregate those that share a price and concession amount, resulting in sales by the net price level. We considered the option of only requesting sales that manufacturers have readily available and not all sales made for the set of international analogs. However, we believe that manufacturers do have access to all sales made for the set of international analogs that correspond to a GUARD Model drug. CMS does allow for some flexibility, however, because we recognize that there may be sales that a manufacturer may not be able to provide for a variety of reasons (for example, delays in payments of price concessions, licensing agreements for third party production of products, and parallel importing arrangements). We describe an approach for how to approach this in extenuating circumstances in our verification of review process that is described later in this Section of this proposed rule.

We also considered, instead of sales, requesting manufacturer revenue. However, given that the purpose of the submission is to determine the GUARD Model updated international benchmark for a GUARD Model drug, we believe sales are the appropriate measure to request. We seek feedback on this proposal of requesting sales instead of another measure and seek comment on whether and to what extent manufacturers can submit all sales.

In Table B6, an example of the voluntary submission by the manufacturer of “GUARD Model drug I” is shown and a description of the data used is found in Table B5. This fictitious GUARD Model drug I has international products in three reference countries. In reference country A, it has two international products; in reference country B, it has four; and in reference country C, it has 3. For reference country A, international product one has five net price levels (sold at five price-price concession combinations); thus, the applicable submission includes gross and net sales amounts and volume in NCPDP units for each of the five levels. Also in reference country A, international product two has three net price levels; thus, the applicable submission includes three gross and net sales amounts with the corresponding volumes. It is possible that there were multiple sales of international analog one for each of those net price levels, but as the sales were at the same price and price concession, the applicable submission includes these aggregated at the net price level.

The four data elements that CMS proposes at § 514.310(d) for reporting at the reference country level are the average net-to-gross ratio, the exchange rate for currency conversion, the country-level average price, and the GDP (PPP) adjuster which will be further described later in this Section of this proposed rule.

The “average net-to-gross ratio” means for a reference country, the total net sales for international products that are part of a GUARD Model drug’s set of international analogs in a reference country divided by the corresponding total gross sales for the same international products. This means that there is one average net-to-gross ratio for each GUARD Model drug per reference country. An example of how the average net-to-gross ratio is calculated is shown in Table B6, where for Reference Country A, the sum of all net sales amounts (including both international analogs) is divided by the sum of all gross sales amounts (including both international analogs) resulting in the average net-to-gross ratio of 0.55.

The “exchange rate for currency conversion,” defined at § 514.5, means the conversion rate used to convert from the currency of each reference country to U.S. dollars for data corresponding to the submission’s performance year. In other words, the rate would correspond to the calendar year during which the sale of international products occurred. CMS proposes at § 514.310(e) that the exchange rate that should be applied would be from the World Bank Atlas,¹⁶¹ and correspond to the submission’s corresponding performance year. This exchange would be applied to all data elements requiring currency conversion in the submission.

CMS considered allowing for different possible data sources for the exchange rate for currency conversion, for instance, the International Monetary Fund exchange rates data,¹⁶² the Federal Reserve Bank foreign exchange rates,¹⁶³

¹⁶¹ The World Bank. (n.d.). *The World Bank Atlas Method: Detailed Methodology*. <https://datahelpdesk.worldbank.org/knowledgebase/articles/378832-the-world-bank-atlas-method-detailed-methodology> (Accessed: 10 December 2025).

¹⁶² International Monetary Fund. (n.d.). *IMF Data Explorer: Exchange Rate Data (4.0.1)*. [https://data.imf.org/en/Data-Explorer?datasetUrn=IMF.STA:ER\(4.0.1\)](https://data.imf.org/en/Data-Explorer?datasetUrn=IMF.STA:ER(4.0.1)) (Accessed: 10 December 2025).

¹⁶³ Annual: Board of Governors of the Federal Reserve System. (2025). *Foreign Exchange Rates—G.5A Annual*. <https://www.federalreserve.gov/releases/g5a/current/> (Accessed: 10 December 2025). Weekly: Board of Governors of the Federal Reserve System. (2025). *Foreign Exchange Rates—H.10 Weekly*. <https://www.federalreserve.gov/releases/h10/current/#> (Accessed: 10 December 2025).

and exchange rates from country-specific sources, however CMS believes that because the rates would be applied across an entire calendar year, it is important for the data source to provide consistency in reporting and methods. The World Bank Atlas provides this by considering not just an annual rate, but also taking into account the 2 preceding years, which adjusts for the difference between the rate of inflation in the country and international inflation, thereby mitigating short-term effects of inflation.¹⁶⁴ We solicit feedback on the data sources considered and others that should be considered for currency conversion; the methods that can be used; the challenges that might arise; and any other pertinent information related to this topic. We are also seeking feedback on whether CMS should provide the exchange rates that are used in the calculations.

The next data element reported at the country-level is the country-level net price. CMS proposes at § 514.300 that “country-level net price” means a weighted average net price, that excludes price concessions, for all international products sold in a reference country that are part of a GUARD Model drug’s set of international analogs during a submission’s corresponding performance year, where the weights are the corresponding volumes of international products sold, expressed as a per unit price, and where the units are the GUARD Model drug’s NCPDP units. To express the country-level average net price in U.S. dollars, the exchange rate for currency conversion (the rate according to § 514.310(e)) is utilized. Using again the example of reference country A from Table B6, each of the net sales amounts for both international products contribute to the average according to how much volume was sold. The net sales amounts are converted from local currency to U.S. dollars using the exchange rate of 0.8 (this is calculated dividing the net sales amount by the rate). This results in an average price for one NCPDP unit of GUARD Model drug I in reference country A, which in this example would be \$187.

The final country-level data element required to be reported under this option is the “GDP (PPP) adjuster,” which CMS proposes at § 514.5, to define as, for a reference country, the U.S. GDP (PPP) per capita divided by

the reference country’s GDP (PPP) per capita rounded to the third decimal place. The GDP (PPP) per capita for the reference country is the most recent estimate of GDP (PPP) per capita for that reference country available in the CIA World Factbook at the end of the corresponding performance year. The reference country’s GDP (PPP) per capita and U.S. GDP (PPP) per capita must be for the same calendar year. CMS proposes the GDP (PPP) adjuster would have a lower bound of 1.000, thus if the resulting GDP (PPP) adjuster is lower than 1.000, it is set to 1.000.

CMS proposes a lower bound of 1.000 for the GDP (PPP) adjuster because CMS believes that the adjuster should not decrease a country-level average price for a drug. Setting this lower bound will ensure that an adjustment is not made that would result in an adjusted country-level average price being lower than the unadjusted country-level average price. CMS believes that the GDP (PPP) adjuster’s purpose is to adjust for countries’ economic resources when they are higher than those of the United States, and the lower bound proposal aims to achieve this. To exemplify this, Country X has a higher GDP (PPP) per capita than the United States, such that its GDP (PPP) adjuster without a lower bound would be 0.500 and an unadjusted country-level average price for an international product part of a GUARD Model drug’s set of international analogs of \$100. Without the proposed lower bound, the adjusted price would be \$50, but with the proposed lower bound the adjusted price would remain \$100. CMS considered not having a lower bound for the GDP (PPP) adjuster to allow for adjustments when a reference country has a higher GDP (PPP) per capita than the United States. CMS seeks feedback on this policy.

The single data element reported at an across-country level is the across-country average net price. At § 514.5, CMS proposes “across-country average net price” to mean the weighted average net price (excluding price concessions) for all international products sold across all reference countries that are part of GUARD Model drug’s set of international analogs during a submission’s corresponding performance year, where the weights are the corresponding volumes of the international product sold in NCPDP units, each price is adjusted using the reference country specific GDP (PPP) adjuster, converted into U.S. dollars using the exchange rate for currency conversion as described at § 514.310(e), and expressed as a per unit price, where the units are the GUARD Model drug’s

NCPDP units. An example of the across country average net price is shown in Table B6. Note that there is one value across all three reference countries. Each net sales amount for all international products in every reference country contributes to this average according to the volume sold. Each of the 29 net sales amounts are converted to U.S. dollars using the appropriate exchange rate (0.8 for the net sales amount for reference country A, 10 for the 14 net sales amount for reference country B, and 0.86 for the 7 net sales amount for reference country C) and adjusted by the reference country’s GDP (PPP) adjuster (1.000 for reference country A, 1.300 for reference country B, and 1.500 for reference country C). This results in an average price of GUARD Model drug I of \$182.761. This means that for GUARD Model drug I, the average price in all reference countries where it is sold is \$182.761, which accounts for how much quantity is sold, the country’s currency, and its GDP (PPP).

We seek feedback on the data elements included in this option.

b. Limited Option

Under this approach, manufacturers would be required to submit a very limited set of data elements that are aggregated at country-level and one data element at the across-country level. CMS proposes at § 514.310(d), that the country level data elements that would be submitted under the limited option are the average net-to-gross ratio, the exchange rate for currency conversion, the country-level average price, and the GDP (PPP) adjuster; all these elements are the same as described for the streamlined option. The one across-country level data element that CMS proposes at § 514.310(d) to be submitted under the limited option is the across-country average net price and it is also the same as described for the streamlined option. Additionally, manufacturers would be required to submit several other data elements under the limited option: the *total* gross sales amount, *total* net sales amount, and *total* volume in NCPDP units, which we describe next.

For all the international products that are part of the set of international analogs corresponding to a GUARD Model drug, for each reference country, CMS would require submission of the *total* gross sales amount, which can be computed by summing all gross sales amounts for the international products part of the GUARD Model drug’s international analogs in the reference country’s currency and in U.S. dollars (using the exchange rate for currency

¹⁶⁴ The World Bank. (n.d.). *The World Bank Atlas Method: Detailed Methodology*. <https://datahelpdesk.worldbank.org/knowledgebase/articles/378832-the-world-bank-atlas-method-detailed-methodology> (Accessed: 10 December 2025).

conversion); *total* net sales amount, which can be computed by summing all net sales amounts for the international products part of the GUARD Model drug's international analogs in the reference country's currency and in U.S. dollars (using the exchange rate for currency conversion); and the corresponding *total* sales volume in NCPDP units corresponding to the GUARD Model drug's NCPDP unit.

We seek feedback on the data elements included in this option.

c. Additional Considerations for Both Options

CMS would require information on how the data elements were compiled and computed, any reasonable assumptions that were made during this process, and any other pertinent information that CMS should consider in its verification process for the data. CMS proposes that if there are sales that the manufacturer has not been able to include, the manufacturer submit an explanation and CMS will consider this as part of the verification review. If the explanation is acceptable, CMS may

consider the submission an applicable submission if it meets all other criteria. CMS considered not allowing this flexibility but given that the data is at a granular level (NDC-9), we believe that this flexibility is necessary. CMS will include in guidance more information on how to calculate these values and the reasonable assumptions manufacturers can make in this process under this option.

CMS recognizes that manufacturers may need to allocate gross and net sales amounts to the international products part of the set of international analogs to provide the data elements required under each of the options presented previously. CMS proposes at § 514.310(b) that any allocation and calculations be done in a manner consistent with the generally acceptable accounting principles (GAAP), international financial reporting standards (IFRS), or other internationally recognized accounting approaches.¹⁶⁵ We solicit feedback on

whether there are other accounting approaches that CMS should consider. CMS will provide further guidance on reasonable assumptions that manufacturers may make in the calculation of these data elements.

Though both options require the same types of data, they differ in granularity of data submitted and CMS' ability to verify the data reported. In the streamlined option, CMS would require reporting of gross sales amount, net sales amount, and volume for each net price level. In the limited option, CMS would require reporting of less granular data with gross sales amount, net sales amount and volume reported across all net price levels. CMS developed the limited option to allow manufacturers to report detailed manufacturer net pricing data but without having to disaggregate at the net price level.

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¹⁶⁵ Ross, S. (2025). *GAAP vs. IFRS: What's the Difference?* Investopedia. [https://](https://www.investopedia.com/ask/answers/011315/what-difference-between-gaap-and-ifrs.asp)

www.investopedia.com/ask/answers/011315/what-difference-between-gaap-and-ifrs.asp (Accessed: 10 December 2025).

TABLE B5: ILLUSTRATIVE TABLE OF DATA ELEMENTS REQUIRED UNDER THE STREAMLINED AND LIMITED OPTIONS

Ref. Country	Gross Sales Amount	Net Sales Amount	Volume (NCPDP units)	Average Net-to-Gross Ratio	Exchange Rate	Country-Level Average Net Price	GDP (PPP) Adjuster	Across Country Average Net Price (Potential Updated IB)
Streamlined Option								
A	Gross Sales A1*	Net Sales A1 *	Volume A1*	Ratio A	Rate A	Volume-weighted Average Net Price for Country A	Adjuster A	Volume-weighted Average GDP (PPP)- Adjusted Net Price
	Gross Sales A2*	Net Sales A2*	Volume A2*					
	Gross Sales A3*	Net Sales A3*	Volume A3*					
B	Gross Sales B1*	Net Sales B1*	Volume B1*	Ratio B	Rate B	Volume-weighted Average Net Price for Country B	Adjuster B	
	Gross Sales B2*	Net Sales B2*	Volume B2*					
C	Gross Sales C1*	Net Sales C1 *	Volume C1*	Ratio C	Rate C	Volume-weighted Average Net Price for Country C	Adjuster C	
	Gross Sales C2*	Net Sales C2*	Volume C2*					
	Gross Sales C3*	Net Sales C3*	Volume C3*					
	Gross Sales C4*	Net Sales C4*	Volume C4*					
D	Gross Sales D1*	Net Sales D1 *	Volume D1*	Ratio D	Rate D	Volume-weighted Average Net Price for Country D	Adjuster D	
	Gross Sales D2*	Net Sales D2*	Volume D2*					
Limited Option								
A	Total Gross Sales A	Total Net Sales A	Total Volume A	Ratio A	Rate A	Volume-weighted Average Net Price for Country A	Adjuster A	Volume-weighted Average GDP (PPP)- Adjusted Net Price
B	Total Gross Sales B	Total Net Sales B	Total Volume B	Ratio B	Rate B	Volume-weighted Average Net Price for Country B	Adjuster B	
C	Total Gross Sales C	Total Net Sales C	Total Volume C	Ratio C	Rate C	Volume-weighted Average Net Price for Country C	Adjuster C	
D	Total Gross Sales D	Total Net Sales D	Total Volume D	Ratio D	Rate D	Volume-weighted Average Net Price for Country D	Adjuster D	

Notes: Ref. Country stands for reference country, as defined at § 514.5; NCPDP stands for National Council for Prescription Drug Program, as defined at § 514.5; GDP (PPP) stands for gross domestic product based on purchasing power parity, as defined at § 514.5; Updated IB stands for updated international benchmark. *Gross and net sales and volume amounts for the streamlined option are reported at the net price level which means, with respect to sales of international products, sales at the same price and price concession. This means that the gross and net sales and volume are aggregated together as long as they correspond to a sale with the same price and price concession regardless of the purchaser identity.

Ref. Cty.	Int. Prod.	Net Price Level	Gross Sales Amt. (LC)	Net Sales Amt. (LC)	Vol. (NCPDP units)*	Ave. Net-to-Gross Ratio	Exch. Rate	Cty.-Level Ave. Net Price	GDP (PPP) Adjuster	Across-Cty. Ave. Net Price
Streamlined Option										
A	1	1	100	65	5	0.549	0.800	87.002	1.000	182.761
		2	460	350	20					
		3	367	270	15					
		4	80	30	10					
	2	5	204	48	15					
		1	321	132	14					
		2	245	89	6					
	3	123	60	23						
B	1	1	540	340	89	0.614	10.000	38.101	1.300	
		2	345	140	90					
		3	76	70	35					
		4	345	260	72					
		5	222	90	34					
	2	1	678	540	90					
		2	856	345	104					
		3	1020	589	302					
		4	345	140	120					
	3	1	567	300	270					
		2	908	650	309					
	4	1	345	301	190					
		2	284	187	102					
		3	401	302	201					
C	1	1	207	130	40	0.580	0.860	533.031	1.500	
		2	196	89	36					
	2	1	467	123	60					
		1	178	90	40					
		2	376	201	32					
		3	999	777	222					
	4	111	60	3						
Limited Option										
A	1	1	1,900	1,044	108	0.549	0.800	187.002	1.000	182.761
		2								
		3								
		4								
		5								
	2	1								
		2								
	3									
B	1	1	5,5404	3,354	1,688	0.614	10.000	38.101	1.300	
		2								
		3								
		4								
		5								
	2	1								
		2								
		3								
	3	4								
		1								
	4	2								
1										
2										
	3									

C	1	1	2,534	1,470	433	0.580	0.860	533.031	1.500	
		2								
	2	1								
		1								
	3	2								
		3								
		4								

Notes: Ref. Cty. stands for reference country; Int. Prod. stands for international product; Vol. stands for volume; Amt. stands for amount; Ave. stands for average; Adj. stands for adjusted; LC stands for local currency; Exch. Rate stands for Exchange Rate for Currency Conversion; NCPDP stands for National Council for Prescription Drug Program; GDP (PPP) stands for gross domestic product based on purchasing power parity. *The volumes in this example are in NCPDP units that correspond to GUARD Model drug I’s NCPDP unit. In this illustrative example, for GUARD Model I the set of international analogs is composed of two international products sold in Country A, four sold in B, and three sold in C. Gross and net sales and volume amounts for the streamlined option are reported at the net price level which means, with respect to sales of international products, sales at the same price and price concession. This means that the gross and net sales and volume are aggregated together as long as they correspond to a sale with the same price and price concession regardless of purchaser identity. For the limited option the net price levels are shown but reporting is at a country level hence there is only one gross and net sales and volume amount for each country. The country-level average net price is a weighted average where the weights are the corresponding volume to each price contributing to the average. The across-country average net price is a weighted average where the weights are the corresponding volume to each price contributing to the average and where each price has been multiplied by the appropriate country’s GDP (PPP) adjuster.

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4. Verification of the Submission

CMS proposes to assess each submission for validity as part of the verification process. For both options, CMS will use existing available information, including, for example U.S. Securities and Exchange Commission (SEC) filings, existing international drug pricing data from vendors, as described in section IV.E. of this proposed rule, reference countries central bank data, health ministry or other national registries and formularies, and other publicly available information to determine whether the values reported for the data elements fall within plausible and reasonable ranges. Some examples of publicly available data that could serve for the verification process are the Schedule of Pharmaceutical Benefits of the Australian Government’s Pharmaceutical Benefits Scheme ¹⁶⁶ and the United Kingdom’s National Health Service Medicines A to Z ¹⁶⁷ and Electronic Drug Tariff data. ¹⁶⁸

¹⁶⁶ Australian Department of Health, Disability and Ageing, Pharmaceutical Benefits Scheme. (n.d.). *A–Z Medicine Listing*. <https://www.pbs.gov.au/browse/medicine-listing> (Accessed: 10 December 2025).

¹⁶⁷ United Kingdom National Health Service. (n.d.). *Medicines A to Z*. <https://www.nhs.uk/medicines/> (Accessed: 10 December 2025).

¹⁶⁸ United Kingdom National Health Service Business Services Authority. (n.d.). *Drug tariff: Part VIII—Basic prices of drugs product list*. <https://www.drugtariff.nhsbsa.nhs.uk/#/00899627-DC/DC00899396/Part%20VIII%20-%20Basic%20Prices%20of%20Drugs%20Product%20List> (Accessed: 10 December 2025).

As part of the verification process, CMS proposes § 514.310(b) to conduct some or all of the following checks: cross reference check against existing international data for the set of international analogs; check for internal consistency; conduct cross-validation using external and public data; conduct technical data quality checks; and carry out any other appropriate checks for verification. CMS proposes to follow a resolution process if errors are identified, which is described later in this Section of this proposed rule.

To cross reference against existing international data for the set of international analogs for which data are submitted, CMS may compare the reported country-level average net prices and across-country average net price to existing data sources that contain gross prices. This will allow CMS to assess whether the reported data are consistent with existing data. For example, if a net price reported by a manufacturer is greater than the publicly available gross prices reported in existing international data sources, CMS may request further information. CMS believes that if this happens, it may be caused by data entry or unit error; misclassification of the price that is reported (for example, the net price estimate may actually reflect an intermediate price and not a net price); timing mismatch (for example, the net price estimate may reflect a different timeframe than the GUARD Model performance year for which it is submitted); inclusion or omission of an international product in the set of

international analogs that is not aligned with the GUARD Model drug (for example, including international products with a dosage form of single-use when the GUARD Model drug is a multi-dose vial or including international products with an oral dosage form—for instance a tablet—and a strength of 5 mg when the GUARD Model drug has an inhaled dosage form and a strength of 5 mg); other errors; or legitimate reasons that require further context. In addition, because some of the reference countries use international reference pricing, we may also compare the reported data against the existing list prices or gross prices in other countries that use international reference prices. This would allow CMS to assess whether the data values submitted are within a reasonable range. If there are questions, CMS may reach out to the manufacturer for an explanation and make a determination based on the explanation.

In addition, CMS may, as part of the verification process and as proposed in § 514.310(b), check for internal consistency, which means that CMS would examine the full set of data submitted along with the explanation of how the data was collected or calculated, compare with publicly available existing data, and make a determination about whether the values are logically consistent. For example, as part of this approach, CMS would conduct net-to-gross ratio checks and use existing data and research to determine whether the values reported are within reasonable ranges. Under this

approach, CMS may compare net-to-gross ratios of a given GUARD Model drug with information from the reference countries about the net price of the drug. For instance, in the United Kingdom, the voluntary scheme for branded medicines pricing, access, and growth (VPAG) requires pharmaceutical companies to pay the National Health Services of the United Kingdom, a percentage of the sales of branded medicines. The percentage for 2025 was 22.9 percent and for 2026 it will be decreased to 14.5 percent.¹⁶⁹ So, for the United Kingdom, CMS would not expect country-level average net-to-gross discounts and rebates to be less than 0.15. CMS seeks comment as to whether a net-to-gross ratio tolerance should be considered or if a specific tolerance level should be defined.

In addition, CMS may consider temporal logic in assessing the validity of the data reported. For example, any changes in net price should track market events. CMS may examine historical publicly available data to determine whether the data submitted is reasonable. CMS encourages manufacturers to submit historical net price data, but CMS decided against making this a requirement due to the burden it might impose on manufacturers. CMS seeks feedback on whether this should be a required data element.

CMS may also conduct technical data quality checks. This includes but is not limited to verification that the data reported are in consistent units; the time period aligns with the GUARD Model performance year for which it is submitted; any sales-weighting is done appropriately; the data is submitted in the correct currency; and that any rounding and scaling is applied consistently and according to guidance.

CMS may also conduct cross-validation using external and public data. This means that CMS may check the data submitted against market data or any other relevant public data, including but not limited to financial filings in the United States as well as in reference countries. CMS may also review how the manufacturer has described the aggregation and weighting process for the set of international analogs that correspond to a GUARD Model drug for which the data was submitted. If there are concerns with the logic of how the data was aggregated, how the sales were allocated, or any

other methodological concern, CMS may reach out to the manufacturer with questions. If the manufacturer is able to provide an explanation that is reasonable as assessed by CMS, CMS may consider the submission an applicable submission.

To facilitate the validation process, CMS recommends that manufacturers provide details for how they calculated the data elements for their selected option and any reasonable assumptions they made in the calculations. As part of the validity assessment, CMS may reach out to manufacturers with questions or request more information. CMS proposes at § 514.310(b) that manufacturers must respond to any questions related to the verification review in 15 calendar days. If a manufacturer does not respond, CMS will consider the submission to be unacceptable.

5. Alternatives Considered for the Submission Options

CMS considered offering a more comprehensive option for manufacturers to submit the international net pricing data. Under this option, in addition to the data elements noted in the previous options, manufacturers would have been required to submit more granular information. Specifically, in addition to submitting net sales amount at the net price level, manufacturers would be required to submit the corresponding price concessions at the net price level. However, we decided not to offer this option due to concerns around burden and challenges that manufacturers may experience in submitting data elements that are more detailed than the proposed options.

CMS also considered offering an option that allows manufacturers to submit, for the entire set of international analogs that correspond to a GUARD Model drug, only total gross revenue, total net revenue, and total volume across all reference countries. However, we decided against including this option in the proposal because CMS' ability to perform any verification would be limited.

We also considered whether, instead of manufacturers, CMS should calculate the country-level average net price and across-country average net price. We decided against this policy because we believe that the burden related to doing the calculations is minimal. In addition, we considered whether to require the manufacturer to also identify the lowest net price (and the reference country with this price) among the set of reference countries for the set of international analogs that correspond to

a GUARD Model drug. However, as this information is already part of the submission, we did not believe it was necessary. We seek feedback on these policies.

In offering the two options noted previously, CMS balanced multiple policy priorities, including administrative burden for manufacturers and CMS; the need for complete and valid data submissions; and potential concerns that may arise from disclosing detailed international drug pricing information. CMS recognizes that manufacturers may encounter challenges in submission of the voluntary net pricing data for a number of reasons, including, for example, due to the way contracts are structured (for example, timing or the bundle of drugs included in sales contracts); the relationships that manufacturers may have with subsidiaries that sell drugs in the reference countries; and for other reasons. CMS seeks feedback on the types of relationships and arrangements manufacturers within U.S. have with the distributors, purchasers or other entities involved in the supply chain of the international analogs that correspond to a GUARD Model drug in the set of reference countries that may pose a challenge for manufacturers to compile and collect these data elements. We also seek feedback on other challenges that manufacturers may face in compiling and calculating these data elements and suggestions to address these challenges. CMS also seeks comments on whether there are specific data reporting issues CMS should consider, including existing mechanisms that could reduce data reporting and collection burden. We also seek comments on the voluntary framework and the proposed options, including the alternative options considered, to report net pricing information for international analogs that correspond to the GUARD Model drugs.

6. Attestation and Submission

CMS proposes that submitted data must comply with data requirements as proposed at § 514.310(b). Each submission must include an attestation by an authorized representative where they certify the completeness and validity of the data submission on behalf of the manufacturer and any third-party entities relied upon for gathering, analyzing, or submitting the manufacturer net pricing data, as proposed at § 514.310(g)(2). At § 514.300, CMS proposes to define "authorized representative" as an individual, designated by a manufacturer, as responsible for

¹⁶⁹ United Kingdom Department of Health and Social Care, & Ahmed, Z. (2025). *Innovative medicines supported as rebate rate falls by a third*. GOV.UK. <https://www.gov.uk/government/news/innovative-medicines-supported-as-rebate-rate-falls-by-a-third> (Accessed: 10 December 2025).

submitting international drug net pricing data, and who is also responsible for managing all communications related to the submission on behalf of the manufacturer. Authorized representatives must provide their contact information and attest that the submission is accurate and complete to the best of the manufacturer's knowledge, the submission is prepared in full compliance with all the requirements of § 514.310(b), and submitted with proper authority on behalf of the manufacturer. If a submission does not include the attestation as described, it would not be considered complete.

At § 514.310(h), CMS proposes to maintain confidentiality of information submitted under this section to the extent permitted by law and in accordance with applicable privacy and security requirements. CMS proposes that the data submission and attestation process would occur through the CMS Health Plan and Management System (HPMS), which is currently used for the Manufacturer Discount Program and the Drug Price Negotiation Program reporting, or another existing CMS data system that would be adapted for this purpose at § 514.310(i). We would adapt the existing functionality that has been used for the Part D Inflation Rebate Program, the Medicare Drug Price Negotiation Program, or other existing CMS program to the extent feasible. Leveraging existing technology and systems will facilitate executing the data agreements and attestations, creating data layouts for the various data submission pathways, and ensure stakeholder confidence that the data will be safely transmitted and securely stored. Further, using existing infrastructure also provides established safeguards comparable to other government price reporting mechanisms.

CMS recognizes the market-sensitive nature of international pricing data and proposes to maintain confidentiality to the extent allowable under law. CMS seeks comments on additional privacy safeguards CMS should consider for international pricing data submissions.

7. Timing, Corrections, and Resubmissions

As discussed previously, CMS proposes at § 514.310(b) that if the manufacturer is electing to submit international drug net pricing information, the data submission must occur within 180 calendar days after the end of a performance year and the data that is contained within the submission must correspond to the performance

year for which the data may be used to determine the GUARD Model updated international benchmark. Recognizing potential challenges in international pricing data compilation, CMS is proposing to allow corrections and restatements of applicable submissions within 15 calendar days of the submission deadline. Following the previous example of the first performance year ending on December 31, 2027, where the manufacturers have to submit by June 29, 2028, at the latest, revisions are due July 14, 2028, at the latest. CMS may also request corrections or amendments, requiring eligible entity response within 15 calendar days of the request. CMS seeks comments on the sufficiency and appropriateness of proposed timelines.

In developing this policy, CMS also considered alternatives such as a longer timeline for submission of international drug net pricing information as manufacturers may need additional time for reconciliation of pricing data after the end of the calendar year. CMS understands that this process may vary widely by manufacturer and by reference country. As such, CMS seeks comments on whether the proposed timeline could create challenges for manufacturers submitting pricing data and how such challenges could be mitigated.

G. Determination of the GUARD Model Applicable International Benchmark

In this Section of this proposed rule, CMS describes the proposed approach to determine the GUARD Model applicable international benchmark that would be used to generate the GUARD Model rebate payment and test the alternative rebate calculation approach, as described in Section IV.H. of this proposed rule. In § 514.5, CMS proposes that the “GUARD Model applicable international benchmark” means, for each GUARD Model drug, the greater of the GUARD Model default international benchmark and, if available, the GUARD Model updated international benchmark; and for which an applicable adjustment factor has been applied.

We propose at § 514.5 that for each GUARD Model drug, the “GUARD Model default international benchmark” (also known as Method I) means for each GUARD Model drug, the lowest price in a set of country-level average prices calculated, using the steps proposed at § 514.410(c), for each reference country identified at § 514.220(d), where international drug pricing data is available from selected data sources per § 514.210 for at least one reference country and at least one reference country-level average price

can be calculated. If the country-level average price is a weighted-average, the weights are the corresponding volume for a price expressed in the terms of the NCPDP unit corresponding to the GUARD Model drug. In other words, the GUARD Model default international benchmark would be the lowest among a set of country-level average prices which are either volume-weighted or not, depending on data availability, and are adjusted by the reference country's specific GDP (PPP) adjuster, per the steps proposed at § 514.410(c).

As mentioned previously, the other possible benchmark is the “GUARD Model updated international benchmark” (also referred to as Method II) which is defined at § 514.5 to mean, for each GUARD Model drug, the across-country average net price, which is a volume-weighted average across all reference countries, identified at § 514.220(d), where an international product that is part of the set of international analogs is sold, and includes GDP (PPP) adjustments; the across-country average net price is part of an applicable submission of international drug net pricing data by manufacturers according to § 514.310. Thus, it is an average net price across all international products that are part of the set of international analogs for a GUARD Model drug and all reference countries where these international products are sold for which data is available, weighted by volume in NCPDP units, expressed as the price for one, and adjusted by the reference country's specific GDP (PPP) adjuster.

1. Calculation of the GUARD Model Default International Benchmark

CMS proposes to calculate for every GUARD Model drug, a GUARD Model default international benchmark, in advance of determining the GUARD Model rebate amount for the first performance year. If after the first performance year, CMS identifies a new GUARD Model drug for any of the 4 subsequent performance years, then CMS would calculate a GUARD Model default international benchmark for the new GUARD Model drug, as described in this Section of this proposed rule, prior to the GUARD Model rebate payment calculation, as described in section IV.H. of this proposed rule, but not for any of the GUARD Model drugs which already have a GUARD Model default international benchmark for the previous performance year.

By proposing at § 514.410(c) that once a GUARD Model default international benchmark is established, it is not changed, the possibility of having no international drug pricing data for one

or a number of GUARD Model drugs during a subsequent performance year, while others continue to have data, would be minimized. While CMS recognizes that there can be varying reasons for data discontinuity, if the GUARD Model drug continues to be sold during the GUARD Model performance period, CMS seeks to mitigate the possibility that lack of data for subsequent performance years is due to manufacturers' limiting availability of international drug pricing data.

In addition, by not changing the GUARD Model default international benchmark, any changes to gross prices in reference countries that do not necessarily represent increases in net prices—for example, due to accompanying increases to price concessions—would not impact the GUARD Model test, mitigating the possibility of price manipulation in reference countries.

For the same reasons, CMS believes that GUARD Model drugs that first qualify as such after the first performance year should be subject to the same process; thus, determination of their GUARD Model default international benchmark would take place prior to GUARD Model rebate payment determination for the earliest subsequent performance year when they qualify as GUARD Model drugs and then not change for the remainder of the GUARD Model performance period.

a. Identifying the Set of International Analogs

For calculation of the GUARD Model default international benchmark, CMS proposes in § 514.410(c) to use the selected data source of international drug pricing data to identify data for the set of international analogs that align with each GUARD Model drug. This involves identifying international products whose identifying characteristics align, as determined by CMS, with those of the GUARD Model drug. The identifying characteristics are active ingredient(s), route of administration, dosage form, and strength. The alignment of the characteristics would be achieved using the standardized method for differentiating products across these dimensions intrinsic to the data source (or sources) selected for use according to § 514.210(b).

To facilitate this identification, CMS would make adjustments as necessary, for example, by measurement unit conversion factors, so that the international products for a given GUARD Model drug are consistent with one another and with the GUARD Model drug's NCPDP unit. These

adjustments would not affect CMS' determination that the set of international analogs—composed of the international products with adjustments if needed—are aligned with the GUARD Model drug. CMS will use all available information to ensure that adjustments are appropriate. Examples of information sources are FDA sources, such as approved product labels, the *Drugs@FDA* regulatory approval database, the Purple Book and Orange Book, and the NDC Directory, the National Library of Medicine's RxNorm database, and the selected data source(s) documentation.

A more detailed description of the identification process follows here. To begin, CMS would identify from the selected data source(s), all of the international products whose identifying characteristics (active ingredient(s), route of administration, dosage form, and strength) are aligned with the GUARD Model drug, without any adjustments.

Next, for international products where their identifying characteristics do not exactly align with the GUARD Model drug's characteristics, standard adjustments that do not materially change the drug's characteristics would be applied. These include, for example, applying measurement unit conversion factors, removing prefixed or suffixes from active ingredient names, matching scientific names to active ingredient(s), and checking for idiosyncratic differences in spelling or formatting. For example, as an illustrative case, this means that if a data source has the chemical name (2S)-2-amino-3-(3,4-dihydroxyphenyl)propanoic acid, this would be equivalent and aligned to the active ingredient, levodopa. Any potential international products that, after these standard adjustments, are aligned across all their identifying characteristics to the GUARD Model drug, would be considered satisfactorily aligned.

For any international products that, after the standard adjustments, are still not aligned across all identifying characteristics of a GUARD Model drug, CMS would conduct further review. Specifically, CMS would determine whether any differences in identifying characteristics can be considered insignificant because, for example, they are attributable to the selected data source(s) internal record keeping or reference country specific considerations.

An example of a difference between product characteristics that CMS would consider equivalent related to a data source's internal record keeping is where a drug has the dosage form

characteristic described as a disposable vial in some countries but in others, the dosage form is a single-dose vial. Disposable vials are single-dose vials (which are not multi-dose vials). In this case, CMS would determine that the potential international analogs with both dosage forms, disposable vial and single-dose vial, are aligned with the GUARD Model drug described at the NDC-9 level as having a single-dose vial dosage form. As another example, CMS could determine that, for a GUARD Model drug with an extended release oral solid formulation, all international products sharing the same active general form (extended release oral solids) with dosage strengths measured on the same basis (for example, active ingredient mass per unit) as the GUARD Model drug could qualify as international analogs, even if the data source used by CMS further differentiates between different subcategories of extended release oral solids (such as tablets and capsules).

An example of country-specific considerations that CMS would take into account relates to the names of active ingredients. Although not a GUARD Model drug, in the U.S. and Japan, acetaminophen is an active ingredient, while in most other countries, instead of being called acetaminophen, it is referred to as paracetamol. In this case, CMS would consider acetaminophen and paracetamol aligned for the active ingredient characteristic.

Next, for any GUARD Model drug that is still not aligned with international products across all identifying characteristics (after the standard adjustments and review for non-significant differences), CMS would conduct further review. CMS proposes to further examine international products where the remaining misalignment is only in strength (this means the GUARD Model drug and the international products align in terms of active ingredient, route of administration, and dosage form) for cases when there is no other international product already aligned for a GUARD Model drug in a reference country. In other words, for reference countries where the GUARD Model drug's set of international analogs has at least one fully aligned international product, strength-misaligned international products would not be considered. However, for reference countries where the GUARD Model drug's set of international analogs has no fully aligned international products, strength-misaligned international products will be further considered depending on the number of strength-

misaligned international products available.

If there is only one strength-misaligned international product within a reference country, then it would be included in the set of international analogs for the GUARD Model drug and be used in determining the GUARD Model default international benchmark.

If there is more than one strength-misaligned-international analog product for a given reference country, CMS would find the relative difference in terms of strength between the two closest (in absolute terms) international analog product strengths to the GUARD Model drug's strength and compare it to the relative difference in prices for those same two strength-misaligned international products, unless the higher strength international product has a lower or equal price to that of the lower strength international product, in which case both international products are included in the set of international analogs. For example, if the GUARD Model drug's strength is 12 mg, and there are two strength-misaligned international analog products with strengths of 10 mg and 20 mg, their relative strength difference would be (20 mg-10 mg)/10 mg or 100 percent. If the prices for those same two strength-misaligned international products were \$2.00 per NCPDP unit for the 20 mg strength and \$1.25 per NCPDP unit for the 10 mg strength, their relative price difference would be (\$2.00-\$1.25)/\$1.25 or 60 percent. If instead the prices of those same two strength-misaligned international products were reversed, meaning the price of the 20 mg strength was \$1.25 and the price of the 10 mg strength was \$2.00, then the price of the larger strength international product is lower than that of the lower strength international product and therefore both the 10 and 20 mg strength international products would be included in the set of international analogs and the comparison between relative differences of strengths and prices would not be considered.

In cases where the comparison of the relative difference in strengths to the relative difference in prices is considered, there are two potential options:

- If the relative price difference is equal to or greater than half of the relative strength difference within a reference country, then CMS would include in the set of international analogs, the international product whose strength is closest in magnitude to the strength of the GUARD Model drug (in that reference country, and in absolute terms, with ties defaulting to the lower-strength international

product). For the above 10 mg and 20 mg example for an arbitrary reference country and a GUARD Model drug with a strength of 12 mg, this means that the 10 mg international product would be included in the set of international analogs for the GUARD Model drug (because 10 mg is closer to 12 mg in absolute terms than 20 mg).

- If the relative price difference is less than half of the relative strength difference, then both of the strength-misaligned international products with the closest strengths in absolute terms to the GUARD Model drug would be included in the set of international analogs for the GUARD Model drug. In the example noted previously, if the strength-misaligned international product with a strength of 20 mg has a starting price of \$1.50 instead of \$2.00, then the relative price difference is 20 percent, which is less than 50 percent. In this case, both the 10 mg and 20 mg international products would be included in the set of international analogs with their prices as observed in the data source and be part of the calculation of the GUARD Model default international benchmark.

Last, CMS may determine that potential international products are aligned with a GUARD Model drug and therefore would be included in the set of international analogs based on other factors, as long as they do not materially differ from the GUARD Model drug and if necessary, CMS would make methodologically appropriate adjustments for such inclusions. For example, for a strength-misaligned GUARD Model drug with more than one active ingredient, if there are combination products with the same set of active ingredients but different configurations of dosage strength in other countries, CMS could determine that the international products are sufficiently aligned with the GUARD Model drug.

Any potential international products that are still not aligned with a GUARD Model drug with respect to its identifying characteristics after the process described previously, would not be included in the set of international analogs used for calculation of the GUARD Model default international benchmark. CMS believes that, using the identification process described previously, we will be able to identify sets of international analogs for each GUARD Model drug to the extent to which the existing data sources of international drug pricing data, selected according to § 514.210(c), include such international analogs for the reference countries, identified in § 514.220(d). Under the proposed approach, CMS

would identify international analogs that are aligned with each GUARD Model drug, accounting for country-specific or data source idiosyncratic differences. CMS seeks comment on the alignment process, the strength-misalignment strategy for cases with no other international products in the set of international analogs, and on other adjustments that could be considered.

b. Exclusion of International Products From the Set of International Analogs

For each GUARD Model drug, once we have identified a set of international analogs that are aligned to the GUARD Model drug, CMS proposes at § 514.410(c)(3)(i) to exclude any international products identified in the selected data source as being an international generic or international biosimilar biological product according to the reference country's regulatory framework. This means that if the international product has sales in multiple reference countries, the data for the reference countries where it is classified in the data source as an international generic or an international biosimilar biological product based on the own-country's regulatory system would be excluded. The data for the reference countries where they are not classified as such would be retained.

By excluding international generics and international biosimilar biological products among international products, CMS aims to keep the differences between the GUARD Model drugs—which do not include any generics or biosimilar biological products—and their set of international analogs as limited as possible to just the country of sale and price. CMS believes that this is reasonable because it means there are no generics or biosimilar biological products among either the GUARD Model drugs or the corresponding set of international analogs.

We considered the option of including international products in the set of international analogs even if they are categorized as international generics and international biosimilar biological products, according to a reference country's regulatory framework. However, CMS believes that given the exclusion of sole-source generics and all biosimilar biological products from the GUARD Model, doing the same among international products results in appropriately matching GUARD Model drugs to their corresponding international products. We seek feedback on this approach.

CMS proposes at § 514.410(c)(3)(i) to exclude an international product from being part of the set of international analogs for a GUARD Model drug if in

the selected data source, its pricing information (price, sales, or volume) aggregated for the entire period observed has a value of zero or less than zero. Exclusion of these international products is necessary because they would not contribute to the calculation of the GUARD Model default international benchmark. We expect that this exclusion would affect very few international products given the data selection requirements from section IV.E. of this proposed rule.

CMS considered excluding an international analog in a reference country where the amount of sales dollars or the number of units sold for the entire 12-month period for that reference country was under a specific threshold. CMS believes that it is not necessary to apply exclusions based on total annual sales or units sold amounts in a reference country because small magnitudes of sales or units sold are valid data points; in the interest of improving precision of the GUARD Model default international benchmark, CMS believes this data should be utilized.

c. Other Considerations for the Sets of International Analogs

Data for the set of international analogs for all reference countries where it is sold for each GUARD Model drug, to the extent that the data is available in the selected data source(s), must be expressed in the GUARD Model drug's unit—the minimum possible dosing unit in a NCPDP standard. To achieve this, CMS would convert the international analog volume data from the selected data source's dosing unit to the corresponding NCPDP standard dosing unit. For example, assume that for the selected period in reference country Y, 100 units of an international analog A were sold. In the selected data source, the unit for international analog A is described as milliliter; the dosage form describes a syringe; and the pack size describes a two-ml syringe. As for the GUARD Model drug's unit, it is an each, which corresponds to 2-ml syringes. Thus, a conversion is needed. In this case, 50 units of international analog A were sold in reference country Y, in terms of NCPDP units.

Additionally, sales and prices would be expressed in U.S. dollars. Since data for the set of international analogs for each GUARD Model drug is across one or more reference countries, it is possible that the selected data source expresses prices and sales amounts in U.S. dollars, local currency, or some other standard currency. Using the selected data source's exchange rates for currency conversion, all prices and sales

amounts would be converted to U.S. dollars.

d. Process To Calculate GUARD Model Default International Benchmark

For each GUARD Model drug, CMS proposes at § 514.410(c)(iii) the steps to calculate a country-level average price for each reference country where international products part of the set of international analogs for a GUARD Model drug are sold, and among this set of country-level average prices, the lowest would be the GUARD Model default international benchmark. The calculation of the country-level average prices would use data for a GUARD Model drug's set of international analogs which includes international products for each reference country for the selected 12-month period per § 514.210; these data would be identified as outlined in § 514.410(c)(3)(i), converted (if necessary) to be in the appropriate GUARD Model drug's NCPDP unit, and converted (if necessary) into U.S. dollars.

The set of country-level average prices is composed either of average prices or volume-weighted average prices and each price of the set is a unitary price. If volume data is available, weights would be used to obtain the volume-weighted average, where the weights are in terms of volume as measured in NCPDP units; if volume data is not available then simply average prices would be calculated.

If volume data is available, the steps CMS proposes for calculating the country-level average price for a reference country, per § 514.410(c)(3)(iii), are as follows:

- First, each price (in U.S. dollars) for an international analog in a reference country will be multiplied by its corresponding volume (in NCPDP units corresponding with the GUARD Model drug unit) to obtain a weighted-price. If instead of a price, the selected data source provides sales amounts, then each sales amount (in U.S. dollars and for NCPDP units) is the weighted-price. The weighted-price is multiplied by the GDP (PPP) adjuster as defined at § 514.5.
- Second, CMS will calculate the reference country total weighted-price by adding up the weighted-prices from the first step, and the reference country total volume by adding up the volumes in NCPDP units.
- Third, CMS will divide total weighted-price and total volume from step two, obtaining the reference country's volume-weighted average price for one NCPDP unit of the international analog.

This process is repeated for each reference country, resulting in a set of country-level average prices from which the lowest in absolute terms is selected as the GUARD Model default international benchmark for the GUARD Model drug.

If volume data is not available—that is, the selected data source only has price data—then, CMS proposes to calculate the average price for a reference country at § 514.410(c)(3)(iii) by first ensuring all prices for a reference country are converted, if necessary, into the GUARD Model drug NCPDP unit, then expressed in terms of a unitary price (the price for one NCPDP unit), and multiplied by the GDP (PPP) adjuster as defined at § 514.5. Next, all these prices are added together and divided by the number of prices available resulting in a reference country's average price for one NCPDP unit. This process is repeated for each reference country, resulting in a set of country-level average prices from which the lowest in absolute terms is selected as the GUARD Model default international benchmark for the GUARD Model drug.

CMS considered excluding from the set of country-level average prices, those prices that are less than 5 or 10 percent of the GUARD Model drug's "performance year Medicare net price" which, as described in section IV.H.2. of this proposed rule and defined at § 514.5, is a per unit net price for the GUARD Model drug during the performance year, expressed in terms of NCPDP units calculated according to § 514.510(b) using the WAC, manufacturer direct and indirect remuneration (DIR), discounts from the Manufacturer Discount Program, and quantity dispensed across all PDE records associated with the GUARD Model drug during a performance year. As an example, if a GUARD Model drug's performance year Medicare net price is \$120 and the set of country-level average prices that resulted from the international products included in the set of international analogs is \$20, \$10, and \$5. The exclusion of country-level average prices that are less than 5 percent of the performance year Medicare net price would mean that prices less than \$6 would be excluded, therefore only the \$20 and \$10 prices would remain in the set to be used in calculating the GUARD Model default international benchmark. The exclusion of volume-weighted average prices that are less than 10 percent of the performance year Medicare net price would mean that prices less than \$12 would be excluded, therefore only the \$20 price would remain in the set to be

used in the calculation of the GUARD Model default international benchmark. However, CMS believes that including all available data increases accuracy and precision so we have not proposed this approach.

CMS also considered using an across country average instead of the lowest country average and using averages without volume-weighting for calculating the GUARD Model default international benchmark. However, an across country average does not represent an actual price paid for a GUARD Model drug in the reference countries, and using averages without volume-weighting, when volume is available, does not best reflect the typical price in a country because the amount a price should influence a country's average should correspond to how much of that country's sales volume is sold at that price.

In summary, the GUARD Model default international benchmark is the lowest (reference) country-level average price in U.S. dollars across international products included in a GUARD Model drug's set of international analogs sold in that reference country. It is calculated using international drug pricing data from selected data sources, excluding any international generics or international biosimilar biological products given the reference country's regulatory framework.

The GUARD Model default international benchmark is calculated for all GUARD Model drugs after the first performance year when they are included—and prior to that performance year's GUARD Model rebate payment determination. Once a GUARD Model default international benchmark has been calculated, it will serve as the GUARD Model default international benchmark for the remainder of the GUARD Model performance period. We welcome comment on this proposal and the alternatives presented.

2. Identification of the GUARD Model Updated International Benchmark

CMS proposes to determine, for every GUARD Model drug with an applicable submission of international drug net pricing data, a GUARD Model updated international benchmark (also referred to as Method II) in advance of the GUARD Model rebate payment determination, for every performance year for which an applicable submission is received, as described in section IV.F. of this proposed rule.

In the case where a GUARD Model drug has a GUARD Model updated international benchmark for a performance year, but for the next performance year, CMS does not receive

an applicable submission—for the next performance year and any subsequent performance years where there is no applicable submission, CMS proposes to utilize the default international benchmark. This is because for there to be a GUARD Model updated international benchmark for a performance year, there must be a corresponding applicable submission covering the dates for that performance year. Thus, for any subsequent performance year without an applicable submission, regardless of whether at any point previously in the GUARD Model performance period there was an applicable submission, CMS proposes that there would be no GUARD Model updated international benchmark.

By proposing that the GUARD Model updated international benchmark be limited to the performance year for which the applicable submission is received, CMS believes the most recent net price data should be used and that there would be no concerns regarding availability of net pricing data should a manufacturer choose to submit it. Manufacturer submitted data would therefore be for the same period as the one CMS would use to obtain the performance year Medicare net price, as discussed in section IV.H.2.a. of this proposed rule, which would be used to calculate the GUARD Model rebate amount for that performance year. CMS considered but decided against, using a GUARD Model updated international benchmark from a previous performance year—meaning it would have been determined from manufacturer submitted data for a previous performance year—because, given the voluntary nature of the data submission, the main focus is on ensuring the data is the most reflective of the specific performance year to which it corresponds. CMS seeks feedback on this approach.

Additionally, CMS believes that since the GUARD Model test would only determine a GUARD Model updated international benchmark if there is an applicable submission and otherwise would use the GUARD Model default international benchmark, it would encourage manufacturers to voluntarily submit data, which increases transparency.

CMS proposes in § 514.410(d) that the GUARD Model updated international benchmark would be the across-country average net price data element part of the applicable submission. This average is across the reference countries where international products that are part of the set of international analogs are sold in each of the reference countries; it is volume-weighted using the volume—

units in NCPDP equivalent; and GDP (PPP)-adjusted to account for country-level differences. CMS would obtain this average from the manufacturer's submission, if it is deemed applicable. The use of an across-country average net price for the GUARD Model updated international benchmark instead of the lowest country average as in the GUARD Model default international benchmark is due to the differing nature of the prices. For the GUARD Model default international benchmark, the set of prices are derived from the selected data source are likely to be ex-manufacturer prices—prices paid to the manufacturer by wholesalers and other distributors—but this is not guaranteed; they could potentially represent prices based on a distribution channel, or another variation, as described in section IV.E. of this proposed rule. Given the increased likelihood that prices are consistent within country but not necessarily across countries (due to using the best available data, which could still potentially be derived from different sources) and the nature of the prices (for example, depending on the time period and reference country), CMS believes it is preferable to select a country price and not average across countries when using the existing international data source. For the GUARD Model updated international benchmark, the net pricing data is reported by the manufacturer who is able to observe actual net prices, so we believe it is acceptable to use an average. We seek feedback on this approach.

3. Adjustment of the Applicable International Benchmark

In § 514.410(b), CMS proposes to determine the “GUARD Model applicable international benchmark” for each GUARD Model drug by identifying the greater of between the default international benchmark and the updated international benchmark and then applying an applicable adjustment factor. We propose at § 514.410(e), that when the GUARD Model applicable international benchmark is based on the GUARD Model default international benchmark, the applicable adjustment factor is 102 percent; if it is based on the GUARD Model updated international benchmark, the applicable adjustment factor is 105 percent. CMS also proposes the GUARD Model default international benchmark and the corresponding applicable adjustment factor would be used when there is no GUARD Model updated international benchmark for a performance year. Table B7 provides an illustrative example of how CMS would determine the GUARD Model applicable

international benchmark for a fictitious GUARD Model drug during the performance period.

CMS believes that a 2 percent adjustment for the GUARD Model default international benchmark accounts for potential differences between the U.S. market and markets in the set of reference countries for which international drug pricing information is available. Although the proposed calculation for the GUARD Model default international benchmark price includes adjustments for economic and purchasing power differences, further adjustment for some potential remaining differences by applying a minimal adjustment could be warranted. Therefore, we propose a 2 percent increase in the GUARD Model default international benchmark amount to account for potential differences between the U.S. market and markets in the reference countries that would not be addressed otherwise, meaning that the GUARD Model default international benchmark would represent 102 percent of the original value after adjustment.

We believe a 2 percent adjustment is appropriate because the GUARD Model default international benchmark is already based on the lowest country-level average price among the set of reference countries.

CMS also believes a 5 percent adjustment for the GUARD Model updated international benchmark accounts for potential differences between the U.S. market and markets in the set of reference countries for which international drug pricing information is available. Although the proposed calculation for the GUARD Model updated international benchmark price includes adjustments for economic and purchasing power differences, further adjustment for some potential remaining differences by applying a minimal adjustment could be warranted. In addition, such an adjustment, if it is greater than the adjustment for the GUARD Model default international benchmark could incentivize manufacturer submission of international net pricing data. Therefore, we propose a 5 percent

increase in the GUARD Model updated international benchmark amount to account for potential differences between the U.S. market and markets in the reference countries that would not be addressed otherwise; this means that the GUARD Model updated international benchmark would represent 105 percent of the original value after adjustment. This would also maintain an incentive for manufacturers to submit the voluntary international net pricing data.

We considered different adjustment factors however, we believe an adjustment factor of 2 percent for the GUARD Model default international benchmark and an adjustment factor of 5 percent for the GUARD Model updated international benchmark is appropriate given the other types of adjustments across the reference countries (for example, GDP (PPP) adjustments). We welcome comments on our proposal for the applicable adjustment factor that may help advance the aims of the model test.

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TABLE B7: ILLUSTRATIVE DETERMINATION OF GUARD MODEL APPLICABLE INTERNATIONAL BENCHMARKS FOR THE GUARD MODEL PERFORMANCE PERIOD

GUARD Model Drug	Intl. Pricing Data that Allows for Calculation of Default Intl. Benchmark	Calculation of the Default Intl. Benchmark	Voluntary Manufacturer Submission	Applicable Submission that Allows for Determination of the Updated Intl. Benchmark	Applicable Intl. Benchmark
<i>PY 1</i>					
1	No	No	No	N/A	None
2	Yes	Yes	No	No	Default intl. benchmark
3	Yes	Yes	Yes	Yes	Greater of default and updated intl. benchmark
<i>PY 2</i>					
1	Yes	Yes	No	No	Default intl. benchmark
2	N/A	No, use PY1	No	No	Default intl. benchmark
3	N/A	No, use PY1	Yes	Yes	Greater of default and updated intl. benchmark
<i>PY 3</i>					
1	N/A	No, use PY2	No	No	Default intl. benchmark
2	N/A	No, use PY1	Yes	No	Default intl. benchmark
3	N/A	No, use PY1	Yes	Yes	Greater of default and updated intl. benchmark
4	Yes	Yes	No	No	Default intl. benchmark
<i>PY 4</i>					
1	N/A	No, use PY2	No	No	Default intl. benchmark
2	N/A	No, use PY1	No	No	Default intl. benchmark
3	N/A	No, use PY1	Yes	Yes	Greater of default and updated intl. benchmark
4	N/A	No, use PY1	No	No	Default intl. benchmark
<i>PY 5</i>					
1	N/A	No, use PY2	No	No	Default intl. benchmark
2	N/A	No, use PY1	No	No	Default intl. benchmark
3	N/A	No, use PY1	Yes	Yes	Greater of default and updated intl. benchmark
4	N/A	No, use PY1	No	No	Default intl. benchmark
5	Yes	Yes	Yes	Yes	Greater of default and updated intl. benchmark

Notes: PY stands for performance year, as defined at § 514.5; Intl. Benchmark stands for International Benchmark; N/A stands for not applicable.

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4. Alternatives Considered

CMS considered an alternate process for identifying the set of international analogs from the selected data source of international drug pricing data. The process proposed in § 514.410(c)(3)(i) is to identify international products whose identifying characteristics align each GUARD Model drug both without any adjustments and with standard adjustments that do not change the drug's characteristics and that have non-significant differences. For any GUARD Model drugs for which there is no international product aligned but there is at least one strength-misaligned international product, CMS proposes in § 514.410(c)(3)(i), a process to consider drug pricing information for the strength-misaligned product(s) for the GUARD Model drug. An alternate process that CMS considered is to apply the process to consider drug pricing information for the strength-misaligned product(s) to all GUARD Model drugs, and not only to those that have no aligned international products. This would result in an increased number of international products contributing to the drug pricing information used to calculate the GUARD Model default international benchmark.

CMS also considered changes to the identification process in relation to which strength-misaligned product(s) would be retained. One alternative possibility that CMS considered was for cases when there is more than one strength-misaligned international product for a reference country; for such a case, records for the two strength-misaligned international products closest in strength (in absolute terms) to the GUARD Model drug's strength would be retained without any further considerations. This is different from the proposed process of comparing the relative strength difference and relative price difference to determine if one or two of the strength-misaligned international products closest in strength to the GUARD Model drug's strength would be retained.

Another possibility that CMS considered was for cases when there is more than one strength-misaligned product for a reference country and the relative difference is equal to or greater than half of the relative strength difference. In these cases, CMS has proposed to retain records for the strength-misaligned international product whose strength is closest in absolute terms to the GUARD Model drug's strength. The alternative CMS considered was to retain the same strength-misaligned international

product whose strength is closest in absolute terms to the GUARD Model drug's strength but to modify its price by multiplying it by the ratio of strengths between the two strength-misaligned international products closest to the GUARD Model. CMS seeks comment on these alternative identification processes.

CMS considered a range of alternatives for identifying the GUARD Model default and updated international benchmarks. Specifically, CMS considered using the lowest country level price for the GUARD Model updated international benchmark, however, we decided against this due to concerns about the sensitivity around net price data. We seek comments on the proposed approach, and in particular, whether we should consider using the lowest country-level average net price for the GUARD Model updated international benchmark. For the GUARD Model default international benchmark, CMS considered the possibility of adjusting annually for inflation. However, it is not clear how best to do that given the differences in reference countries that exist and because each drug may have a different reference country that is used to identify the GUARD Model default international benchmark; it is also not clear if inflation adjustment should be only relative to a U.S. price or if it should consider inflation in reference countries. Therefore, we are soliciting comments on this potential policy to inflation adjust the GUARD Model default international benchmark and the best ways to implement this.

CMS also considered, for the calculation of the GUARD Model default international benchmark, not adjusting country-level average prices to account for economic differences among countries, such as GDP per capita, prior to the comparison of the available set of country-level average prices to identify the lowest country-level average price for a GUARD Model drug. We considered that perhaps there was not a need to GDP (PPP) adjust a single country-level average price for several reasons. First, the default GUARD Model default international benchmark represents an average within a country that would be expressed in U.S. dollars using the appropriate exchange rate for currency conversion. Second, while adjusting for GDP (using PPP) is valuable for selecting economically comparable countries, at the more granular level, it is limited in its ability to account for local differences in costs,

taxes, tariffs, and competition.¹⁷⁰ Third, CMS considered that allowing the GUARD Model default international benchmark to remain unadjusted would create a benefit for manufacturers should they choose to submit net pricing information as discussed in Section IV.F. of this proposed rule. However, we decided against this because we believe that GDP (PPP) adjustment is the best practice when examining prices across countries. CMS welcomes comments on this alternative considered and other alternatives presented here, as well as our policy proposals.

Another alternative for calculation of the GUARD Model default international benchmark considered was updating said benchmark each performance year if a subsequent performance year's calculation resulted in a lower benchmark or if it changed at all. However, we decided against this to ensure that data availability did not result in some GUARD Model drug's being updated and others not.

We also considered a different approach to calculating the adjustment factor for the GUARD Model default and updated international benchmarks. In developing our proposal for the adjustment factor, we considered two options for structuring the adjustment: (1) applying a fixed adjustment (such as a percentage amount) for all GUARD Model drugs regardless of the benchmark method; or (2) applying a variable adjustment that reflects one or more characteristics of the GUARD Model drug, the alternative rebate calculations, or reference countries. Another alternative CMS considered was to delay enactment of the adjustment factor. This would mean that instead of applying the adjustment factor in performance year one, it would be applied during a subsequent performance year. We seek comment on whether the enactment of the adjustment factor should be implemented as proposed or delayed to a subsequent performance year. We also considered that no adjustment would be necessary. However, we opted to prioritize a straightforward approach that is intuitive and easy to implement. We seek feedback on whether an adjustment factor should be applied to the GUARD Model default and updated international benchmarks and the value of the adjustment factor, including any rationale for why it should be increased

¹⁷⁰ Pakko, M.R., and Pollard, P.S. (2003). *Burgernomics—A Big Mac™ Guide to Purchasing Power Parity*. *Review*, 85 (Nov), 9–28. Federal Reserve Bank of St. Louis. <https://fedinprint.org/item/fedlr/25916>.

or decreased or applied in a different way.

CMS welcomes feedback on all of the policies presented in this section of this proposed rule and the alternatives considered.

H. Determination of the GUARD Model Rebate Payment Amount

The GUARD Model would test an alternative calculation of the rebate amount described in subsection (b) of section 1860D–14B of the Act for the purpose of testing whether this reduces Medicare expenditures while preserving or enhancing quality of care; this alternative calculation would yield the “GUARD Rebate Payment Amount.” Under the GUARD Model, we would waive the calculation described in subsection (b) of section 1860D–14B of the Act—replacing it with the GUARD Rebate Payment Amount—in circumstances where the per unit GUARD Model rebate, as described later in this Section of this proposed rule, exceeds the per unit Part D inflation rebate amount for a GUARD Model drug in a given GUARD Model performance year.

In this Section of this proposed rule, we describe our proposal for the alternative calculation of the rebate amount described in section 1860D–14B(b) of the Act to yield the GUARD Rebate Payment amount, including the steps to calculate the performance year Medicare net price and the per unit GUARD Model rebate, as well as determining whether the per unit GUARD Model rebate exceeds the per unit Part D inflation rebate amount. To clearly identify the alternative rebate under the GUARD Model test, CMS would calculate the total GUARD Model rebate payment amount for which manufacturers would be accountable.

To avoid potential duplication across activities under the Medicare Part D Drug Inflation Rebate Program, an incremental per unit GUARD Model rebate amount (calculated by comparing the per unit Part D inflation rebate amount to the per unit GUARD Model rebate) would be multiplied by the total GUARD billing units to calculate the Total Incremental GUARD Model rebate amount (as described later in this section of this proposed rule). This amount would be used to reconcile the amounts invoiced through the Medicare Part D Inflation Rebate Program against the total GUARD Model rebate payment amount.¹⁷¹ This amount would be reflected in the follow-on steps for GUARD Model reporting, invoicing, and rebate payment as discussed in section IV.I. of this proposed rule. The Total Incremental GUARD Model rebate amount would be adjusted prior to these follow-on steps, when applicable, for GUARD Model drugs in shortage or when there is a severe supply chain disruption or likely shortage, as discussed in this Section of this proposed rule. We also include proposals for how we aim to account for the Manufacturer Discount Program.

The alternative calculation tested under the GUARD Model that would be used to yield the GUARD Model Rebate Amount compares a Medicare net price (that excludes manufacturer direct and indirect remuneration (DIR) and discounts paid under the Manufacturer Discount Program) for each GUARD Model drug against the GUARD Model applicable international benchmark. Comparison against a Medicare net price that is exclusive of the manufacturer DIR and Manufacturer Discount Program discount amounts ensures that the GUARD Model applicable international benchmark is

compared against a price that takes into account rebates and discounts provided by manufacturers. CMS proposes this approach so that manufacturers receive “credit” for the rebates and discounts that they have provided to Part D plans or their PBMs and these amounts are subtracted in the calculation of the GUARD Model Rebate amount.

1. Calculation of the Total GUARD Model Rebate Drug Amount

At proposed § 514.510, CMS describes the calculation of the total GUARD Model rebate amount for a GUARD Model drug for a performance year. Specifically, CMS is proposing that the total GUARD Model rebate amount would be equal to the product of (1) the per unit GUARD Model Rebate amount for such GUARD Model drug for the performance year, and (2) the total number of units of the GUARD Model drug dispensed under Part D and covered by Part D plan sponsors for beneficiaries residing in the GUARD Model geographic areas during the performance year.

2. Calculation of the per Unit GUARD Model Drug Rebate Amount

To calculate the per unit GUARD Model rebate amount, CMS is proposing at § 514.510(b) that CMS would determine the amount by which the performance year Medicare net price for a GUARD Model drug exceeds the GUARD Model applicable international benchmark, illustrated in Figure B1. CMS proposes calculations for the performance year Medicare net price and comparison of these amounts to produce the per unit GUARD Model rebate amount.

Figure B1: Calculation of Per Unit GUARD Model Rebate Amount



a. Calculation of the Performance Year Medicare Net Price

CMS is proposing that the performance year Medicare net price for

a GUARD Model drug would be a per unit net price for the GUARD Model Part D rebatable drug during the performance year, expressed in terms of NCPDP units. To generate the

performance year Medicare net price, CMS proposes to first calculate a performance year aggregate gross price using WAC, then subtract manufacturer rebates derived from detailed DIR¹⁷²

¹⁷¹ There are differences in timing between the GUARD Model’s performance year and the Part D Drug Inflation Rebate Program’s applicable period. Specifically, while the GUARD Model’s performance year would be implemented on a calendar year schedule, the Part D Drug Inflation Rebate Program’s applicable period is based on a fiscal year schedule. As a result, there would be

Part D inflation rebate amounts from 2 fiscal years of the Part D Inflation Rebate Program that contribute to the GUARD Model’s single performance year report for a GUARD Model drug. To compare the per unit Part D inflation rebate amount to the per unit GUARD Model rebate, the Part D inflation rebate amount would be weighted to produce a per unit performance year Part D

inflation rebate amount as described in this section of this proposed rule.

¹⁷² Centers for Medicare & Medicaid Services. (2025). *HPMS memos—Week 4: April 21–25*. U.S. Department of Health and Human Services. <https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-april-21-25> (Accessed: 10 December 2025).

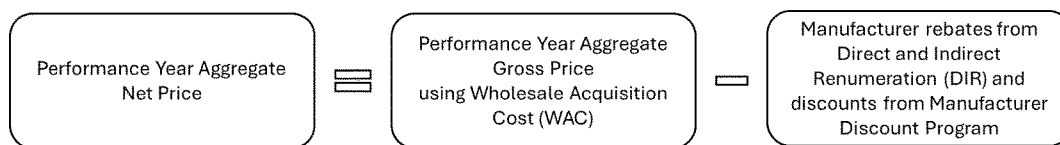
reported by Part D plan sponsors and discount amounts provided by manufacturers via the Manufacturer Discount Program to produce a performance year aggregate net price. Finally, CMS proposes to divide the

performance year aggregate net price by the sum of the total quantity dispensed across all PDE records associated with the GUARD Model drug during the performance year to yield the performance year Medicare net price.

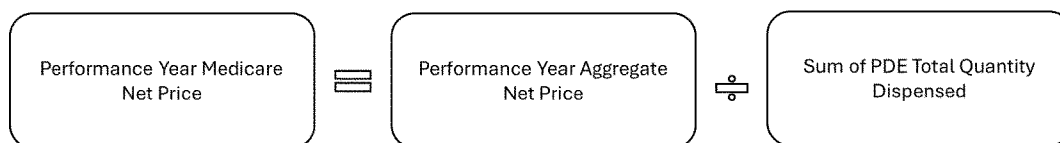
These steps are illustrated in Figure B2 and described in further detail.

Figure B2: Calculation of Performance Year Medicare Net Price for a GUARD Model Drug

Step 1: Calculate performance year aggregate net price



Step 2: Calculate performance year Medicare net price



CMS proposes at § 514.510(b) to use WAC as the starting point to calculate the performance year Medicare net price for the purpose of calculating the GUARD Model rebate amount. Section 1847A(c)(6)(B) of the Act defines WAC as the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States as reported in wholesale price guides or other publications of drug pricing data. We believe that using WAC is appropriate for these reasons: (1) WAC is the manufacturer determined list price for the drug and the starting point for negotiations within the pharmaceutical drug supply chain market; (2) WAC does not include any discounts, rebates, or any other price concessions, which means it is an appropriate price from which to subtract manufacturer rebates, as identified in DIR, as well as discount amounts from the Manufacturer Discount Program, to calculate the performance year Medicare net price; and (3) WAC is publicly posted, which promotes transparency.

We considered using the gross covered prescription drug costs (GCPDC) reported to Medicare in PDE in lieu of WAC; however, GCPDC is based on the plan and Part D enrollee payments and does not represent the manufacturer price for a given drug. GCPDC is a beneficiary—and claim-level—spending measure and not a manufacturer pricing measure. It captures the sum of payments by plans, beneficiaries, and Medicare at the negotiated point-of-sale price, and it has no relationship with the manufacturer's list or invoice price. Manufacturer

rebates are paid retrospectively, and they are not matched to individual GCPDC claims. Therefore, we do not believe it is an appropriate cost measure to use for this calculation.

CMS also considered using the AMP as the starting point to calculate the Medicare net price. AMP is the average unit price paid to the manufacturer by wholesalers for drugs distributed to retail pharmacies, and it is used as the basis for the Part D inflation rebate calculation. AMP is calculated using sales transaction data and reflects cash discounts, volume discounts, and other reductions in the actual price paid, as specified in 42 CFR 447.504(b). CMS proposes *not* to use AMP as the starting point to calculate the Medicare net price for the purpose of the GUARD Model Rebate calculation for two main reasons. First, there may be some differences in the way that AMP is calculated across manufacturers. CMS allows manufacturers to make reasonable assumptions that are consistent with statutory requirements in calculating AMP. A survey by the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) found that manufacturers reported the need for more guidance related to accounting for bona fide service fees and rebates to PBMs in the calculation of AMP, and noted that there may be differences in how manufacturers are incorporating these components into their AMP calculations.¹⁷³ Second,

there are differences in how AMP is calculated for inhalation, infusion, instilled, implanted, or injectable (5i) drugs, which have a high share of units reimbursed through non-retail pharmacies. These differences would complicate the calculation of the Medicare net price (and the GUARD Rebate amount) by creating discrepancies between 5i drugs and non-5i drugs. Specifically, manufacturers with 5i drugs are required to follow an alternative methodology for AMP calculation. If 70 percent or more of the sales in units are to entities other than retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies, then a manufacturer must use the 5i methodology for the monthly AMP calculation.¹⁷⁴ There is also the possibility, depending on sales, that the drug may be subject to the 5i AMP methodology in 1 calendar quarter, but not subject to that methodology in the next calendar quarter. One study examined differences in AMP, Medicaid rebates, and net Medicaid costs under the standard and 5i AMP methodologies and found that AMP was 42 percent lower on average because of the differences between the 5i methodology compared to the standard methodology.¹⁷⁵

Services. <https://oig.hhs.gov/oei/reports/oei-12-17-00130.pdf> (Accessed: 10 December 2025).

¹⁷⁴ Section 1927(k)(1)(B)(i)(IV) of the Act, 42 U.S.C. 1396r–8; 42 CFR 447.504(d) and 447.507. https://www.ssa.gov/OP_Home/ssact/title19/1927.htm (Accessed: 10 December 2025).

¹⁷⁵ Dickson, S., et al. (2022). Reduction in Medicaid Rebates Paid by Pharmaceutical

¹⁷³ Office of the Inspector General. (2019). *Reasonable Assumptions in Manufacturer Reporting of AMPs and Best Prices* (OEI–12–17–00130). U.S. Department of Health and Human

For these reasons, although we believe that AMP is appropriate for the Part D inflation rebate calculation when examining year-over-year differences in manufacturer prices within the U.S., we do not believe AMP is appropriate for calculating the Medicare net price for purposes of the GUARD Model. Whereas the GUARD Model makes a point-in-time comparison of the Medicare net price to the GUARD Model applicable international benchmark, which is a single benchmark based on reference countries, the Part D inflation rebate calculation compares the same price measure over time within the U.S.

CMS also considered using National Average Drug Acquisition Cost (NADAC), which represents the prices paid by pharmacies for prescription drugs. However, because this represents a pharmacy retail price, we do not believe it is appropriate to subtract the manufacturer DIR and Manufacturer Discount Program discount amounts from this price measure. CMS seeks feedback on our approach to calculate the Medicare net price for the purpose of calculating the GUARD Model Rebate amount, including any feedback on the proposed use of WAC in lieu of AMP, GCPDC, and NADAC to calculate the Medicare net price.

(1) Performance Year Aggregate Gross Price

As proposed at § 514.510(b)(1)(i), CMS is proposing to use WAC to calculate the performance year aggregate gross price. CMS is proposing to first identify all PDE records for all NDC–11s associated with the NDC–9 of the GUARD Model drug, and with dates of service during the performance year. Second, for each of the PDE records, CMS would identify a WAC based on the NDC–11 and multiply the quantity dispensed reported on the PDE record by the identified WAC value. Third, CMS would sum all the results of the second step across all PDE records to produce the performance year aggregate gross price.

It is necessary to assign a WAC to all PDE records associated with the GUARD Model drug during the performance year because manufacturer rebates and Manufacturer Discount Program discount amounts will reflect all such PDE records. The identification of the WAC for each PDE record would involve two elements. For the first element, CMS would use third party sources to identify the WAC based on

the NDC–11 for each PDE record with dates of service during the performance year. If the WAC is not available for that NDC–11, then CMS would use a WAC that is available for another NDC–11 with the same associated NDC–9, having confirmed that the WAC is expressed in a per unit amount.

The second element for the identification of the WAC for each PDE record, would involve CMS identifying the WAC in effect¹⁷⁶ on the date of service reported on the PDE record. If there was not an effective WAC as of the date of service for any PDE records during the performance year, CMS proposes to use the most recently effective WAC available. If the GUARD Model drug has some PDE records during the performance year for which there was an effective WAC as of the date of service, but other PDE records during the performance year for which there was not an effective WAC as of the date of service, CMS proposes to impute a WAC for the latter category of PDE records based on the available WAC that was in effect most recently before the date of service on the PDE record. If there was no WAC in effect before the date of service on the PDE record, but there was a WAC in effect after the date of service, CMS proposes that the WAC that was in effect after the date of service would be applied to that PDE record.

If after considering both elements of the identification previously described there is no WAC available for any NDC–11 associated with the NDC–9 of the GUARD Model drug, CMS will not calculate a performance year aggregate gross price or issue a GUARD Model Rebate Report for that performance year.

CMS considered whether we should use a different measure other than WAC if there is no WAC available, such as the AMP, NADAC, average wholesale price (AWP), GCPDC, or other appropriate measure. However, we believe that WAC is available for most drugs and therefore, another pricing measure is not necessary. We seek feedback on this approach and whether alternative measures such as AMP, NADAC, AWP, or GCPDC should be considered.

(2) Performance Year Aggregate Net Price

As proposed at § 514.510(b)(1)(ii), CMS would next calculate the performance year aggregate net price by subtracting manufacturer rebates derived from DIR reported by Part D

sponsors and Manufacturer Discount Program discount amounts from the performance year aggregate gross price. First, for each Part D plan and each NDC–9 of a GUARD Model drug, CMS would sum the total manufacturer rebate amounts obtained from the detailed DIR report across all plans and associated NDC–11s for the GUARD Model drug for the performance year. CMS would then subtract this sum from the performance year aggregate gross price. CMS would not subtract other price concessions reflected in the DIR reports because manufacturers do not incur those amounts.

Next, CMS would calculate the total Manufacturer Discount Program discount amounts that would also be subtracted out of the performance year aggregate gross price. As described in the Revised Medicare Part D Manufacturer Discount Program Final Guidance (Manufacturer Discount Program Final Guidance), the Manufacturer Discount Program was enacted into law in section 11201 of the Inflation Reduction Act of 2022, Public Law 117–169 (IRA) and codified in sections 1860D–14C and 1860D–43 of the Act.¹⁷⁷ Under the Manufacturer Discount Program, participating manufacturers are required to provide discounts on their applicable drugs (defined in section 1860D–14C(g)(2) of the Act and in section 130 of the Manufacturer Discount Program Final Guidance as proposed in the Medicare Program; Contract Year 2027 Policy and Technical Changes to the Medicare Advantage Program proposed rule (90 FR 95148; November 28, 2025)¹⁷⁸ when dispensed to Part D enrollees in the initial and catastrophic phases of the Part D benefit. As described in section 50 of the Manufacturer Discount Program Final Guidance, discounts are equal to 10 percent of the negotiated price of the applicable drug when dispensed to an applicable beneficiary in the initial coverage phase of the Part D benefit, and 20 percent of the negotiated price of the applicable drug when dispensed to an applicable

¹⁷⁷ Centers for Medicare & Medicaid Services. (2024). *Revised Manufacturer Discount Program Final Guidance*. U.S. Department of Health and Human Services. <https://www.cms.gov/files/document/revised-manufacturer-discount-program-final-guidance122024.pdf> (Accessed: 10 December 2025).

¹⁷⁸ Centers for Medicare & Medicaid Services. (2025). *Medicare Program; Contract Year 2027 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program* (Proposed Rule, 90 FR 54894). <https://www.federalregister.gov/documents/2025/11/28/2025-21456/medicare-program-contract-year-2027-policy-and-technical-changes-to-the-medicare-advantage-program> (Accessed: 10 December 2025).

Manufacturers for Outpatient Infused, Injected, Implanted, Inhaled, or Instilled Drugs: The 5i Loophole. *Journal of Health Politics, Policy and Law*, 47(6), 835–851. <https://doi.org/10.1215/03616878-10041219>.

¹⁷⁶ The WAC in effect on a date of service is the WAC that has the closest effective date prior to the date of service and either an end date after the date of service or no end date listed.

beneficiary in the catastrophic phase of the Part D benefit. As discussed in section 50.1 of the Manufacturer Discount Program Final Guidance, the IRA establishes lower percentages for discounts during a multi-year phase-in period for certain applicable drugs of specified manufacturers dispensed to applicable beneficiaries who are eligible for a low-income subsidy (LIS) under section 1860D–14(a) of the Act and for certain applicable drugs of specified small manufacturers when dispensed to any applicable beneficiary. CMS proposes to sum the Manufacturer Discount Program discount amounts paid by a manufacturer for a GUARD Model drug during the performance year, as well as the discounts that would have been paid by a manufacturer for a GUARD Model drug if not for the specified manufacturer and specified small manufacturer phase-ins, and subtract these amounts from the performance year aggregate gross price. The resulting amount (that is, the performance year aggregate gross price, net of manufacturer rebates and Manufacturer Discount Program discount amounts) would equal the performance year aggregate net price. The reason that CMS proposes to include the discount amounts that would have been paid by a manufacturer for a GUARD Model drug if not for the specified manufacturer and specified small manufacturer phase-ins in the total amount subtracted is to allow manufacturers to continue to experience the benefit of the phase-ins, as applicable, rather than transferring liability for the full discount amounts to the GUARD Model.

(a) Calculating Manufacturer Discount Program Discount Amounts for Non-Phase-In Eligible Drugs

CMS is proposing to derive Manufacturer Discount Program discount amounts from accepted final action, non-delete PDE records for the relevant performance year. For applicable drugs that do not have a specified manufacturer or specified small manufacturer phase-in applied, CMS would aggregate the Manufacturer Discount Program discount amounts for the performance year by NDC–9 by summing the amounts in the Reported Manufacturer Discount field on the PDE Inbound file layout.¹⁷⁹ The Reported

Manufacturer Discount amount is reported by the Part D sponsor to convey the Manufacturer Discount Program discount amounts to CMS on the PDE. Therefore, summing amounts in this field on accepted final action, non-delete PDE records for each NDC–9 not subject to phase-in would provide reliable Manufacturer Discount Program discount amounts for these manufacturers.

(b) Calculating Manufacturer Discount Program Discount Amounts for Phase-In Eligible Drugs

For PDE records of applicable drugs that do have a phase-in applied, CMS is proposing at § 514.510(b)(ii) to calculate the discount as if the phase-in had not been applicable and then aggregate the Manufacturer Discount Program discount amounts for the performance year by NDC–9 as described previously for non-phase-in eligible drugs.

CMS' proposed three-phase methodology would preserve the statutory intent to delay imposition of full Manufacturer Discount Program discount amounts for specified manufacturers or specified small manufacturers. This three-phase methodology includes: (1) identifying the phase-in eligible PDEs records; (2) determining which of the associated PDE records were adjudicated during the Initial Coverage Phase or Catastrophic Phase; and (3) calculating the 10 percent or 20 percent discount based on the benefit phase identified to derive the Manufacturer Discount Program discount amount for each NDC–9.

Specifically, CMS would identify accepted final action, non-delete PDE records where a phase-in discount was applied through use of two fields on the PDE Outbound File Layout: Applicable Discount Percentage for Specified Small Manufacturer Drugs and Applicable Discount Percentage for Specified Manufacturer Drugs Dispensed to LIS Beneficiaries.¹⁸⁰

For the identified PDE records, CMS would calculate the Manufacturer Discount Program amount that would be subtracted from the Performance Year Aggregate Net Price. First, CMS would determine the drug costs that fall into the Initial Coverage and Catastrophic Phases of the Part D benefit. If the True

Out-of-Pocket (TrOOP) Accumulator field included on the PDE is less than the defined standard (DS) deductible, CMS would subtract the difference between the DS deductible and the TrOOP Accumulator from the Gross Drug Cost Below the Out-of-Pocket Threshold (GDCB) amount to find the drug cost that falls in the Initial Coverage Phase. If the TrOOP Accumulator is higher than or equal to the DS deductible, then the full GDCB amount represents the drug cost that falls in the Initial Coverage Phase. The Gross Drug Cost Above the Out-of-Pocket Amount (GDCA) represents the drug cost that falls in the Catastrophic Phase. Second, CMS would calculate a discount of 10 percent for drug costs that fall in the Initial Coverage Phase and a discount of 20 percent for drug costs that fall in the Catastrophic Phase. The sum of the calculated discounts for each NDC–9 for both phases would be subtracted from the Performance Year Aggregate Net Price.

If a GUARD Model drug is not an applicable drug under the Manufacturer Discount Program, the methodology described previously to subtract Manufacturer Discount Program discount amounts from the Performance Year Aggregate Net Price would apply no differently. In other words, the Manufacturer Discount Program amount subtracted from the Performance Year Aggregate Net Price would equal zero. As discussed previously in section IV.B.2. of this proposed rule and proposed § 514.120(c)(1), CMS is proposing that generic drugs and biosimilar biological products would be excluded from the definition of GUARD Model drugs. If the proposal to exclude generic drugs and biosimilar biological products from the definition of a GUARD Model drug is finalized in a final rule establishing the GUARD Model, CMS believes that all remaining GUARD Model drugs would be applicable drugs.

(c) Converting the Performance Year Aggregate Net Price to a Per Unit Price

To generate the performance year Medicare net price, CMS is proposing at § 514.510(b)(1)(iii) to convert the performance year aggregate net price for a GUARD Model drug into a per unit price by dividing the performance year aggregate net price by the total quantity dispensed of the GUARD Model drug during the performance year. First, CMS would sum the amounts reported in the quantity dispensed field across all PDE records identified at proposed § 514.510(b)(1)(i) and described previously. CMS would then divide the performance year aggregate net price by

¹⁷⁹ Centers for Medicare & Medicaid Services. (2025). *PDE Outbound File Layout Effective 01/01/2025*. U.S. Department of Health and Human Services. [https://www.csscooperations.com/internet/csscw3.nsf/DIDC/YINH9MCGVW-Prescription%20Drug%20Program%20\(Part%20D\)-File%20](https://www.csscooperations.com/internet/csscw3.nsf/DIDC/YINH9MCGVW-Prescription%20Drug%20Program%20(Part%20D)-File%20)

and%20Report%20Layouts (Accessed: 10 December 2025).

¹⁸⁰ Centers for Medicare & Medicaid Services. (2025). *PDE Outbound File Layout Effective 01/01/2025*. U.S. Department of Health and Human Services. [https://www.csscooperations.com/internet/csscw3.nsf/DIDC/YINH9MCGVW-Prescription%20Drug%20Program%20\(Part%20D\)-File%20and%20Report%20Layouts](https://www.csscooperations.com/internet/csscw3.nsf/DIDC/YINH9MCGVW-Prescription%20Drug%20Program%20(Part%20D)-File%20and%20Report%20Layouts) (Accessed: 10 December 2025).

this sum to produce the performance year Medicare net price.

b. Comparing the Performance Year Medicare Net Price to the Applicable International Benchmark To Identify the Per Unit GUARD Model Rebate Amount

To calculate the per unit GUARD Model rebate amount, CMS would compare the performance year Medicare net price to the applicable international benchmark. Specifically, CMS is proposing at § 514.510(b) that the per unit GUARD Model rebate amount would equal the difference between the performance year Medicare net price and the applicable international benchmark. As proposed at § 514.510(b)(2), in cases where CMS determines that the applicable international benchmark price is not available for the GUARD Model drug, a per unit GUARD Model rebate amount for the performance year will not be assessed, and the total GUARD Model rebate amount would be invoiced as zero dollars in the GUARD Model Rebate Report.

3. Determination of the Per Unit and Total Incremental GUARD Model Rebate Amounts

As described in section IV.H.1. of this proposed rule, CMS is proposing that the total GUARD Model rebate amount would be equal to the product of: (1) the per unit GUARD Model rebate amount for such GUARD Model drug for the performance year; and (2) the total number of units of the GUARD Model drug dispensed under Part D and

covered by Part D plan sponsors for GUARD Model beneficiaries in the GUARD Model geographic areas during the performance year.

Under the circumstance in which CMS would waive the rebate amount described in section 1860D–14B(b) of the Act (that is, when the per unit GUARD Model rebate exceeds the performance year per unit Part D inflation rebate amount, as described in more detail later in this Section of this proposed rule) and instead apply the GUARD Model rebate amount, the GUARD Model rebate amount would be invoiced to the manufacturer in two stages. First, CMS would invoice the Part D inflation rebate amounts described in section 1860D–14B(b) of the Act through the Medicare Part D Inflation Rebate Program. Second, CMS would reconcile the amounts invoiced through the Medicare Part D Inflation Rebate Program against the GUARD Model rebate amount via an additional invoice that is specific to the GUARD Model. This invoicing process would occur three times, as described in greater detail later in this Section of this proposed rule: the GUARD Model Rebate Report, the GUARD Model First Reconciliation Rebate Report, and the GUARD Model Second Reconciliation Rebate Report.

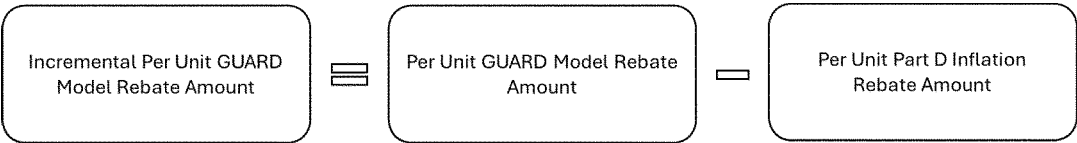
The amount that would be reflected in the GUARD Model-specific invoice, used to reconcile the amounts invoiced through the Medicare Part D Inflation Rebate Program against the GUARD Model rebate amount, would be the Total Incremental GUARD Model rebate

amount. The Total Incremental GUARD Model rebate amount would be equal to the product of the incremental per unit GUARD rebate amount as described later in this Section of this proposed rule and proposed at § 514.510(c)(1) and the total units dispensed during the performance year for the GUARD Model drug to GUARD Model beneficiaries, as described later in this Section of this proposed rule and determined under proposed § 514.510(d).

a. Calculation of the Incremental Per Unit GUARD Model Rebate Amount

As proposed at § 514.510(c)(1) and illustrated in Figure B3, CMS would compare the per unit GUARD Model rebate amount determined at proposed § 514.510(b) to the per unit Part D inflation rebate amount as defined at 42 CFR 428.202(a). For line extensions as defined at proposed § 514.500, CMS would compare the per unit GUARD Model rebate amount to the greater of the per unit Part D rebate inflation amount determined under § 428.202(a) for such line extension drug or the alternative line extension per unit Part D inflation rebate amount, equal to the product of the amounts determined under § 428.204(c)(1) and (2). The GUARD Model would waive the rebate amount described in subsection (b) of section 1860D–14B of the Act when the per unit GUARD Model rebate exceeds the per unit Part D rebate inflation amount.

Figure B3: Calculation of Incremental Guard Model Rebate Amount



To make this comparison, CMS is proposing a few adjustments to the per unit Part D inflation rebate amount to account for differences in the GUARD Model and Part D inflation rebate reporting cycles and in the unit type used by each. While the per unit GUARD Model rebate amount is calculated on a calendar year basis, the per unit Part D inflation rebate amount is calculated on a fiscal year basis. As such, CMS is proposing at § 514.500 to calculate the performance year per unit Part D inflation rebate amount by computing the weighted sum of the per unit Part D inflation rebate amount for the first applicable period that overlaps with the first three quarters of the

performance year and the per unit Part D inflation rebate amount for the second applicable period that overlaps with the last quarter of same performance year. CMS would weigh each per unit Part D inflation rebate amount according to the number of months of overlap between the respective applicable period and the performance year. If a GUARD Model drug is a Part D rebatable drug only during the months in which one of the applicable periods overlaps with the performance year, but not the months in which the other applicable period overlaps with the performance year, the performance year per unit Part D inflation rebate amount would equal the per unit Part D inflation rebate amount

for the applicable period in which the drug was a Part D rebatable drug during the months that overlap with the performance year.

Units reported on PDE are industry standard NCPDP defined values of each, milliliter and grams. In contrast, manufacturers can report the AMP unit for their drugs in the Medicaid Drug Programs systems with 10 different unit types (that is, each, capsule, tablet, suppository, transdermal patch, injectable antihemophilic factor, millicurie, microcurie, gram, and milliliter). Therefore, the per unit Part D inflation rebate amount is expressed in per-AMP unit terms and the per unit

GUARD rebate is expressed in per-NCPDP unit terms.

Once these adjustments have been made, CMS proposes to calculate the incremental per unit GUARD Model rebate amount. If the per unit GUARD Model rebate amount is greater than the performance year per unit Part D inflation rebate amount, the incremental per unit GUARD Model rebate amount is equal to the difference. If the per unit GUARD Model rebate amount is less than or equal to the performance year per unit Part D inflation rebate amount, the incremental per unit GUARD Model rebate amount is zero and so CMS would not waive the rebate amount described in section 1860D–14B(b) of the Act. In instances where the performance year per unit Part D inflation rebate amount is equal to zero, the incremental per unit GUARD Model rebate amount will equal the per unit GUARD Model rebate amount.

b. Calculation of the Total Incremental GUARD Model Rebate Amount

As described previously, CMS is proposing that the Total Incremental GUARD Model rebate amount would represent the amount to be paid by a manufacturer for a GUARD Model drug via the GUARD Model invoicing process for the performance year. To reconcile the amount already invoiced under the Medicare Part D Inflation Rebate Program against the total GUARD Model rebate amount, CMS is proposing at § 514.510(c)(2) that the Total Incremental GUARD Model rebate amount would be equal to the incremental per unit GUARD Model rebate amount described previously and determined under proposed § 514.510(c)(1), multiplied by the total units dispensed during the performance year for the GUARD Part D rebatable model drug for GUARD Model beneficiaries, as described later in this Section of this proposed rule and determined under proposed § 514.510(d). CMS is further proposing at § 514.510(c)(2) that the Total Incremental GUARD Model rebate amount would be subject to adjustment based on any reductions in accordance with § 514.520 or any reconciliations in accordance with subpart G.

4. Determination of the Total Units Dispensed

CMS would determine the total units dispensed during the performance year for the GUARD Model drug, less any applicable exclusions. First, as proposed at § 514.510(d)(1), CMS would calculate the total number of units dispensed consistent with the methodology used in the Part D Drug Inflation Rebate

Program and set forth at § 428.203. The total number of units would reflect units associated with the months of the performance year in which the GUARD Model drug meets the definition of a Part D rebatable drug (as defined at § 428.20) as set forth at § 428.203(b)(1). CMS proposes to exclude units of each dosage form and strength of a GUARD Model drug for which the manufacturer provides a discount under the program under section 340B of the PHS Act, as described in section 1860D–14B(b)(1)(B) of the Act and set forth at § 428.203(b)(2). CMS also proposes to exclude units associated with compounded drugs as set forth at § 428.101(b)(1). To test an alternative calculation for the Part D inflation rebate calculation in the GUARD Model beneficiary population, CMS is also proposing at § 514.510(d)(2) to remove units for PDE records that are not associated with a GUARD Model beneficiary, as that term is defined at proposed § 514.5 and identified at proposed § 514.130(a).

5. Reducing the Total Incremental GUARD Model Rebate Amount for Drugs in Shortage and/or When There is a Severe Supply Chain Disruption or Likely Shortage

Under section 1860D–14B(b)(1)(C)(i) of the Act as codified in § 428.301, CMS will reduce the total Part D inflation rebate amount determined under § 428.201(a), if any is owed, for a Part D rebatable drug that is currently in “shortage”, as set forth in § 428.300, at any point during the applicable period. CMS proposes at § 514.520(a) to reduce the Total Incremental GUARD Model rebate amount using a modification of the formula specified in § 428.301(b)(1). Specifically, to closely align with the Part D Drug Inflation Rebate Program, for each applicable period that overlaps with the performance year, we propose to use the applicable percent reduction and percentage of time the drug was currently in shortage during the applicable period, weighted according to the number of quarters of overlap between the applicable period and performance year. In proposed § 514.520(a)(2), we propose that the reduced Total Incremental GUARD Model rebate amount would equal:

For GUARD Model drugs that were Part D rebatable drugs during both applicable periods that overlap with the performance year, the sum of:

- The Total Incremental GUARD Model rebate amount *multiplied by* 0.75 *multiplied by* (1 *minus* (the applicable percent reduction determined under § 428.301(b)(2) for the applicable period that overlaps with the first three

quarters of the performance year *multiplied by* the percentage of time the GUARD Model drug was currently in shortage during the first three quarters of the performance year determined by CMS pursuant to § 428.301(b)(3)); and

- The Total Incremental GUARD Model rebate amount *multiplied by* 0.25 *multiplied by* (1 *minus* (the applicable percent reduction determined under § 428.301(b)(2) for the applicable period that overlaps with the last quarter of the performance year *multiplied by* the percentage of time GUARD Model drug was currently in shortage during the last quarter of the performance year determined by CMS pursuant to § 428.301(b)(3))).

Our proposed calculation:

$$R_M = \{G * 0.75 [1 - (P_1 * S_1)]\} + \{G * 0.25 [1 - (P_2 * S_2)]\},$$

where—

- R_M = reduced Total Incremental GUARD Model rebate amount for GUARD Model Part D rebatable drugs that were Part D rebatable drugs during both applicable periods that overlap with the performance year;
- G = Total Incremental GUARD Model rebate amount;
- P_1 = the applicable percent reduction determined under § 428.301(b)(2) for the applicable period that overlaps with the first three quarters of the performance year;
- S_1 = the percentage of time the GUARD Model drug was currently in shortage during the first three quarters of the performance year determined by CMS under § 428.301(b)(3);
- P_2 = the applicable percent reduction determined under § 428.301(b)(2) for the applicable period that overlaps with the last quarter of the performance year; and
- S_2 = the percentage of time GUARD Model drug was currently in shortage during the last quarter of the performance year determined by CMS pursuant to § 428.301(b)(3).

For GUARD Model drugs that were Part D rebatable drugs during only one of the applicable periods that overlap with the performance year, the Total Incremental GUARD Model rebate amount *multiplied by* (1 *minus* (the applicable percent reduction determined under § 428.301(b)(2) for the applicable period that overlaps with the performance year and during which the GUARD Model drug was a Part D rebatable drug *multiplied by* the percentage of time the GUARD Model drug was currently in shortage during that applicable period determined by CMS under § 428.301(b)(3))).

Our proposed calculation:

$$R_S = G * [1 - (P_3 * S_3)],$$

where—

- R_S = reduced Total Incremental GUARD Model rebate amount for GUARD Model

- drugs that were Part D rebatable drugs during only one of the applicable periods that overlap with the performance year;
- G = Total Incremental GUARD Model rebate amount;
- P_3 = the applicable percent reduction determined under § 428.301(b)(2) for the applicable period that overlaps with the performance year and during which the GUARD Model drug was a Part D rebatable drug;
- S_3 = the percentage of time the GUARD Model drug was currently in shortage during that applicable period determined by CMS under § 428.301(b)(3).

As an alternative to our proposed approach, we considered whether, for purposes of the GUARD Model, the applicable percent reduction should be greater than or less than the applicable percentage reduction specified in § 428.301(b)(2). To maintain consistency with the Part D Drug Inflation Rebate Program and avoid creating different manufacturer incentives for addressing shortages and supply chain disruptions, CMS is proposing to apply, for purposes of the GUARD Model, the same applicable percentage reduction as used under the Part D Drug Inflation Rebate Program.

Pursuant to section 1860D–14B(b)(1)(C)(ii) of the Act as codified in § 428.302, CMS will reduce the total Part D inflation rebate amount determined under § 428.201(a), if any is owed, for a generic Part D rebatable drug or biosimilar biological product when CMS determines there is a severe supply chain disruption during the applicable period such as that caused by a natural disaster or other unique or unexpected event. As discussed in Section IV.B.2. of this proposed rule and proposed § 514.120(c)(1), CMS is proposing that generic drugs and biosimilar biological products would be excluded from the definition of GUARD Model drugs. In the event that the proposal to exclude generic drugs and biosimilar biological products from the definition of a GUARD Model drug is not finalized in a final rule establishing the GUARD Model, CMS is proposing that for any GUARD Model drug that is a generic or biosimilar biological products as described at § 428.300, CMS would reduce the Total Incremental GUARD Model rebate amount, if any, when there is a severe supply chain disruption during the performance year in the same manner as specified in § 428.302, including the limitation on rebate reductions in § 428.302(b)(4).

Accordingly, because a manufacturer already submits to CMS a rebate reduction request for a Part D rebatable drug pursuant to § 428.302(c), a manufacturer would not be required to submit to CMS a separate rebate

reduction request for purposes of reducing the Total Incremental GUARD Model rebate amount. Specifically, CMS is proposing to codify in § 514.520(b) that, if CMS reduces the total Part D inflation rebate amount determined under § 428.302(a), if any is owed, for a generic Part D rebatable drug or biosimilar biological product that is a GUARD Model drug for an applicable period that overlaps with the performance year, CMS would reduce the Total Incremental GUARD Model rebate amount determined pursuant to § 514.510(c)(2), if any is owed, using a weighted average of the same percentage reduction that CMS applied under § 428.302 for each applicable period that overlaps with the performance year, weighted by the number of quarters of overlap between each applicable period and the performance year, as described in the first equation in this section of this proposed rule. For a GUARD Model drug that was a Part D rebatable drug during only one of the applicable periods that overlaps with the performance year, CMS would not use a weighted average and would instead simply reduce the Total Incremental GUARD Model rebate amount by the same percentage reduction that CMS applied under § 428.302 for the applicable period that overlaps with the performance year and during which the GUARD Model drug was a Part D rebatable drug, as described in the second equation in this Section of this proposed rule.

Under section 1860D–14B(b)(1)(C)(iii) of the Act as codified in § 428.303, CMS will reduce the total Part D inflation rebate amount determined under § 428.201, if any is owed, for a generic Part D rebatable drug when CMS determines that the generic Part D rebatable drug is likely to be in shortage, as set forth in § 428.300. As noted previously, CMS is proposing that generic drugs would be excluded from the definition of GUARD Model drugs. In the event that the proposal to exclude generic drugs from the definition of a GUARD Model drug is not finalized in a final rule establishing the GUARD Model, CMS is proposing that for any GUARD Model drug that is a generic drug as described at § 428.300, CMS would reduce the Total Incremental GUARD Model rebate amount, if any, when CMS determines that the generic GUARD Model drug is likely to be in shortage in the same manner as specified in § 428.303, including the limitation on rebate reductions in § 428.303(b)(4). Accordingly, because a manufacturer already submits to CMS a rebate reduction request for a Part D

rebatable drug pursuant to § 428.303(c), a manufacturer would not be required to submit to CMS a separate rebate reduction request for purposes of reducing the Total Incremental GUARD Model rebate amount. Specifically, CMS is proposing to codify in § 514.520(c) that, if CMS reduces the total Part D inflation rebate amount determined under § 428.201(a), if any is owed, for a generic Part D rebatable drug that is a GUARD Model drug for an applicable period that overlaps with the performance year, CMS would reduce the Total Incremental GUARD Model rebate amount determined pursuant to § 514.510(c)(2), if any is owed, using a weighted average of the same percentage reduction that CMS applied under § 428.303 for each applicable period that overlaps with the performance year, weighted by the number of quarters of overlap between each applicable period and the performance year, as described in the first equation in this Section of this proposed rule. For a GUARD Model drug that was a Part D rebatable drug during only one of the applicable periods that overlaps with the performance year, CMS would not use a weighted average and would instead simply reduce the Total Incremental GUARD Model rebate amount by the same percentage reduction that CMS applied under § 428.303 for the applicable period that overlaps with the performance year and during which the GUARD Model drug was a Part D rebatable drug, as described in the second equation in this Section of this proposed rule.

CMS seeks comment on the proposal for reduction of the GUARD Model rebate amount for GUARD Model drugs in shortage, when there is a severe supply chain disruption, or that are likely to be in shortage.

6. Alternatives Considered

As explained in section IV.H.2.b. of this proposed rule, CMS is proposing at § 514.510(b)(1) to calculate the performance year Medicare net price for a GUARD Model drug by subtracting manufacturer rebates and Manufacturer Discount Program discount amounts from a performance year aggregate gross price and converting the result to a per unit price by dividing by the total quantity dispensed of the GUARD Model drug. CMS is proposing at § 514.510(b)(1)(i) to use WAC to calculate the performance year aggregate gross price but considered alternative data sources. Specifically, CMS considered using GCPDC, AMP, or NADAC to calculate the performance year aggregate gross price. We refer readers to section IV.H.2.b. of this

proposed rule for further details on these alternatives considered and CMS' rationale for not using these alternatives.

I. Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments

In alignment with the Part D Inflation Rebate Program Rebate Report process described in 42 CFR 428.400 through 428.405, CMS proposes at § 514.610 to send a GUARD Model Rebate Report to each manufacturer of a GUARD Model drug with the following information for each performance year: (1) the total GUARD Model rebate amount; (2) the per unit GUARD Model rebate amount; (3) the performance year per unit Part D inflation rebate amount; (4) the incremental per unit GUARD Model rebate amount as calculated in § 514.510(c)(1) for each GUARD Model drug; (5) the total units dispensed during the performance year for the GUARD Model drug; and (6) the Total Incremental GUARD Model rebate amount for each GUARD Model drug as calculated in § 514.510(c)(2). Because a portion of the total GUARD Model Rebate amount will already have been invoiced via the Rebate Report through the Medicare Part D Inflation Rebate Program, the Total Incremental GUARD Model rebate amount will be the amount invoiced through the GUARD Model Rebate Report. The manufacturer of a GUARD Model drug must pay the Total Incremental GUARD Model rebate amount for each GUARD Model drug no later than 30 calendar days after the receipt of the GUARD Model Rebate Report.

Specifically, CMS proposes to send a Preliminary GUARD Model Rebate Report followed by a GUARD Model Rebate Report, as described in proposed § 514.610(b), to all manufacturers of a GUARD Model drug, even if the amount due is \$0; all GUARD Model rebate amounts would be subject to reconciliation as proposed in § 514.610(d). CMS does not intend to send notice to manufacturers for drugs that are not considered GUARD Model drugs pursuant to proposed § 514.120.

To address the completeness and accuracy of the GUARD Model rebate amount, CMS proposes to conduct regular reconciliations at 2 points in time to determine whether the Total Incremental GUARD Model rebate amount must be adjusted due to updated claims and other reported data used in the calculation of such Total Incremental GUARD Model rebate amount (specified in proposed § 514.510(c)(2): (1) within 12 months after the issuance of the GUARD Model

Rebate Report; and (2) within 36 months after the issuance of the GUARD Model Rebate Report. The reporting process for each reconciliation would be the same process described for the original GUARD Model Rebate Report, with payment due for any outstanding rebate amount 30 calendar days after receipt of a reconciled GUARD Model Rebate Report with a reconciled Total Incremental GUARD Model rebate amount, as proposed in § 514.640(a)(1). In addition to regular reconciliations, CMS proposes a process to conduct reconciliations of the Total Incremental GUARD Model rebate amount as needed to correct agency error and when CMS determines that the information used by CMS to calculate a GUARD Model rebate amount was inaccurate due to manufacturer misreporting.

1. Definitions

In proposed § 514.600, CMS proposes to define the following term applicable to subpart G (§ 514.600 through 514.650): “Date of receipt” is the calendar day following the day on which a report of a Total Incremental GUARD Model rebate amount (as set forth in § 514.510(c)(2)) is made available to the manufacturer of a GUARD Model drug by CMS.

For example, if CMS issues a GUARD Model Rebate Report through the method and process described in proposed § 514.630 on July 1, 2029, then July 2, 2029, will be the date of receipt and day 1 of the 30-calendar day payment period.

2. Reports of Rebate Amounts and Suggestion of Error

Consistent with the process specified in 42 CFR 428.401, 428.403, and 428.405 involving preliminary and final reports for the Medicare Part D Inflation Rebate Program, CMS proposes to codify a multistep process to provide a manufacturer as defined in proposed §§ 514.610 and 514.620 with the GUARD Model rebate information described at proposed § 514.610(b)(2). CMS believes adopting the process described for the Medicare Part D Inflation Rebate Program will provide manufacturers participating in the GUARD Model with a familiar and consistent process for paying a GUARD Model rebate amount due, thereby minimizing the potential burden on participating manufacturers. Further, adopting the process described at 42 CFR 428.401, 428.403, and 428.405 provides CMS with sufficient operational time to acquire the relevant information specified in the proposed part 514; sufficient operational time to calculate the GUARD Model rebate

amount and the Total Incremental GUARD Model rebate amount specified in subparts F and G of the proposed part 514; and sufficient operational time to ensure the accuracy of the Total Incremental GUARD Model rebate amount through reconciliation.

As discussed further in this section of this proposed rule and at proposed § 514.610, CMS proposes to use an initial Preliminary GUARD Model Rebate Report (see proposed § 514.610(b)) and a subsequent GUARD Model Rebate Report (see proposed § 514.610(c)), with an opportunity for manufacturers to identify certain mathematical errors (see proposed § 514.620) and two regular reconciliations of the Total Incremental GUARD Model rebate amount to account for updates to claims and other reported data within 12 months and 36 months after the GUARD Model Rebate Report is issued (see proposed § 514.610(d)).

a. Identifying the Manufacturer Responsible for Paying the GUARD Model Rebate

As proposed in § 514.5, CMS proposes that, for the purposes of the GUARD Model, “manufacturer” will have the same meaning as defined for purposes of the Medicare Part D Inflation Rebate Program in section 1927(k)(5) of the Act and 42 CFR 428.20 thereby identifying the manufacturer that is responsible for paying a rebate using the same approach used for reporting AMP data. The reason for identifying the responsible manufacturer that is responsible for paying a rebate using the same approach as the Medicare Part D Inflation Rebate Program is to ensure that the manufacturer responsible for Part D inflation rebate amounts for a given Part D rebatable drug in geographies not included under the GUARD Model will be the same manufacturer responsible for GUARD Model rebate amounts in the geographies included under the GUARD Model. This approach would also ensure that the manufacturer responsible for a GUARD Model rebate amount is invoiced for the entire amount, since a portion of the amount will be invoiced under the Medicare Part D Inflation Rebate Program.

3. GUARD Model Rebate Reports

CMS proposes in proposed § 514.610 that the multi-step reporting process for providing GUARD Model rebate information to a manufacturer would include: (1) an initial report, which CMS proposes to entitle the Preliminary GUARD Model Rebate Report in proposed § 514.610(b); and (2) a second report, which CMS proposes to entitle

the GUARD Model Rebate Report in proposed § 514.610(c). The GUARD Model Rebate Report would serve as the invoice for the Total Incremental GUARD Model rebate amount due, if any, for each product determined to be a GUARD Model drug for the performance year, as specified in proposed § 514.610(c)(2). Manufacturers of GUARD Model drugs would receive a GUARD Model Rebate Report for their GUARD Model drugs even if the amount due is \$0. CMS proposes at § 514.610(d) two regular reconciliations of the rebate amount to occur within 12 months and 36 months after issuance of the GUARD Model Rebate Report specified in proposed § 514.610(c), which would include any restatements that have occurred in the drug pricing data and claims billing data reported to CMS and used in the GUARD Model rebate calculation specified in subpart F of this part.

As the first step in the reporting process, as proposed in § 514.610(b) and consistent with the Part D Inflation Rebate Program, CMS would provide each manufacturer of a GUARD Model drug with the preliminary Total Incremental GUARD Model rebate amount through a Preliminary GUARD Model Rebate Report at least 1 month prior to the issuance of the GUARD Model Rebate Report specified in proposed § 514.610(c) for a performance year.

By structuring the GUARD Model Rebate Report process to include a Preliminary GUARD Model Rebate Report, CMS is able to provide manufacturers with an opportunity to review the Preliminary GUARD Model Rebate Report before the Total Incremental GUARD Model rebate amount is invoiced via the GUARD Model Rebate Report. CMS believes the Preliminary GUARD Model Rebate Report will facilitate manufacturer understanding of the GUARD Model Rebate Report and believes it would be beneficial for manufacturers to review the report for mathematical errors that could be corrected before invoicing via the GUARD Model Rebate Report. Further, a Preliminary GUARD Model Rebate Report would provide additional notice to manufacturers regarding whether they may owe a Total Incremental GUARD Model rebate amount.

As the second step in the reporting process, CMS proposes in § 514.610(c) to provide the Total Incremental GUARD Model rebate amount to the manufacturer through the GUARD Model Rebate Report not later than 22 months after the end of each performance year. As proposed in

§ 514.610(c)(1), the GUARD Model Rebate Report would include the same data elements as the Preliminary GUARD Model Rebate Report (specified in proposed § 514.610(b)(2)(i) through (xii)) and include any recalculations based on CMS acceptance of a manufacturer's Suggestion of Error from proposed § 514.620, or any CMS-determined recalculations from proposed § 514.610(d)(2), if applicable. CMS proposes that manufacturers must pay the Total Incremental GUARD Model rebate amount within 30 calendar days from the date of receipt of the GUARD Model Rebate Report as proposed in § 514.640(a)(1). We considered whether "day 1" of the 30-calendar day payment deadline should begin on the date of receipt of the GUARD Model Rebate Report, as defined at proposed § 514.600, or the calendar day following the date of receipt. We believe defining the date of receipt as day 1 of the 30-calendar day payment deadline is acceptable. We seek feedback on our proposed policies. For example, if the GUARD Model Rebate Report is provided on August 1, 2029, then August 2, 2029, would be the date of receipt and therefore day 1 of the 30-calendar day payment period; payment would be due no later than 11:59 p.m. PT on August 31, 2029.

a. GUARD Model Rebate Report Information

To facilitate manufacturer understanding of the Preliminary GUARD Model Rebate Report, CMS is proposing in § 514.610(b)(2)(i) through (xii) that the Preliminary GUARD Model Rebate Report would include the following information: information related to the Part D inflation rebate amount for quarters corresponding to the relevant performance year; the NDC(s) for the GUARD Model drug as defined under proposed § 514.120(a); the total number of units covered under Part D for the GUARD Model drug for the performance year as determined under proposed § 514.510(d) (which would remove units acquired through the 340B Program, units for PDE records associated with beneficiaries outside of the Model geographic areas, units associated with compounded drugs, and units dispensed when the drug does not meet the criteria for a GUARD Model drug as outlined in proposed § 514.120); the GUARD Model applicable international benchmark as described in proposed § 514.410(a); the performance year Medicare net price as identified in proposed § 514.510(b)(1); the total GUARD Model rebate amount as determined in proposed § 514.510(a); the per unit GUARD Model rebate

amount for the GUARD Model drug for the performance year as determined in proposed § 514.510(b); the performance year per unit Part D inflation rebate amount in proposed § 514.500; the incremental per unit GUARD Model rebate amount as determined under proposed § 514.510(c)(1); any applied reductions as described in proposed § 514.520; the total Part D inflation rebate amount as described in § 428.201(a); and the Total Incremental GUARD Model rebate amount due as specified in proposed § 514.510(c)(2).

When determining what information should be included on GUARD Model Rebate Reports, CMS considered which data elements are necessary to review the Preliminary GUARD Model Rebate Report for error, as described in this Section of this proposed rule, and how to ensure proprietary information is protected. The elements listed previously provide sufficient information for a manufacturer to review the Preliminary GUARD Model Rebate Report for mathematical error, while protecting proprietary information, and these elements are operationally feasible for CMS to provide within the proposed reporting timelines described in Table B8. CMS considered whether the GUARD Model applicable international benchmark should not be included in the GUARD Model Rebate Reports due to the possibility that its data source of origin is proprietary and there may be other possible limitations. CMS welcomes comments on this inclusion, and that of the other elements.

b. Suggestion of Error

In proposed § 514.620, CMS proposes a process in which a manufacturer may suggest to CMS that the manufacturer believes the Preliminary GUARD Model Rebate Report includes a mathematical error within 10 calendar days after the date of receipt of the Preliminary GUARD Model Rebate Report. For example, if the Preliminary GUARD Model Rebate Report is provided on June 1, 2029, then June 2, 2029, would be the date of receipt and also day 1 of the 10 calendar day period to submit a Suggestion of Error; the Suggestion of Error would be due at 11:59 p.m. PT on June 11, 2029, in this example. This suggestion of error period is in alignment with the same process for reports issued under the Part D Inflation Rebate Program as described in § 428.403. As with the Part D Inflation Rebate Program, CMS believes a 10-calendar day period is sufficient when considering the volume of the data to be provided to manufacturers, the narrow scope of items that may be identified as

a Suggestion of Error, and the operational time necessary for CMS to provide a GUARD Model Rebate Report. As such, CMS proposes a Suggestion of Error period of 10 calendar days in § 514.620(c).

The Suggestion of Error process would be limited to mathematical steps involved in determining the total GUARD Model rebate amount and Total Incremental GUARD Model rebate

amount as specified in proposed § 514.510(c)(2). Additionally, in accordance with the restriction on administrative and judicial review as described in section 1860D–14B(f) of the Act, CMS is not providing an administrative dispute resolution process. CMS intends to consider all in-scope submissions under the Suggestion of Error process (for example, suggestions regarding a mathematical

error) as described in proposed § 514.620(a). CMS does not intend to review suggestions of error that are out-of-scope or submissions for a GUARD Model drug with a Total Incremental GUARD Model rebate amount due of \$0.

Table B8 summarizes the proposed GUARD Model Rebate Report milestones and deadlines.

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TABLE B8: PROPOSED GUARD MODEL REBATE REPORT MILESTONES AND DEADLINES

Milestone	Timing/Deadline*
Preliminary GUARD Model Rebate Report sent to Manufacturers	Not later than 20 months after the end of the performance year
Manufacturer Reviews	Manufacturer Suggestion of Error must be submitted to CMS not later than 10 calendar days following receipt of the Preliminary GUARD Model Rebate Report
GUARD Model Rebate Report sent to Manufacturers	Not later than 22 months after the end of the performance year
Manufacturer GUARD Model Rebate Amount Due (if applicable)	Not later than 30 calendar days after receipt of the GUARD Model Rebate Report
First Reconciliation Preliminary GUARD Model Rebate Report sent to Manufacturers	Not later than 11 months after the receipt of the GUARD Model Rebate Report
Manufacturer Reviews	Manufacturer Suggestion of Error must be submitted to CMS not later than 10 calendar days following receipt of the First Reconciliation Preliminary GUARD Model Rebate Report
First Reconciliation GUARD Model Rebate Report sent to Manufacturers	Not later than 12 months after the receipt of the GUARD Model Rebate Report
Manufacturer Reconciled Rebate Amount Due (if any)	Not later than 30 calendar days after receipt of the First Reconciliation GUARD Model Rebate Report
Second Reconciliation Preliminary Rebate Report sent to Manufacturers	Not later than 35 months after the receipt of the GUARD Model Rebate Report
Manufacturer Reviews	Manufacturer Suggestion of Error should be submitted to CMS not later than 10 calendar days following receipt of the Second Reconciliation Preliminary GUARD Model Rebate Report
Second Reconciliation GUARD Model Rebate Report sent to Manufacturers	Not later than 36 months after the receipt of the GUARD Model Rebate Report
Manufacturer Reconciled GUARD Model Rebate Amount Due (if any)	Not later than 30 calendar days after receipt of the Second Reconciliation GUARD Model Rebate Report

Notes: *The months referred to in these timelines represent calendar months. This means, for example, that if a Performance Year ends December 31, 2027, the Preliminary GUARD Model Rebate Report could be issued up until August 31, 2029.

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c. Timing

As discussed previously and in proposed § 514.1(c), the GUARD Model would begin January 1, 2027, with a 5-year performance period and 5 performance years aligning with

calendar years 2027 through 2031, and 7 payment years. To calculate the GUARD Model rebate as described in proposed § 514.510(c)(2), CMS will require WAC data, quarterly Manufacturer Discount Program data, DIR data, and data from the Medicare Part D Inflation Rebate Program. Table

B9 illustrates when data for performance year 1 (calendar year 2027) will be available for each of these inputs to calculate the Total Incremental GUARD Model rebate for the Preliminary GUARD Model Rebate Report.

TABLE B9: GUARD Model Performance Year 1 Data Availability

Data Required	PY 1/CY 2027 Data Available
Manufacturer Discount Program	September 2028
DIR	September 2028
Medicare Part D Inflation Rebate Program	June 2029
WAC	Immediately

Notes: PY stands for performance year, as defined at § 514.5. CY stands for calendar year. DIR stands for detailed direct and indirect remuneration, § 514.5. WAC stands for Wholesale Acquisition Cost, § 514.5.

As a result of the data lag described previously, the Preliminary GUARD Model Rebate Report for performance year 1 would be sent to manufacturers no later than August 2029 and would follow the process and cadence described at proposed § 514.610 and this section of this proposed rule. As described in proposed § 514.610(c), the GUARD Model Rebate Report cycle would occur annually thereafter until a Preliminary GUARD Model Rebate

Report, GUARD Model Rebate Report, and the associated reconciled GUARD Model Rebate Report has been issued for every performance year of the performance period. As such, claims processing, data collection, invoicing, payment of GUARD Model rebates, and reconciliation would continue into CY 2036. Table B10 summarizes this proposed timeline. CMS understands the reconciliation activities for some performance years extend beyond the

end of the GUARD Model payment period but we believe the reconciliation activities pose minimal burden to manufacturers. Examples of reconciliation activities that could take place after the end of the GUARD Model payment period are responses to reconciliation reports, suggestion of errors, and payment of any reconciled rebate amounts due or owed.

TABLE B10: PROPOSED TIMELINE FOR GUARD MODEL REBATE REPORTS AND RECONCILIATION FOR EACH PERFORMANCE YEAR

Performance Year (Calendar Year)	Initial GUARD Model Rebate Report	First Reconciliation	Second Reconciliation
1 (CY 2027)	CY 2029	CY 2030	CY 2032
2 (CY 2028)	CY 2030	CY 2031	CY 2033
3 (CY 2029)	CY 2031	CY 2032	CY 2034
4 (CY 2030)	CY 2032	CY 2033	CY 2035
5 (CY 2031)	CY 2033	CY 2034	CY 2036

Note: CY stands for calendar year.

d. Payment Submission

At proposed § 514.630 CMS describes a proposed standard method and process to issue GUARD Model Rebate Reports and accept manufacturer GUARD Model rebate payments using the online portal used for the same purpose in the Medicare Part D Inflation Rebate Program. This portal is called the Manufacturer Payment Portal (MPP). CMS has already onboarded many manufacturers to the secure, online portal that is facilitated by a CMS-contracted Third-Party Administrator (TPA) where reports and suggestions of calculation error for the Inflation Rebate Program are posted. CMS believes it will be less burdensome for manufacturers to use the existing secure, online portal rather than accessing a new portal for the purposes of receiving GUARD Model Rebate Reports, submitting suggestions of error, and making payments. CMS may consider the option of using a different data system for

payment submission, including adapting a system that currently exists.

If this rule is finalized, CMS intends to provide future technical instructions to manufacturers of GUARD Model drugs regarding how to access GUARD Model Rebate Reports and how to receive notifications alerting the manufacturer when such information is available. CMS also intends to issue reminder notices to manufacturers regarding the due date of payments. Per the definition of manufacturer in proposed § 514.5, CMS notes that the manufacturer that may access GUARD Model Rebate Reports and make applicable payments is the manufacturer responsible for paying a GUARD Model rebate, and, as stated previously, CMS proposes to identify the manufacturer that is responsible for paying a GUARD Model rebate using the same approach used for reporting AMP data.

J. Reconciliation of a Rebate Amount

CMS considered the need to establish a standardized method and process to determine appropriate adjustments to the Total Incremental GUARD Model rebate amount for a GUARD Model drug for each performance year to account for revisions to Manufacturer Discount Program, DIR, WAC, and Medicare Part D Inflation Rebate Program data as well as options for recalculation based on CMS identifying an agency error or manufacturer misreporting. As such, CMS is proposing policies for reconciliation, including with respect to enforcement of payment of any reconciled GUARD Model rebate amount, consistent with the statutory framework for the Part D Inflation Rebate Program and the express authority in sections 1102 and 1871 of the Act to adopt regulations for the proper administration of the Medicare Program.

As proposed at § 514.610(d), CMS believes that it is necessary and

appropriate for CMS to recalculate the GUARD Model rebate amount for each performance year at regular intervals to include updated information about key data elements included in the calculation of the GUARD Model rebate amount. These data elements as set forth in proposed § 514.610(d)(1)(i)(A) through (H) include: total units as specified at § 514.510(d); the total GUARD Model rebate amount specified at § 514.510(a); the per unit GUARD Model rebate amount specified at § 514.510(b); the incremental per unit GUARD Model rebate amount as calculated at § 514.510(c)(1); and the Total Incremental GUARD Model rebate amount as calculated at § 514.510(c)(2). Updating these calculation inputs at regular reconciliation intervals will result in a GUARD Model rebate amount that more fully reflects the majority of shifts in the underlying data following additional time for claims run-out, which refers to the maturation of PDE records in CMS' internal PDE database. Because the information extracted represents the PDE records' status in CMS' internal PDE database at that moment in time, additional run-out may yield different information, either because more PDE records with dispensing dates during the applicable period were finalized and added to the database or because the status of the existing PDE records changed. CMS refers to "X months of runout" as the period between the end of the applicable period and the date when CMS accesses information about the PDE records; for example, "3 months of runout" means that PDE records are accessed for PDE records with dispensing dates during a performance year 3 months after the end of such performance year. Conducting a reconciliation of the Total Incremental GUARD Model rebate amount with additional claims runout will improve the accuracy of the Total Incremental GUARD Model rebate amount. Additionally, reconciliation of payment amounts is consistent with the approach to the calculation of the payment amounts in other CMS programs (such as the Manufacturer Discount Program) that provide for a reconciliation period.

CMS notes that the reconciliation of the Total Incremental GUARD Model rebate amount, whether during a reconciliation proposed at § 514.610(d)(1) or a discretionary reconciliation proposed at § 514.610(d)(2) discussed further later in this Section of this proposed rule, will not create a separately payable and distinct Total Incremental GUARD Model rebate amount. Rather,

reconciliation updates the prior Total Incremental GUARD Model rebate amount owed to CMS, if any, by a manufacturer of a GUARD Model drug so that the Total Incremental GUARD Model rebate amount ultimately accounts for shifts in the underlying data following additional time for claims runout after the GUARD Model Rebate Report is issued as well as subsequently identified data integrity issues, if applicable, to reflect a more precise calculation of the Total Incremental GUARD Model rebate amount. This reconciliation approach aligns with the reconciliation process described in 42 CFR 428.401(d). Moreover, because the reconciled Total Incremental GUARD Model rebate amount is an adjustment of the prior Total Incremental GUARD Model rebate amount, CMS proposes at § 514.610(d)(1)(i)(G) for a report of a reconciled Total Incremental GUARD Model rebate amount to also identify the difference between the Total Incremental GUARD Model rebate amount due as specified on the GUARD Model Rebate Report set forth in proposed § 514.610(b)(2)(xii) and the reconciled Total Incremental GUARD Model rebate amount. CMS would only collect the net Total Incremental GUARD Model rebate amount due, if any, upon reconciliation to prevent any duplicate payments. CMS also proposes to refund any overpayment made by a manufacturer, as determined during reconciliation, as discussed in proposed § 514.640(b).

As CMS noted in the CY 2025 Physician Fee Schedule (89 FR 97710) for the Inflation Rebate Program, CMS evaluated several options to reconcile the inflation rebate amount for Part D rebatable drugs to account for revised information. This informed the current proposal to establish two regular reconciliations at regular intervals to reconcile the Total Incremental GUARD Model rebate amount to account for revised information. As in the Part D Inflation Rebate Program, CMS considerations for the GUARD Model included the length of time needed to capture relevant changes to data inputs for recalculation and manufacturer burden. Specifically, CMS considered the average time span needed to ensure submission of the majority of Part D plan unit revisions specified in section 1860D–14B(b)(6) of the Act and proposed § 514.510(d), and the average time span needed for the submission of data from Manufacturer Discount Program, DIR, and the Medicare Part D Inflation Rebate Program. CMS believes a longer period of claims runout (at least

12 and 36 months of runout time under the proposed approach) would ensure that CMS more fully accounts for capturing of revised units. Further, the first reconciliation would include at least 13 months of claims runout for the performance year and would be issued within 12 months after the GUARD Model Rebate Report for the same performance year. The second reconciliation would include at least 37 months of claims runout for the performance year and would be issued 36 months after the GUARD Model Rebate Report for the same performance year.

The first reconciliation, issued 12 months after the GUARD Model Rebate Report, would provide sufficient time to capture the majority of updates to the data specified in proposed § 514.610(d)(1)(i)(A) through (H). The second reconciliation, to be issued 36 months after the GUARD Model Rebate Report, is sufficient to capture the remainder of the updates to the data specified in proposed § 514.610(d)(1)(i)(A) through (H) while also closing out the calculation of the Total Incremental GUARD Model rebate amount for a performance year within a reasonable time period after the GUARD Model Rebate Report is issued (except for the circumstances in proposed § 514.610(d)(2) regarding CMS' identification of mathematical errors or manufacturer misreporting).

Further, in considering whether consistency across CMS programs is critical, CMS believes that consideration for the completeness of data, as discussed previously, should be prioritized over consistency across program timelines. That is, when examining timelines from other CMS programs that collect data contributing to calculation of the Total Incremental GUARD Model rebate amount, CMS prioritized completeness and accuracy of the data elements contributing to the calculation of the Total Incremental GUARD Model rebate amount rather than prioritizing consistency among the data collection and reconciliation timelines themselves. To ensure an accurate Total Incremental GUARD Model rebate amount, CMS proposes to update additional calculation inputs as described in proposed § 514.610(d)(1)(i)(A) through (H). CMS believes that a restatement of each data element included in proposed § 514.610(d)(1) to reconcile the Total Incremental GUARD Model rebate amount provided in the GUARD Model Rebate Report in proposed § 514.610(c)(1) is appropriate to capture an updated Total Incremental GUARD Model rebate amount and is in line with

other CMS programs that provide for a reconciliation period. While some data points may not change, CMS would review the data to determine if there are any updates and use the updated data in the reconciliation to provide a reconciled Total Incremental GUARD Model rebate amount to the manufacturer. CMS notes that the applicable international benchmark will not be updated during reconciliation.

Based on these considerations, similar to the multistep process for the GUARD Model Rebate Report proposed in § 514.610(b) and (c), CMS proposes a multistep process to provide each manufacturer of a GUARD Model drug with a reconciled Total Incremental GUARD Model rebate amount on a regular basis. At both the 12-month reconciliation point and the 36-month reconciliation point, CMS proposes a reconciliation process that would include: (1) a preliminary reconciliation of the total GUARD Model rebate amount and Total Incremental GUARD Model rebate amount, which CMS would provide to manufacturers of GUARD Model drugs as proposed in § 514.610(d)(1)(i); and (2) a reconciled total GUARD Model rebate amount and Total Incremental GUARD Model rebate amount, which CMS would provide to manufacturers of a GUARD Model drug as proposed in § 514.610(d)(1)(ii). CMS also proposes to apply the Suggestion of Error process specified in proposed § 514.620 to each preliminary reconciliation.

1. Regular Reconciliation

First, as specified in proposed § 514.610(d)(1) and similar to the Preliminary GUARD Model Rebate Report process proposed in § 514.610(b) and (c), for each reconciliation CMS proposes to provide the manufacturer with information about the preliminary reconciliation of the total GUARD Model rebate amount and Total Incremental GUARD Model rebate amount within 60 calendar days prior to the issuance of the reconciled total GUARD Model rebate amount and Total Incremental GUARD Model rebate amount (see proposed § 514.610(d)(1)(i)) to each manufacturer of a GUARD Model drug for a performance year. CMS proposes in § 514.610(d)(1)(i)(A) through (H) that the preliminary reconciliation would include, at a minimum, the same information outlined for the GUARD Model Rebate Report and the following updated information, if applicable: updated total number of units, including updates submitted by a PDP or MA-PD plan sponsor and updates to 340B units and units excluded as specified in proposed

§ 514.510(d); the total GUARD Model rebate amount if any inputs are restated within the reconciliation run-out period as specified in proposed § 514.510(a); the per unit GUARD Model rebate amount if any inputs are restated within the reconciliation run-out period as specified in proposed § 514.510(b); the incremental per unit GUARD Model Rebate Amount as specified in proposed § 514.510(c)(1), using the most recent per unit Part D inflation rebate amount for the performance year (if any inputs are restated within the reconciliation run-out period); WAC for the performance year; the reconciled Total Incremental GUARD Model rebate amount as set forth in proposed § 514.610(c)(2); and the difference between the Total Incremental GUARD Model rebate amount due as specified on the GUARD Model Rebate Report and the reconciled Total Incremental GUARD Model rebate amount as set forth in proposed § 514.610(d)(1)(i)(G).

Second, CMS proposes in § 514.610(d)(1)(ii) to provide a reconciled Total Incremental GUARD Model rebate amount to the manufacturer within 12 months and 36 months after the GUARD Model Rebate Report was issued for each performance year. As proposed in § 514.610(d)(1)(i)(A) through (H), the information in the report for a reconciled total GUARD Model rebate amount would include the same data elements as provided to the manufacturer of a GUARD Model drug in the report detailing a preliminary reconciliation of a total GUARD Model rebate amount and would include any recalculations based on CMS acceptance of a manufacturer's Suggestion of Error from proposed § 514.620. A reconciliation of the Total Incremental GUARD Model rebate amount may result in an increase, decrease, or no change to the total GUARD Model rebate amount or Total Incremental GUARD Model rebate amount, compared to the GUARD Model Rebate Report for a performance year or a previous reconciliation in the case of reconciliation conducted 36 months after issuance of the GUARD Model Rebate Report (see proposed § 514.610(d)(3)).

2. Suggestion of Error

Similar to the Suggestion of Error process described in section IV.I.3. of this proposed rule, CMS proposes in § 514.620(c) a process by which the manufacturer of a GUARD Model rebatable drug may submit a Suggestion of Error within 10 calendar days after the date of receipt of the information about the preliminary reconciliation of

the total GUARD Model rebate amount. CMS proposes that a manufacturer may suggest to CMS that the manufacturer believes the difference between the preliminary reconciliation of the total GUARD Model rebate amount and Total Incremental GUARD Model rebate amount contains a mathematical error. CMS believes a 10-calendar day period is sufficient due to the same considerations of data volume, the narrow set of in-scope items for review, and the operational time necessary for CMS to publish the reconciled total GUARD Model rebate amount and Total Incremental GUARD Model rebate amount.

3. Reconciliation Due to Error or Misreporting

CMS considered options for establishing circumstances where a recalculation of the total GUARD Model rebate amount or Total Incremental GUARD Model rebate amount may be appropriate for a performance year after issuing the GUARD Model Rebate Report and/or a reconciled total GUARD Model rebate amount or Total Incremental GUARD Model rebate amount based on CMS identifying an error or CMS determining that the information used by CMS to calculate a total GUARD Model rebate amount or Total Incremental GUARD Model rebate amount was inaccurate due to false reporting or similar fault by the manufacturer. CMS also considered potential time limits for revisions and whether certain circumstances, such as instances of false reporting, should be exempt from such time limits.

Based on these considerations, CMS believes that, to capture an accurate total GUARD Model rebate amount and Total Incremental GUARD Model rebate amount, and consistent with reconciliations of data submitted to CMS that provide for revisions when necessary due to errors, including mathematical errors, and manufacturer misreporting, certain circumstances merit reconciliation of the total, GUARD Model rebate amount and/or Total Incremental GUARD Model rebate amount separate from the 12-month and 36-month reconciliations proposed at § 514.610(d)(1). Specifically, CMS proposes in § 514.610(d)(2) that CMS may reconcile a total GUARD Model rebate amount and/or a Total Incremental GUARD Model rebate amount of an issued GUARD Model Rebate Report when CMS identifies either: 1) an agency error such as a mathematical error or an error in the information specified in a GUARD Model Rebate Report as described in proposed § 514.610(c) or report of a

reconciled GUARD Model rebate amount as described in proposed § 514.610(d)(1), including reporting system or coding errors; or 2) CMS determines that information used to calculate the total GUARD Model rebate amount or Total Incremental GUARD Model rebate amount was inaccurate due to manufacturer misreporting. Examples of agency errors could include CMS incorrectly calculating the billing units per GUARD Model drug or the GUARD Model Rebate Report incorrectly displaying the Total Incremental GUARD Model rebate amount. Examples of manufacturer misreporting could include instances in which the manufacturer has made a correction to previously submitted data as well as instances in which the reporting individual or entity reporting data or information to CMS on behalf of the manufacturer knows or should know is inaccurate or misleading (for example, inaccurate manufacturer pricing or product data under section 1927(b)(3) of the Act), including information submitted by the manufacturer related to the international benchmark. This does not include standard restatements to WAC or other data outside of the standard process of issuing a reconciled Total Incremental GUARD Model rebate amount. In addition to manufacturer-initiated corrections, CMS may become aware of manufacturer misreporting based on fact finding and conclusions of enforcement authorities, for example, the HHS OIG, the CMS Center for Program Integrity, or the Department of Justice. In a situation where an error or manufacturer misreporting is identified prior to the 12- or 36-month reconciliation of the total GUARD Model rebate amount and Total Incremental GUARD Model rebate amount proposed in § 514.510(c)(1), CMS may choose to include a correction based on the circumstances proposed in § 514.610(d)(2) concurrently with the 12- or 36-month reconciliation. When CMS reconciles data due to an instance of agency error or manufacturer misreporting, CMS proposes that the agency would limit the scope of the reconciliation to the specific information that is the basis for the reconciliation and not update or otherwise revise any other data elements in the GUARD Model Rebate Report (specified in proposed § 514.610(b)(2)(i) through (xii)) or the reconciled GUARD Model Rebate Report (specified in proposed § 514.610(d)(1)(i)(A) through (H)) unless the correction directly impacts additional data fields. For example,

updates to WAC effective dates may not change the performance year Medicare net price if the new effective WAC for a date of service matches the WAC that CMS had imputed for that date of service.

In addition, because reconciling a Total Incremental GUARD Model rebate amount imposes substantial administrative burden on CMS to reprocess the total GUARD Model rebate amount and Total Incremental GUARD Model rebate amount, retest the reporting system, and reissue a reconciled GUARD Model Rebate Report, CMS proposes in § 514.610(d)(2) that it may exercise discretion not to initiate recalculation of the total GUARD Model rebate amount or Total Incremental GUARD Model rebate amount in these situations which are outside of the regular reconciliation process proposed in § 514.610(d)(1).

4. Timeframe for Reconciliation Due to Agency Error

CMS proposes that for a recalculation due to an agency error, the error must be identified within 5 years of the date of receipt of the GUARD Model Rebate Report for the performance year (see proposed § 514.610(d)(2)(i)). Identification means that CMS has knowledge of the error; CMS does not need to have completed its revision of the impacted data or determined if the revision impacts the total GUARD Model rebate amount or Total Incremental GUARD Model rebate amount within the 5-year period. CMS would timely complete these steps and determine, when reconciliation does impact the total GUARD Model rebate amount and/or Total Incremental GUARD Model rebate amount, whether the reconciliation could be included in an upcoming reconciled Total Incremental GUARD Model rebate amount for the performance year or if the reconciliation must be conducted outside of the regular reconciliation process described at proposed § 514.610(d). CMS proposes 5 years to account for the additional time of the second reconciliation that would be conducted at 36-months as proposed in § 514.610(d)(1). CMS believes that a 5-year period dating from the issuance of the GUARD Model Rebate Report allows for sufficient time to include restatements of underlying data while also placing a reasonable time limit on potential discretionary reconciliations, after which a manufacturer of a GUARD Model drug would not receive additional GUARD Model Rebate Report.

5. Timeframe for Manufacturer Misreporting

CMS proposes in § 514.610(d)(2)(ii) that for a circumstance in which a manufacturer misreports data, CMS may recalculate a rebate at any time if the information used by CMS to calculate the rebate amount was inaccurate due to manufacturer misreporting. For example, if a determination is made that a manufacturer misreported WAC, which affected the calculation of the model year Medicare net price, then CMS may recalculate the total GUARD Model rebate amount and the Total Incremental GUARD Model rebate amount owed for a GUARD Model drug. CMS requests comments on the proposals related to manufacturer misreporting.

6. Payment Deadline and Report Issuance

CMS proposes in § 514.640(a)(1) that upon receipt of a reconciled Total Incremental GUARD Model rebate amount, manufacturers must pay that reconciled Total Incremental GUARD Model rebate amount within 30 calendar days from the date of receipt of the reconciled Total Incremental GUARD Model rebate amount. A 30-calendar day payment deadline aligns with the payment period for the initial GUARD Model Rebate Report and for similar reconciliations in the Inflation Rebate Program described at 42 CFR 428.405.

As specified in proposed § 514.630(a)(1), CMS would use the same method and process for issuing GUARD Model Rebate Reports and submission of payments for reports with a reconciled Total Incremental GUARD Model rebate amount. CMS would provide notice to manufacturers for reports with a reconciled Total Incremental GUARD Model rebate amount. CMS proposes in § 514.640(b) that if a refund is owed to a manufacturer based on a reconciled Total Incremental GUARD Model rebate amount, CMS would initiate the process to issue such refund within 60 calendar days from the date of receipt of the reconciled Total Incremental GUARD Model rebate amount. CMS will issue additional information on this method and process through future program communications.

K. Enforcement of Manufacturer Payment of Rebate (§ 514.650)

Consistent with the Medicare Part D Drug Inflation Rebate Program and enabled by CMS' waiver of subsection (b) of section 1860D–14B of the Act, and as described in this Section of this

proposed rule, CMS proposes that manufacturers of a GUARD Model drug that have failed to timely pay the Total Incremental GUARD Model rebate amount as described in proposed § 514.510(c)(2) may be subject to a Civil Money Penalty (CMP). Given the importance of these rebates, CMS may impose available CMP authority under regulations at 42 CFR 428.500 of the Medicare Part D Inflation Rebate Program under section § 1860D–14B(e) of the Act to ensure timely compliance with payments. CMS proposes in § 514.650 to impose a CMP equal to 125 percent of the rebate amount described at § 514.510(c) for each GUARD Model drug for each performance year that a manufacturer fails to pay the rebate amount for each dosage form and strength for each GUARD Model drug.

Consistent with the Medicare Part D Inflation Rebate Program at Section 1860D–14B(e), and the implementing regulations at 42 CFR 428.500, the proposed § 514.650 would implement the already established procedures for imposing and collecting a CMP. The total GUARD rebate payment amount, which would replace the rebate amount described at section 1860D–14B(b) of the Act, would be invoiced in two separate parts: the rebate amount in the Medicare Part D Inflation Rebate Program's Rebate Reports plus the Total Incremental GUARD Model rebate amount in the GUARD Model Rebate Report for a GUARD Model drug.¹⁸¹ Because CMS would have already imposed any potential CMP on the rebate amounts in the Medicare Part D Inflation Rebate Program's Rebate Reports, the GUARD Model would calculate any additional CMP owed as an amount equal to 125 percent of the Total Incremental GUARD Model rebate amount due or a reconciled Total Incremental GUARD Model rebate amount due for the GUARD Model drug in the relevant performance year.

Additionally, CMS proposes to rely on our general CMP authority in section 1128A of the Act, also referenced in section 1860D–14B(e) of the Act, and the implementing regulations at 42 CFR 428.500. Specifically, section 1128A(a)(8) of the Act allows a CMP to be imposed against anyone who

“knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items or services furnished under a Federal health care program.” CMS believes that any GUARD Model manufacturer that knowingly fails to comply with the GUARD Model requirements as set forth in this regulation, could be subject to a CMP under section 1128A of the Act. Any CMP imposed against a GUARD Model manufacturer would be an amount equal to 125 percent of the Total Incremental GUARD Model rebate amount due for the drug and applicable calendar year in addition to the Medicare Part D Inflation rebate amount that is due.

CMS is proposing it may impose a CMP when a manufacturer fails to pay the GUARD Model rebate amount in full for a GUARD Model drug by the payment deadlines in proposed § 514.640(a)(1). This means a manufacturer may be subject to a CMP if the manufacturer fails to pay the Total Incremental GUARD Model rebate amount as invoiced in the GUARD Model Rebate Report or any reconciled Total Incremental GUARD Model rebate amount that is greater than the amount invoiced in the GUARD Model Rebate Report. More specifically, a manufacturer could be subject to a CMP when a manufacturer fails to pay a Total Incremental GUARD Model rebate amount due by any payment deadline proposed in § 514.640(a)(1) for: (1) a GUARD Model Rebate Report specified in proposed § 514.610(c); or (2) a reconciled Total Incremental GUARD Model rebate amount greater than the amount reflected in the GUARD Model Rebate Report specified in proposed § 514.610(d). As discussed earlier in section IV.J. of this proposed rule, CMS notes that the reconciled or corrected Total Incremental GUARD Model rebate amount is not a separately payable and distinct rebate amount. Rather, the reconciled Total Incremental GUARD Model rebate amount is an update to the Total Incremental GUARD Model rebate amount owed to CMS by a manufacturer of a GUARD Model drug.

CMPs are due at the applicable GUARD Model Rebate payment deadline, which occurs 30 calendar days after the date of receipt of a GUARD Model Rebate Report or a report of a reconciled Total Incremental GUARD Model rebate amount. CMS proposes to establish the same methodology as in 42 CFR 428.500 for determining the amount of the CMP as equal to 125 percent of the Total Incremental GUARD Model rebate amount for such drug for a performance

year. This penalty would be due in addition to the Total Incremental GUARD Model rebate amount due. That is, a manufacturer would be responsible for paying the Total Incremental GUARD Model rebate amount due in addition to any CMP imposed because of late payment. CMS is proposing this approach to apply CMPs based on a violation of section 1860D–14B(a)(2) of the Act, and its regulatory enforcement mechanism at 42 CFR 428.500, which this model is adopting and cross-referencing, as described in § 514.650 for each GUARD Model drug. CMS believes that the ability to impose a CMP is necessary to ensure compliance with the GUARD Model in all circumstances where a manufacturer fails to make a rebate payment that is due for a Total Incremental GUARD Model rebate amount to CMS.

The CMP would be calculated based on the outstanding Total Incremental GUARD Model rebate amount due at the payment deadline, which is defined in proposed § 514.640(a)(1) as 30 calendar days after the date of receipt of a GUARD Model Rebate Report or a report of a reconciled Total Incremental GUARD Model rebate amount containing any Total Incremental GUARD Model rebate amount due. Once a GUARD Model CMP is imposed due to a late payment, the penalty would remain in effect through any appeal procedures even if the manufacturer pays the outstanding Total Incremental GUARD Model rebate amount after the penalty is imposed due to a missed payment deadline. Any CMP would be assessed before the next 12- or 36-month reconciliation.

As described at § 428.500, CMPs for the Medicare Part D Drug Inflation Rebate Program may be calculated at several points in time associated with missing a payment deadline for the rebate amount owed by the manufacturer. Accordingly, CMS is proposing that a CMP may be imposed after missing a payment deadline associated with any Total Incremental GUARD Model rebate amount if the Total Incremental GUARD Model rebate amount is reconciled to be greater than the amount invoiced in the GUARD Model Rebate Report. As these separate events can result in distinct and separate impositions of CMPs, this means that CMS would not modify a CMP from a prior missed payment deadline based on changes to the Total Incremental GUARD Model rebate amount due following reconciliation, including scenarios where the Total Incremental GUARD Model rebate amount is reduced following reconciliation. However, in the event

¹⁸¹ There are differences in timing between the GUARD Model performance year and the Part D Inflation Rebate Program. Specifically, while the GUARD Model would be implemented on a calendar year schedule, the Part D Inflation Rebate Program is based on a fiscal year (FY) schedule. As a result, there would be inflation rebate amounts from 2 FYs of the Part D Inflation Rebate Program that contribute to the GUARD Model's single performance year report for a GUARD Model drug. The inflation rebate amounts would be weighted as described in section IV.H. of this proposed rule.

that the Total Incremental GUARD Model rebate amount due on a GUARD Model Rebate Report was not paid and a CMP was issued for violation of the payment deadline, CMS would not issue a second CMP on a reconciled Total Incremental GUARD Model rebate amount if reconciliation decreased the Total Incremental GUARD Model rebate amount stated on the GUARD Model Rebate Report. CMS believes that enforcing this requirement after each payment deadline, regardless of what Total Incremental GUARD Model rebate amount a manufacturer may or may not owe at a future payment deadline, is necessary to maintain the integrity of the model and consistency of the implementation of the model. Further, CMS is proposing this approach to ensure an enforcement approach that is operationally feasible and applied consistently in all cases.

Payment of any CMP by a GUARD Model manufacturer would be in addition to any GUARD Model rebate amount due for a GUARD Model drug. In addition, CMS is evaluating all available options to ensure manufacturers' timely compliance with their Total Incremental GUARD Model rebate payment obligations, including, without limitation, potential recovery approaches and enforcement actions. For example, CMS may refer manufacturers to the Department of Justice, Department of the Treasury, and/or the HHS OIG for further review and investigation.

As described at § 428.500(c), and also reflected in proposed § 514.650, if CMS makes a determination to impose a CMP on a manufacturer for violation of a payment deadline, CMS would send a written notice of the decision to impose a CMP that includes a description of the basis for the determination, the basis for the penalty, the amount of the penalty, the date the penalty is due, the manufacturer's right to a hearing, and information about where to file the request for a hearing. To ensure a consistent approach to civil money penalties, CMS proposes using existing appeal procedures for CMPs in § 1128A as referenced in section 1860D–14B(e) of the Act, and in 42 CFR 423, subpart T for manufacturers appealing a CMP imposed under the GUARD Model, consistent with the approach taken for the Medicare Part D Drug Inflation Rebate Program. CMS has utilized this appeals process for many years for CMP determinations affecting MA organizations and Part D sponsors. CMS therefore proposes to use this well-established legal process for CMP appeals from manufacturers that do not make inflation rebate payments by the

payment deadline. CMS also proposes that the scope of appeals is limited to: (1) CMS determinations relating to whether payment of the Total Incremental GUARD Model rebate amount was made by the payment deadline; and (2) the calculation of the civil monetary penalty amount.

Section 1860D–14B(e) of the Act states that the provisions of section 1128A of the Act (except subsections (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a CMP or procedure section 1128A of the Act. In alignment with the procedures outlined in section 1128A of the Act, CMS proposes that collection of the CMP would follow expiration of the timeframe for requesting an appeal, which is 60 calendar days from the civil money penalty determination in cases where the manufacturer did not request an appeal. In cases where a manufacturer requests a hearing and the decision to impose the CMP is upheld, CMS would initiate collection of the CMP once the administrative decision is final, recognizing that the manufacturer still has appeal rights.

CMS proposes in that in the event that a manufacturer declares bankruptcy, as described in Title 11 of the United States Code, and as a result of the bankruptcy, fails to pay either the Total Incremental GUARD Model rebate amount owed or the total sum of CMP imposed, the government reserves the right to file a proof of claim with the bankruptcy court to recover the unpaid Total Incremental GUARD Model rebate amount and/or civil monetary penalties owed by the manufacturer.

L. Quality and Monitoring Strategy

In this section of the proposed rule, we describe the quality and monitoring strategy for the GUARD Model. The CMS Innovation Center is testing the GUARD Model to monitor and evaluate whether the alternative payment methodology proposed under the GUARD Model reduces Medicare spending while preserving or improving quality of care. The proposed quality measurement strategy is consistent with section 1115A(b)(4) of the Act, including the measurement of patient-level outcomes and patient-centeredness criteria. CMS proposes to implement robust monitoring and evaluation activities to identify any changes in quality.

1. General

The GUARD Model tests an alternative to the inflation rebate payment calculation to understand whether this leads to greater savings

while preserving or enhancing quality of care. The GUARD Model does not introduce any new financial incentives tied to quality performance for manufacturers, plans, or any stakeholder in the prescription drug supply chain. However, the GUARD Model does introduce additional liabilities for manufacturers in the form of rebate payments if the Medicare net price is greater than the GUARD Model applicable international benchmark, as described in section IV.H. of this proposed rule. We do not expect these additional liabilities to reduce quality of care. It is possible that manufacturers respond to the GUARD Model by reducing their Medicare net price in an effort to reduce the GUARD Model rebate payments, or reduce their launch prices over time for new drugs likely to be included in the GUARD Model during the performance period. If manufacturers respond in these ways, it is possible there would be a series of changes throughout the pharmaceutical supply chain. For example, if manufacturers reduce the net price of a GUARD Model drug, that may result in reductions in coinsurance rates for GUARD Model drugs, which would improve affordability for Part D enrollees who take these medications. However, given that this is a test, we cannot say precisely how manufacturers will respond; therefore, it is necessary to monitor quality and evaluate certain quality measures to fully understand the impact of the Model.

Consistent with the evaluation provisions of section 1115A(b)(4) of the Act, CMS proposes utilizing quality measures to monitor and evaluate whether quality of care improves or is maintained. This includes monitoring, and if appropriate, evaluating changes in patient level outcomes that may occur as a result of the proposed alternative inflation rebate payment approach that is being tested under the GUARD Model drugs. To determine whether quality is preserved or enhanced in the GUARD Model, at § 514.720(a), CMS proposes to examine multiple domains of quality, including but not limited to utilization of care, out-of-pocket costs, access to GUARD Model drugs, changes in Part D plan premiums, and patient experience, as described later in this Section of this proposed rule. Monitoring activities would take place at least annually and as appropriate based on availability of the data discussed in this section. CMS is interested in public feedback on how to structure and monitor quality of care in the GUARD Model.

To detect possible changes in quality of care that may be associated with the

GUARD Model, CMS proposes in § 514.720(b), to examine a range of outcomes using existing data. For example, administrative claims data such as PDE data may be used to conduct historic comparisons of trends in GUARD Model drug utilization and program spending (for example, Medicare Part D total gross drug spending and total out-of-pocket spending for the GUARD Model drugs). The Part D Formulary File¹⁸² could be used to examine prescribing patterns (including observing for any shift to compounded or other categories of drugs that are not included in the GUARD Model). We would also use existing claims-based or administrative data to examine changes in MA–PD plan and PDP monthly premiums, MA–PD plan and PDP enrollment, and other indicators of quality of care. We anticipate that monitoring activities may also include patient and/or provider survey data analytics and tracking patient complaints and appeals. Examining these and other measures will help CMS assess quality of care, which must be evaluated under section 1115A(b)(4) of the Act.

The proposed GUARD Model does not test the efficacy of pharmacy dispensed prescription drugs, but rather, it tests the impact of an alternative Part D inflation rebate calculation. Thus, CMS does not propose new monitoring of changes to drug-related adverse events. If, during the GUARD Model, the patient experience of care, quality measures, and claims-based monitoring strategies are found to be insufficient to adequately monitor and measure the quality of care that GUARD beneficiaries are receiving, CMS may specify additional measures to monitor quality.

2. Quality Measures

CMS proposes at § 514.720 to use a variety of data sources to monitor and evaluate the quality of care, including patient-level factors. For example, CMS may monitor or evaluate outcomes related to any of the following:

- Changes in Part D prescribing patterns (for example drug substitution effects, use of certain drug formulations or therapeutic alternatives over others, high-risk medication prescribing).
- Changes in enrollment of standalone PDPs or MA–PD plans that are beyond expected variation.

- Changes in drug formularies and tiering of Part D drugs in regions.
- Patient experience measures for prescription drugs (for example medication access, refills, communication with prescribers).
- Medication adherence (for example proportion of days covered).
- Changes in costs to Medicare beneficiaries (for example, monthly Part D premiums, coinsurance, copayments).
- Changes in generic drug substitution rates.

As proposed at § 514.720(b), CMS may also find it necessary to supplement these measures by surveying beneficiaries who receive Part D medications dispensed at a pharmacy to better understand their individual experiences. In such a scenario, CMS plans to utilize existing surveys such as the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey or the MCBS, whenever possible. Any new surveys would limit stakeholder burden to a minimum and utilize validated survey items.

CMS believes that examining these and other quality measures will allow us to promptly identify any unintended consequences and assess whether quality of care improves or is maintained under the GUARD Model. CMS seeks feedback on our approach to monitoring quality of care and what other data sources or measures we should consider.

M. Beneficiary Protections and Compliance Related Activities

CMS recognizes that stakeholders may have concerns about the potential changes that may occur as the GUARD Model is implemented. For example, stakeholders may have concerns over potential disruptions to Medicare Part D enrollees' access to drugs covered under Medicare Part D, including those that are GUARD Model drugs, as a result of changing financial incentives under the GUARD Model. To alleviate these concerns, CMS has considered ways to protect beneficiary access to Medicare Part D drugs during the model performance period, which we describe later in this Section of this proposed rule, along with our approach for compliance, audits and record retention, and enforcement authority and remedial action.

1. Beneficiary Protections

CMS proposes to use the Complaints Tracking Module,¹⁸³ as described in

§ 423.129(a), an existing reporting system maintained by CMS, to record and track complaints submitted to CMS from beneficiaries, and others. CMS would periodically, but no more than monthly, examine whether complaints submitted are related to the GUARD Model drugs. Analyses conducted of complaints submitted could notify CMS that a particular drug has become harder to source or obtain after the implementation of the GUARD Model. A reporting system such as this would allow CMS to gather information to inform potential follow-up investigations to determine if any drug access issues are occurring. Therefore, CMS proposes at § 514.710(b) to use the existing Complaints Tracking Module as described in § 423.129(a) to monitor for complaints related to the GUARD Model.

Additionally, as proposed at § 514.710(b)(2) and as stated, for all CMS Innovation Center models at § 512.150(b), CMS proposes to address as appropriate, any information related to the GUARD Model drugs that is reported through the existing Medicare hotline phone number (1–800–MEDICARE), including but not limited to requesting additional information from the submitter and conducting additional analyses to determine whether the report requires further action from CMS or other governmental entities. In addition, the Medicare hotline phone number will also be posted on the GUARD Model website along with an email address that beneficiaries or other stakeholders can use to share concerns with CMS about the GUARD Model.

To ensure full and continued compliance with existing beneficiary protections, CMS expects Part D plans to continue to fulfill all of the existing Part D requirements under 42 CFR part 423, including:

- Compliance with all enrollment and anti-discrimination requirements stated in subpart B of part 423, and in particular the following:

++ Allowing enrollment of all eligible beneficiaries who choose to enroll regardless of their anticipated drug utilization or costs.

++ Not restricting enrollees' pharmacy choices or taking any actions that would discourage enrollment or discriminate against beneficiaries based on their health status, prescription drug needs, or other factors indicating higher expected costs.

- Compliance with all benefits and beneficiary protections including access

¹⁸² The Medicare Part D Formulary file is a suite of five sub-files: Formulary, Excluded Drug, Over-the-Counter Drug, Indication-based Formulary, and Part D Senior Savings (PDSS) Model that contain information on how the plan covers the prescription drugs filled (as described in the Part D Drug Event (PDE) file. Available at: <https://resdac.org/cms-data/files/part-d-formulary-file>.

¹⁸³ Centers for Medicare & Medicaid Services. (2025). *Updated Complaints Tracking Module Standard Operating Procedures*. U.S. Department of Health and Human Services. <https://ncpa.org/sites/default/files/2025-01/CTMSOP01062025.pdf>

(Accessed: 10 December 2025).

to covered Part D drugs stated in Subpart C of Part 423 and in particular the following:

- ++ Preserving enrollees' fundamental access rights to Part D covered drugs, which would include GUARD Model drugs, from any pharmacy.

- ++ Disclosure and transparency requirements, specifically, providing clear, accurate, and timely information about changes in enrollees' drug coverage, cost sharing, or access to medications as well as changes to formularies or utilization management requirements.

- Compliance with beneficiary coverage determinations and appeals processes stated in Subpart M of Part 423, and, in particular, the right to request formulary exceptions, tiering exceptions, and prior authorization exceptions under existing Part D requirements and adhering to existing timeframes, processes, and standards for coverage determinations, redeterminations, reconsiderations, or Administrative Law Judge hearings.

2. Monitoring and Compliance Activities

The CMS Innovation Center has designed and tested numerous alternative payment models that each include specific payment, quality, and other policies. However, there are some general provisions that are very similar across models. The general provisions address various topics, including but not limited to monitoring and compliance, described at 42 CFR 512.150, and the requirement of model participants to cooperate in model evaluation and monitoring described at 42 CFR 512.130. We propose at § 514.730 to apply these general provisions on monitoring and compliance, based on the similar requirements that have been previously finalized in existing model tests.

In addition, as described in section IV.L. of this proposed rule and as allowed under proposed § 514.720(a), CMS intends to monitor for specific potential issues that could arise under the GUARD Model. Specifically, CMS intends to monitor for major changes in Part D enrollees' access to GUARD Model drugs, cost sharing for Part D enrollees who are taking GUARD Model drugs, and other measures, as described in section IV.L. of this proposed rule, at least annually and as appropriate based on data availability. CMS would also monitor changing list prices in the United States and the Medicare net price as part of understanding how manufacturers respond to the GUARD Model. CMS may also consider examining any changes in drug

innovation, research and development; changes in launch prices of drugs; and timing of drugs coming to market in the United States. CMS also proposes to collaborate with the FDA to review shortage lists and determine whether the number of drugs or length of time on the shortage list changes over time.

Consistent with other CMS Innovation Center models, and as stated at § 512.150(b) and (c), CMS, as described previously, would conduct monitoring, and compliance activities for the GUARD Model to ensure the integrity of the GUARD Model and that the model is implemented safely and appropriately. As part of the CMS Innovation Center's assessment of the impact of new models such as the GUARD Model, we have a special interest in ensuring that model tests do not interfere with the integrity and sustainability of the Medicare program from a financial, policy, and beneficiary-rights perspective.

For these reasons, as part of the models currently being tested by the CMS Innovation Center, CMS or its designee(s) monitors model participants to assess compliance with model terms and with other applicable program laws and policies as well as to ensure that model participants are not falsifying data, increasing program costs, or taking other actions that compromise the integrity of the model or are not in the best interests of the model, the Medicare program, or Medicare beneficiaries. As stated at § 512.150(b) for all CMS Innovation Center models, GUARD Model participants would also be monitored to determine the effects of the GUARD Model on GUARD beneficiaries, pharmacies and other dispensing entities, and on the Medicare program and to facilitate real time identification and response to any potential issues.

Further, as proposed specifically for the GUARD Model at § 514.750(a) and as stated generally for all CMS Innovation Center models at § 512.160, a GUARD Model participant could be subject to the remedial actions as stated at § 512.160(b) if CMS determines that one of the violations stated at § 512.160(a) exists.

CMS also proposes at § 514.750(b), that a manufacturer of a GUARD Model drug is required to notify CMS within 15 calendar days after becoming aware that the manufacturer of the GUARD Model drug is under investigation or has been sanctioned by the federal, state, or local government, or any licensing authority (including, without limitation, the imposition of program exclusion, debarment, civil monetary penalties,

corrective action plans, and revocation of Medicare billing rights).

3. Audits and Record Retention

We propose to adopt the audit, access, and record retention requirements set forth in § 512.135(a) and (b) for the GUARD Model. As stated in proposed § 514.740, which applies specifically to the GUARD Model, and as detailed in § 512.135(a), which applies to all CMS Innovation Center models, the Federal Government, including CMS, HHS, the Comptroller General, and their designees, has the right to inspect, investigate, and evaluate any documents and other evidence regarding implementation of an Innovation Center model. As stated in § 512.135(b), manufacturers of GUARD Model drugs are required to maintain and provide to the Federal government access to any documents and other evidence regarding all items set forth in § 512.135(b).

4. Enforcement Authority and Remedial Action

It is necessary for CMS to have the ability to impose remedial actions to address non-compliance with the requirements of the GUARD Model and to ensure that the GUARD Model does not interfere with the program integrity interests of the Medicare Program. As stated explicitly for all CMS Innovation Center models at § 512.150(e), nothing contained in subpart A of part 500 including the newly proposed part 514, limits or restricts the authority of the HHS OIG or any other Federal Government authority to audit, evaluate, investigate, or inspect the manufacturer of a GUARD Model drug.

Therefore, as proposed specifically for the GUARD Model at § 514.750(a), and as stated for all CMS Innovation Center Models at § 512.160, CMS may take the remedial actions stated at § 512.160(b) if CMS determines that one or more grounds for remedial action enumerated at § 512.160(a) exists. To assist CMS in its responsibility of oversight, at § 514.750(b), we propose that CMS requires the GUARD participant to notify CMS within 15 calendar days after becoming aware that the GUARD participant is subject to investigation or sanction by the federal, state, or local government, or any licensing authority.

N. Interaction and Coordination With Other Models and Programs

CMS is committed to ensuring people with Medicare continue to have access to robust and affordable prescription drug benefits. Upon reviewing potential interactions with other models and programs, we have found some

interaction between the GUARD Model and the existing programs and policies; however, we do not believe these interactions pose significant challenges, largely due to the intentional design of the GUARD Model. Namely, the GUARD Model has been designed to work with and in addition to all Part D benefit modifications pursuant to the IRA. Most of the IRA-related Part D provisions will have been implemented before the GUARD Model is implemented. Where there may be opportunities for interactions, CMS has designed the GUARD Model to avoid any serious complications for the GUARD Model test due to overlap or interactions with other models, or for the existing program or policies.

1. Approach for Overlap With CMS Innovation Center Models

Upon reviewing existing and ongoing CMS Innovation Center models, we have not identified any models that would have significant overlap or interaction with the GUARD Model at this time. We seek comments on any significant impacts on other models that the GUARD Model might have, as well as impacts on the GUARD Model by any other models. We anticipate model overlap may occur between the proposed GUARD Model and future CMS Innovation Center models or programs not yet implemented. If the proposed GUARD Model is finalized, CMS would take the GUARD Model into consideration in the development of future model designs to address potential impacts of overlap with the GUARD Model.

In summary, we are not proposing to modify or adjust any CMS Innovation Center model or CMS program or initiative with respect to model overlap with the proposed GUARD Model as we have presently not identified any significant overlap. If, in the future, CMS determines a modification or adjustment to the GUARD Model or other CMS Innovation Center model or CMS program or initiative is necessary for purposes of testing the GUARD Model, CMS would pursue such modification or adjustment at such time through the appropriate mechanisms. For example, modifications or adjustments to the GUARD Model would be pursued through notice and comment rulemaking whereas it might be appropriate for modifications or adjustments to other CMS Innovation Center models or CMS programs and initiatives to be pursued through updates to model policies and participation agreements, or program participation criteria or requirements.

2. Medicare Drug Price Negotiation Program

The Medicare Drug Price Negotiation Program, codified in sections 1191 to 1198 of the Act, gives the Secretary authority to negotiate a MFP for a specified number of certain high expenditure, single source drugs without generic or biosimilar competition with participating drug manufacturers.¹⁸⁴ In August 2023, CMS published the list of 10 drugs covered under Medicare Part D selected for the initial price applicability year and for which MFPs will go into effect on January 1, 2026. The second set of 15 drugs was announced in January 2025 and the MFP for these drugs is expected to go into effect in 2027.¹⁸⁵ The GUARD Model avoids significant interaction with the Medicare Drug Price Negotiation Program by excluding any Part D drug from being a GUARD Model drug when an MFP for that drug is in effect.

3. Part D Premium Stabilization and Part D Premium Stabilization Demonstration

As established by the IRA, codified at section 1860D–13(a)(8) of the Act, the premium stabilization provision caps the annual increase in the base beneficiary premium at 6 percent for each year from 2024 through 2029.¹⁸⁶ Further, the Part D Premium Stabilization Demonstration went into effect in 2025 to test an approach to stabilize the year-over-year changes in premiums for PDPs during the implementation of IRA's Part D redesign.¹⁸⁷

We acknowledge that the GUARD Model may affect the Part D plan sponsor market. Therefore, we seek

¹⁸⁴ Congressional Research Service. (2023). *Medicare Drug Price Negotiation Under the Inflation Reduction Act: Industry Responses and Potential Effects*. https://www.congress.gov/crs_external_products/R/PDF/R47872/R47872.5.pdf (Accessed: 10 December 2025).

¹⁸⁵ Centers for Medicare & Medicaid Services. (2015). *HHS Announces 15 Additional Drugs Selected for Medicare Drug Price Negotiations in Continued Effort to Lower Prescription Drug Costs for Seniors*. U.S. Department of Health and Human Services. <https://www.cms.gov/newsroom/press-releases/hhs-announces-15-additional-drugs-selected-medicare-drug-price-negotiations-continued-effort-lower> (Accessed: 10 December 2025).

¹⁸⁶ Congressional Research Service. (2025). *Medicare Part D Premium Stabilization Demonstration*. https://www.congress.gov/crs_external_products/IF/PDF/IF12889/IF12889.2.pdf (Accessed: 10 December 2025).

¹⁸⁷ Centers for Medicare & Medicaid Services. (2025). *2026 Medicare Part D Bid Information and Part D Premium Stabilization Demonstration Parameters*. U.S. Department of Health and Human Services. <https://www.cms.gov/newsroom/fact-sheets/2026-medicare-part-d-bid-information-and-part-d-premium-stabilization-demonstration-parameters> (Accessed: 10 December 2025).

comments on any potential impacts on, or interactions with, the Part D plan market, particularly for standalone PDPs. CMS acknowledges that the recent IRA related changes to the Part D program, as discussed in section II. of this proposed rule, have placed pressure on the Part D plan market, which can be observed from the increase in Part D plan bids and premiums that would have occurred if the base beneficiary premium stabilization had not gone into effect. We seek comments on whether and to what extent there may be additional pressures placed on the Part D plan market due to the GUARD Model and potential solutions to avoid or mitigate such impacts. We also seek comments on any potential interactions with the market for MA–PD plans.

4. 340B Drug Discount Program

The Health Resources and Services Administration (HRSA) administers the 340B Drug Pricing Program that allows certain hospitals and other health care providers (covered entities) to obtain discounted prices on covered outpatient drugs (as defined at section 1927(k)(2) of the Act) from drug manufacturers. HRSA calculates a 340B ceiling price for each covered outpatient drug, which represents the maximum price a manufacturer can charge a covered entity for the drug that is provided to an eligible patient. Several types of hospitals as well as clinics that receive certain federal grants from the HHS may enroll in the 340B program as covered entities.¹⁸⁸ To coordinate with the 340B program, GUARD Model drug units associated with claims for GUARD Model drugs under the 340B program would be removed as discussed in section IV.H. of this proposed rule.

5. Part D Direct Subsidy and Reinsurance

Under section 1860D–15 of the Act, Medicare provides direct subsidy payments to Part D plan sponsors to help cover the cost of providing prescription drug benefits. The direct subsidy calculation is based on the Medicare Part D National Average Monthly Bid Amount (NAMBA).¹⁸⁹ Additionally, Medicare's reinsurance

¹⁸⁸ Congressional Research Service. (2022). *Overview of the 340B Drug Discount*. https://www.congress.gov/crs_external_products/IF/PDF/IF12232/IF12232.4.pdf (Accessed: 10 December 2025).

¹⁸⁹ Centers for Medicare & Medicaid Services. (2025). *2026 Medicare Part D Bid Information and Part D Premium Stabilization Demonstration Parameters*. U.S. Department of Health and Human Services. <https://www.cms.gov/newsroom/fact-sheets/2026-medicare-part-d-bid-information-and-part-d-premium-stabilization-demonstration-parameters> (Accessed: 10 December 2025).

program provides additional financial protection to Part D plan sponsors by covering a portion of drug costs for brand-name drugs and biological products for enrollees who reach the catastrophic coverage phase. CMS acknowledges the need for increased stability of the Part D benefit, which has recently been transformed pursuant to the IRA.¹⁹⁰ The GUARD rebate calculation methodology does not directly impact the Part D program direct subsidy nor how reinsurance payments are reconciled post-coverage year. CMS solicits feedback on any relevant considerations related to the Part D program direct subsidy and reinsurance.

6. Part D Low-Income Subsidies (LIS)

Under section 1860D–14 of the Act, the LIS provides premium and cost sharing subsidies for eligible Part D enrollees with income and resources below statutory thresholds. The subsidy structure reduces beneficiary liability for premiums, deductibles, and other cost sharing consistent with the requirements of the statute and regulations.¹⁹¹

The GUARD Model is designed to coordinate with the LIS by maintaining all existing LIS eligibility criteria and benefit structures, which would allow beneficiaries to continue receiving appropriate cost sharing protections. Therefore, the GUARD Model rebate payments are structured to work alongside, not modify, existing LIS provisions.

7. Request for Comments

We seek comment on our proposed approach to address overlap between the proposed GUARD Model and other ongoing or future Innovation Center models and CMS programs, as described in this Section of this proposed rule. We also seek comment on the potential need for any specific modifications or adjustments to the proposed GUARD Model that would be necessary to support a robust model test of the model or other CMS Innovation Center models. We also seek feedback on potential impacts on the Part D market with respect to unintended changes to market

competition, Part D plan benefit and network offerings, and Part D plan bids and premiums. We welcome suggestions for potential policy options that may help to address any potential challenges. We welcome comments on the potential ways the proposed GUARD Model may impact CMS programs and initiatives and the potential need for modifications or adjustments to the proposed GUARD Model that may be necessary to minimize model overlap impacts.

O. Evaluation

P. Limitations on Review

CMS would conduct an evaluation of the proposed GUARD Model, as required under section 1115A(b)(4) of the Act and as proposed at § 514.720(a). The evaluation would analyze changes in Medicare spending and quality of care attributable to the GUARD Model. The evaluation would require, as needed, the collection of representative information from manufacturers of GUARD Model drugs, Part D plans (standalone PDPs and MA–PD plans), drug purchasers, providers, and beneficiaries. The collection and analysis of this data would inform how such a model might function were it to be integrated within the Medicare program.

All CMS Innovation Center models, which would include the GUARD Model, are rigorously evaluated on their ability either to improve quality without increasing spending or reduce spending without reducing quality. In addition, we routinely evaluate data from CMS Innovation Center models for potential unintended consequences of the model that run counter to the stated objective of lowering costs without adversely affecting quality of care. The design and evaluation methods, the data collection methods, key evaluation research questions, the evaluation period and anticipated reports for the GUARD Model are outlined as follows.

1. Evaluation Methods

The evaluation methodology would deploy multiple, mixed-method strategies to identify the effect of the GUARD Model's impact on the net cost to Medicare and the quality of care for beneficiaries. The evaluation's primary outcome is net Medicare Part D drug and total spending, which would be estimated by assessing the change in net spending for beneficiaries residing in geographic areas subject to the model intervention compared to areas not subject to the model intervention.

We would also conduct additional analyses that help isolate the effect of

the GUARD Model on additional outcomes of interest through, for example, an interrupted time-series which would exploit the introduction of the GUARD Model to assess how trends in “pre” period were disrupted to identify the model's effects; a threshold analysis that exploits the drug spending threshold to assess the model's effect on key outcomes associated with those drugs that were just above the threshold for inclusion in the model compared to those just below the threshold for exclusion from the model; and the use of alternative comparison groups that are not part of the model, such as beneficiaries who are in EGWPs or therapeutic classes of drugs excluded from the GUARD Model.

We are considering several populations of interest for the GUARD Model evaluation, such as Medicare beneficiaries who are likely to receive one of the GUARD Model drugs based on recent diagnoses and/or prior treatment or other patient populations. Population subgroup analyses would capture the model's specific impact on beneficiaries affected by the changes due to the model.

Medicare spending would be examined in terms of net Part D drug spending for GUARD Model drugs, net Part D drug spending for any Part D drugs, total Parts A and B spending, and potentially other spending measures for specific types of health care services (for example, inpatient hospital spending). Total Medicare spending to the extent available would be net of DIR.

CMS believes the proposed model may have some downstream impacts and the evaluation would examine quality to ensure it is maintained or enhanced. The evaluation of any impact of the model on quality of care would examine patient experience, drug access, and health care utilization. Patient experience would be measured through patient experience surveys and measures of patient costs, inclusive of premiums and out-of-pocket costs. Drug access would be measured by prescribing patterns and claims-based drug utilization (for example, rates of any use and duration of use) of both Part D (both GUARD Model drugs and non-GUARD drugs) and Part B drugs (particularly, for Part B drugs that can substitute for GUARD rebateable drugs). We would also examine non-drug health care utilization that may change because of the GUARD Model to estimate any downstream impacts on access to care. Examples of health care utilization include hospitalizations, emergency department visits, and condition specific utilization related to a given subgroup of beneficiaries. The impact

¹⁹⁰ MedPAC. (2025). *Chapter 12, The Medicare Prescription Drug Program (Part D): Status Report*. www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch12_MedPAC_Report_To_Congress_SEC.pdf (Accessed: 10 December 2025).

¹⁹¹ Feyman, Y., et al. (2024). *Medicare Enrollees and the Part D Drug Benefit: Improving Financial Protection through the Low-Income Subsidy*. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. https://www.ncbi.nlm.nih.gov/books/NBK611501/pdf/Bookshelf_NBK611501.pdf (Accessed: 10 December 2025).

estimates would reflect the collective effect of the GUARD Model's changes to Medicare rebates for GUARD rebatable drugs.

CMS also proposes assessing the model's market impact by examining its effect on the broader Part D drug market and on Part D plans, including through assessing various stakeholders' responses. We also recognize that it is important to evaluate if the model resulted in any unintended consequences.

2. Data Collection Methods

We are considering multiple sources of data to evaluate the effects of GUARD. We expect to base much of our analysis on secondary data sources such as Medicare enrollment and claims data. Beneficiary level claims data would be analyzed to estimate the GUARD Model's impacts on Medicare expenditures (total and by type of drug and service). We would examine other sources of data that may include rebate or provider discount information and international pricing data.

For Part D drugs, we would analyze data on drug utilization patterns, pricing, and expenditures. We would also consider CMS evaluation contractor administered site visits, interviews or surveys with appropriate samples of providers, plans, manufacturers, wholesale drug purchasers, and beneficiaries. These qualitative methods would provide information that would help us understand better the dynamics and interactions occurring among the stakeholders in the GUARD Model that cannot be estimated using the proposed secondary data sources.

3. Key Evaluation Research Questions

Our evaluation would assess the impact of the GUARD Model on reducing Medicare net drug spending and preserving or enhancing quality of care. This would include assessments of drug pricing dynamics, Medicare expenditures, and beneficiary access to medications. For example, we would explore how net savings, if any, were related to specific aspects of the payment test, such as how the alternative benchmarks were identified, as discussed in section IV.G. of this proposed rule, and other secondary analyses. Our key evaluation questions would include, but are not limited to, the following:

- **Medicare Payments.** Did the model result in net savings to Medicare, and if so, how?
- **Market Impact.** How did manufacturer behavior change in response to the model? Is there evidence of broader changes to the

pharmaceutical market, such as changes in the supply of drugs? How did Part D plans (standalone PDPs or MA-PD plans) respond, including making changes to formulary placement or premiums? How did other stakeholders such as PBMs respond to the model?

- **Quality.** What was the impact of the model on the patient's quality of care, including patient experience? Did beneficiaries' costs, including premiums and cost sharing or access to drugs change under the model, and if so, how? Were there changes in drug or other health service utilization patterns that can be attributed to the model?

- **Unintended Consequences.** Did the GUARD Model result in unintended consequences?

The GUARD Model evaluation will gather evidence to inform certification through a rigorous, evidence-based process to determine how this model would perform if expanded nationally across the Medicare program. The evaluation would provide evidence to demonstrate if the model achieved its goals during the test period. It would also assess if the results were generalizable at a national scale and financially and operationally sustainable.

4. Evaluation Period and Anticipated Reports

As proposed, the GUARD Model would have a 5-year model performance period beginning in January 2027. The evaluation period would encompass this entire model performance period, the payment test period, and a baseline period. The evaluation would continue until all reconciliation has been completed. Continued evaluation after the end of the performance period and the payment period is necessary to fully assess the impact of the GUARD Model on reducing Medicare expenditures and preserving or enhancing quality. We would evaluate the GUARD Model on a continuous basis and release public evaluation reports annually.

We recognize that interim results are subject to changing policies and issues such as sample size and market fluctuations. Hence, while CMS intends to release periodic summaries to offer useful insight during the model test, a final analysis after the end of the model would be important for synthesizing and validating results.

Section 1115A(d)(2) of the Act precludes administrative and judicial review of certain specified model decisions. These preclusions are applicable for the GUARD Model, and there is no administrative or judicial review under section 1869 or 1878 of the Act, or otherwise, of the specified

model decisions. We are also proposing to adopt section 1860D–14B(f) of the Act which would preclude administrative and judicial review of specific data inputs or calculations related to the underlying GUARD Model Rebate Report and reconciliation; therefore, such data and calculations are not appealable through this process.

Q. Program Waivers

We believe it may be necessary and appropriate to waive only to the extent necessary, certain requirements of title XVIII of the Act for the testing of the GUARD Model. We propose to issue these waivers using our waiver authority under section 1115A(d)(1) of the Act. The purpose of these waivers would be to allow Medicare to test the GUARD Model described in this Section of this proposed rule, with the goal of reducing Medicare expenditures while improving or maintaining the quality of beneficiaries' care. Section 1115A(d)(1) of the Act provides authority for the Secretary to waive such requirements of title XVIII of the Act as may be necessary solely for the purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. This provision affords broad authority for the Secretary to waive statutory Medicare program requirements as necessary to carry out the provisions of section 1115A of the Act.

We welcome comments on other possible waivers under section 1115A of the Act of certain Medicare program rules beyond those specifically discussed in this proposed rule that might be necessary to test this model. We will consider the comments that are received during the public comment period and may make future proposals regarding program rule waivers during the course of the model test.

1. Waiver of the Calculation of the Rebate Amount

At § 514.800, we propose to waive program requirements that are necessary solely for the purposes of testing the GUARD Model. Specifically, we propose to waive the provisions in section 1860D–14B(b)(1) of the Act, which are the Medicare Part D inflation rebate calculation provisions, to implement the proposed alternative calculation for the rebate amount.

We believe that section 1115A of the Act is broad and grants us significant flexibility in the design and implementation of new models. Further, in section 1115A(b)(2)(A) the Act provides the Secretary with broad authority to test innovative payment and service delivery models. We believe

this supports our proposed implementation of the GUARD Model test that incorporates drug pricing information from economically comparable countries to reduce Medicare Part D expenditures while preserving or enhancing quality of care. Further, the Secretary has the authority under section 1115A(d)(1) of the Act to waive certain Medicare and Medicaid statutory requirements “as may be necessary solely for purposes of carrying out this Section of this proposed rule with respect to testing models.”

We believe this proposed waiver of the Part D inflation rebate calculation provisions in section 1860D–14B(b)(1) of the Act, is necessary to implement the proposed alternative calculation for the rebate amount as described in section IV.H. of this proposed rule. The GUARD Model would test an alternative calculation of the rebate amount described in section 1860D–14B(b) of the Act; this alternative calculation would yield the GUARD Rebate Payment Amount. The GUARD Model would waive the calculation described in section 1860D–14B(b)(1) of the Act—replacing it with the GUARD Rebate Payment Amount—in circumstances where the per unit GUARD Model rebate (described later in this section) exceeds the per unit Part D inflation rebate amount for a GUARD Model drug in a given GUARD Model performance year. As such, we believe the proposed waiver of the Medicare Part D inflation rebate calculation in section 1860D–14B(b)(1) of the Act as part of the GUARD Model test is necessary to implement the proposed alternative calculation for the rebate amount.

We seek comment on our proposed waiver of section 1860D–14B(b)(1) of the Act.

2. Waiver of Timing Requirements

In proposed § 514.800, we propose to waive program requirements as necessary solely for the purposes of testing the GUARD Model. Specifically, we propose to waive section 1860D–14B(a)(1) of the Act and instead we propose the following deadlines, effective dates, and time period requirements for the GUARD Model. Section 1860D–14B(a)(1) of the Act describes the timing requirements for manufacturer rebate reports issued by CMS—this section specifies that CMS will issue these rebate reports within nine months of the applicable period; we are proposing to waive these timing requirements and establish new deadlines for the rebate reports in the GUARD Model.

First, as described in section IV.I. of this proposed rule, we propose in

§ 514.610(b)(1) that no later than 20 months after the end of the first performance year, CMS would, for each GUARD Model Drug, issue the Preliminary GUARD Model Rebate Report to the GUARD manufacturers; the Preliminary GUARD Model Rebate Report would include the following for such performance year: per unit GUARD Model rebate amount, applicable GUARD Model billing units, and total GUARD Model Rebate Amount. We propose at § 514.610(c) that CMS would, for each GUARD Model Drug, issue the GUARD Model Rebate Report to the GUARD manufacturers no later than 22 months after the end of each performance year. The GUARD Model Rebate Report, as is the case for all the other rebate reports, would include the following for such performance year: per unit GUARD Model rebate amount, applicable GUARD Model billing units, and total GUARD Model Rebate Amount.

We also propose in § 514.610(d)(1) that no later than 12 months after the receipt of the GUARD Model Rebate Report, CMS would, for each GUARD Model Drug, issue the First Reconciliation of the Preliminary GUARD Model Rebate Report to the GUARD manufacturers. No later than 12 months after the receipt of the GUARD Model Rebate Report, CMS would, for each GUARD Model Drug, issue the First Reconciliation of the GUARD Model Rebate Report to the GUARD manufacturers; the First Reconciliation of the GUARD Model Rebate Report would include the following for such performance year: per unit GUARD Model rebate amount, updated applicable GUARD Model billing units, and total GUARD Model Rebate Amount. Within 30 calendar days of receipt of the First Reconciliation of the GUARD Model Rebate Report, the Manufacturer Reconciled Rebate Amount would be due.

We also propose in § 514.610(d)(1)(ii) that no later than 36 months after the receipt of the GUARD Model Rebate Report, CMS would, for each GUARD Model Drug, issue the Second Reconciliation of the Preliminary GUARD Model Rebate Report to the GUARD manufacturers. No later than 36 months after the receipt of the GUARD Model Rebate Report, CMS would, for each GUARD Model Drug, issue the Second Reconciliation of the GUARD Model Rebate Report to the GUARD manufacturers. Within 30 calendar days of receipt of the Second Reconciliation of the GUARD Model Rebate Report, the Manufacturer Reconciled Rebate Amount would be due.

As described in this section of this proposed rule, we believe these waivers are necessary to implement the GUARD Model on the timeline proposed herein given various operational considerations necessary to calculate GUARD Model Rebate Amounts. We believe that by issuing these rebate reports on the schedule outlined previously instead of the schedule specified in section 1860D–14B(a)(1) of the Act, CMS would be able to both calculate the necessary information for comprehensive rebate reports as well as align with the need to provide timely information about Medicare Part D inflation rebates and GUARD Model Rebate Amounts to GUARD Manufacturers. As such, we propose waiving section 1860D–14B(a)(1) of the Act to the extent necessary to allow CMS to issue GUARD rebate reports on the schedule outlined previously.

We seek comments on our proposed waiver of section 1860D–14B(a)(1) of the Act.

R. Severability

We propose at § 514.900 that should any provision of the proposed part 514 be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provisions would be severable from the remainder of part 514 and the invalidity or unenforceability would not affect the remainder of the provisions of part 514. For example, should the proposed alternate rebate calculation payment methodology in this proposed rule be deemed invalid or unenforceable, the underlying obligation under current statute will continue.

We seek comment on our proposed severability policies.

S. Model Terminations

We propose at § 514.910(a) that the standard provisions for Innovation Center models relating to termination of an Innovation Center model by CMS as set forth at § 512.165 would apply to the GUARD Model. Consistent with these provisions, if we terminate the GUARD Model, we would provide, as required at § 512.165(b), written notice to manufacturers of GUARD Model drugs specifying the grounds for termination and the effective date of such termination or ending. We propose to state at § 514.910(b), that consistent with section 1115A(d)(2) of the Act, termination of the GUARD Model is not subject to administrative or judicial review.

We seek comments on our proposed model termination policies.

IV. Collection of Information Requirements

As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of Centers for Medicare & Medicaid Services (CMS) Innovation Center Models. As a result, the information collection requirements contained in this proposed rule need not be reviewed by the Office of Management and Budget (OMB). However, costs incurred through information collections are discussed in section IV. of this proposed rule.

V. Regulatory Impact Analysis

A. Statement of Need

As explained in section II of this proposed rule, existing research finds that the prices of drugs sold in the United States are much higher than the prices of the same drugs sold in other countries. For brand-name originator drugs,¹⁹² U.S. prices are approximately 422 percent of prices in economically comparable countries. The disparity between U.S. drug prices and prices in other economically comparable countries may have several drivers, but a key component is the substantial difference in the way prescription drug prices are determined in the United States and other economically comparable countries. Although there is wide variation in the way drug prices are determined in economically comparable countries, in general, many countries take a more centralized approach to drug pricing and/or have greater involvement in determining prices for drugs than the United States.¹⁹³

High prescription drug prices in the United States influence Part D spending, which have also increased over time. As discussed in Section II of this proposed rule, total Part D gross drug spending increased from \$121 billion in 2014 to \$276 billion in 2023, an increase of over 100 percent, as reported by the Medicare Payment Advisory Commission (MedPAC).¹⁹⁴ High drug costs limit access to care and treatment, which in turn, can have cascading

consequences that lead to poor health for patients, increased medical spending, and potentially avoidable expenditures for Medicare beneficiaries.¹⁹⁵

Within the United States, the prices of certain types of drugs have been increasing over time, as discussed in section II of this proposed rule, which impacts spending in Part D and affordability of Part D coverage for Medicare beneficiaries. Brand-name drugs and biologics, in particular, represent a large portion of Part D spending in spite of the fact that generic drugs have a higher volume of use.^{196 197} The Inflation Reduction Act of 2022 (IRA), Public Law 117–169, addresses certain high drug costs under Part D, however, the IRA provisions—specifically the Drug Price Negotiation Program—focuses on a small set of drugs and only after they are available in the market for a period of time. The current Part D Inflation Rebate Program requires manufacturers to pay a rebate for certain drugs that exceed the rate of inflation based on price changes over time within the United States. While this approach is useful for curbing post-launch increases in drug prices, the Part D Inflation Rebate Program does not address the high launch prices of drugs, which continue to increase over time and contribute to high Medicare drug spending.

Under the CMS Innovation Center's statutory authority under section 1115A of the Act, CMS proposes to address this key issue of persistent high domestic Medicare drug spending for certain drugs and biologics through the GUARD Model, which tests changes to the Part D inflation rebate provision by implementing an innovative alternative payment method for the purpose of reducing Medicare drug spending and preserving or improving quality of care for Part D enrollees.

This proposed rule is necessary to test and implement the alternative payment model that modifies the Part D inflation rebate calculation for GUARD Model drugs using international drug pricing information for the purpose of

understanding whether this change results in reduced spending for Medicare and maintains or improves quality of care for Medicare Part D enrollees. Specifically, as described in section IV.F. of this proposed rule, the model would include testing more than one method for identifying a benchmark amount for the modified rebate calculation—namely, the default international benchmark (also referred to as Method I) and the updated international benchmark (also referred to as Method II). The evaluation would examine the impact of changing the Part D inflation rebate calculation for GUARD Model drugs. CMS expects that the innovative alternative rebate calculation would reduce Medicare Part D expenditures while preserving or enhancing beneficiaries' quality of care.

As detailed in section IV.A. of this proposed rule, the proposed GUARD Model would establish a 5-year performance period and a 7-year GUARD Model alternative payment test for a subset of Part D rebatable drugs that are dispensed to Medicare beneficiaries who are in the cohort and that are paid under the GUARD Model. As described in section IV.C. of this proposed rule, and subject to certain exclusions, participants would include manufacturers of proposed GUARD Model drugs. GUARD Model participants would be subject to the requirements during the GUARD Model test period, as described in section IV.C.2. of this proposed rule.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993); Executive Order 13132 “Federalism”; Executive Order 14192, “Unleashing Prosperity Through Deregulation”; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Act (impact on small rural hospitals); section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (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 regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as 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

¹⁹² The 2024 ASPE report defines brand-name originators as “the original drugs developed and licensed or approved via 351(a) or a New Drug Application (NDA) pathway.” The authors of the study are solely responsible for how brand-name originator drugs were defined for the study.

¹⁹³ Syversen, I.D., et al. (2024). A Comparative Analysis of International Drug Price Negotiation Frameworks: An interview study of key stakeholders. *Milbank Quarterly*, 102(4), 1004–1031. <https://doi.org/10.1111/1468-0009.12714>.

¹⁹⁴ MedPAC. (2025). *Health Care Spending and the Medicare Program*. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf (Accessed: 16 December 2025).

¹⁹⁵ Nekui, F., et al. (2021). Cost-related Medication Nonadherence and Its Risk Factors Among Medicare Beneficiaries. *Medical Care*, 59(1):13–21. <https://doi.org/10.1097/MLR.0000000000001458>.

¹⁹⁶ Trish, E. & Blaylock, B. (2025). *Shifting Cost-Sharing Burden to Beneficiaries in Medicare Part D*. U.S.C. Schaeffer Center White Paper Series. White Paper No. 2025–06. <https://schaeffer.usc.edu/research/cost-sharing-burden-medicare-part-d/> (Accessed: 16 December 2025).

¹⁹⁷ MedPAC. (2025). *Health Care Spending and the Medicare program*. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf (Accessed: 10 December 2025).

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; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts 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 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 E.O. 12866. Based on our estimates, OMB's Office of Information and Regulatory Affairs (OIRA) has

determined this rulemaking is significant per section 3(f)(1) of E.O. 12866. Accordingly, we have prepared a regulatory impact analysis that presents, to the best of our ability, the estimated costs and benefits associated with this rulemaking.

C. Accounting Statements and Tables

As required by OMB Circular A-4,¹⁹⁸ in Table C1, we have prepared an accounting statement showing the transfers associated with the provisions of this proposed rule over a 6-year period spanning fiscal years 2028 through 2033. This demonstrates that the first effects of the proposed GUARD Model that begins in January 2027 would be observed in calendar year 2028. We cannot accurately predict

what will happen during the reconciliation years so only 6 years are presented. Table C1 is based on the analysis discussed in the "Estimated Impacts of the Proposal" Section in this RIA in this proposed rule.

As stated later in this section, we estimate that the GUARD Model would result in an overall aggregate saving of \$14.1 billion in Medicare Part D net spending during the model period. In this estimate, we assume manufacturer behavior changes. When annualized over a 6-year period, we estimate that the GUARD Model would result in an overall cost savings in Medicare Part D net spending of approximately \$2.2 to 2.3 billion when the effects of discount of 3 or 7 percent are taken into consideration.

TABLE C1: ACCOUNTING TABLE (\$ MILLIONS)

Item	Annualized at 3%	Annualized at 7%	Period	Who is Affected
Transfers	(2,307.1)	(2,246.7)	2027-2031	The numbers represent reductions in cost to the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund arising from reduced payments of plans to manufacturers for certain prescription drugs.

D. Estimated Impacts of the Proposal

In this section of this proposed rule, we discuss the estimated overall impact of the proposed GUARD Model on Medicare spending (and specifically, the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund) and the impact on Part D enrollees; we also show that the information burden associated with these activities is negligible in comparison.

1. Estimated Impacts to Medicare

The proposed GUARD Model modifies the existing Part D inflation rebate calculation for certain Part D rebatable drugs administered to beneficiaries under Medicare Part D. For beneficiaries in model geographic areas, a performance year Medicare net price for model drugs will be compared to an international benchmark and the inflation-adjusted payment amount, with the manufacturer rebating any excess to CMS (referred to as the "Total Incremental GUARD Model rebate amount" as set forth at § 514.510(c)). The performance year Medicare Part D net price for GUARD is defined as the

wholesale acquisition cost (WAC) minus the per unit manufacturer rebate (from direct and indirect remuneration (DIR)) and per unit manufacturer discount program payment amount. The rebates would exclude units that are currently exempt from the existing inflation rebate calculation, including units acquired through the 340B program. The proposed model would also exclude units dispensed to enrollees in employer group waiver plans (EGWPs) as beneficiaries enrolled in EGWPs are proposed to be excluded from the GUARD Model. Additionally, certain drugs may be excluded from the model based on therapeutic categories, spending thresholds, ineligibility for the inflation rebate program, or competitive status within the market.

The estimates presented in this section of this proposed rule assume that all manufacturers are included in this mandatory model. If certain manufacturers were excluded due to interactions with other CMS Innovation Center models or for any other reason, the impacts from this proposed demonstration could be significantly less than described in this analysis.

In developing our estimate of the potential GUARD Model spending impacts, we started with 2024 Part D claims data for GUARD Model drugs. The CMS Office of the Actuary (OACT) relied on the CMS Innovation Center for a list of drugs that would have been included in the model in 2024, and we estimate that GUARD Model drugs would have comprised approximately 35 percent of non-EGWP Part D gross drug spending for 2024. The model excludes drugs that are paid based on a maximum fair price (MFP) that has been negotiated through the Medicare Drug Price Negotiation Program; as new drugs are selected for the negotiation program and have a payment limit that is based on the MFP, we expect the proportion of drugs targeted by the GUARD Model will decrease over time.

We estimated which drugs would have an effective MFP during the model performance period and reduced the model rebate to account for the exclusion of these drugs from the model. OACT estimates of which drugs would be negotiated were developed independently, without input from the

¹⁹⁸ Office of Management and Budget. (2003). OMB Circular A-4: Regulatory analysis. <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf> (Accessed: 10 December 2025).

trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf

[whitehouse.gov/files/omb/circulars/A4/a-4.pdf](https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf) (Accessed: 10 December 2025).

Medicare Drug Rebate and Negotiation Group within CMS.

By the end of the model, we estimate that GUARD Model drugs comprise approximately 16 percent of non-EGWP Part D drug spending for 2024, which reflects the increased amount of spending expected to be subject to the Medicare Drug Price Negotiation Program over time.

The model geographic areas will be selected to comprise 25 percent of Part D beneficiaries, further reducing the drug spending targeted by the GUARD Model. The model also excludes 340B units. The Medicare Part D prescription drug event (PDE) data does not currently track whether a Part D claim is 340B; therefore, we assumed that 10 percent of Part D units were 340B based on estimates in available literature.¹⁹⁹

To reflect the international benchmarks that would be used in the model, we relied on international data furnished by the CMS Innovation Center, after adjustments for gross domestic product (GDP) and purchasing power parity (PPP). On average these

international benchmarks were approximately 49 percent below the estimated Medicare Part D net price if GUARD was in effect in 2024, adjusted to reflect a 2027 benefit structure. This would reflect the upper limit of potential savings as we expect that manufacturers and other stakeholders may engage in a variety of responses that may reduce the potential Federal savings of the model.

Our first anticipated manufacturer reaction is to report their international net pricing data to CMS in cases where that data shows higher prices than the GUARD Model default international benchmark (Method I). Under the GUARD Model, manufacturers would be eligible to voluntarily report international drug net pricing data, and if those prices are higher than the GUARD Model default international benchmarks, the GUARD Model updated international benchmarks (Method II) would become the GUARD Model applicable international benchmark for the GUARD Model rebate calculation for those GUARD Model

drugs for which the international net pricing data is submitted. This effect would have an upward pressure on the GUARD Model applicable international benchmarks over time and would reduce the GUARD Model rebates paid by manufacturers. Manufacturers will need to overcome the difference between the prices used under the GUARD Model default international benchmarks (Method I) and the net prices submitted under the GUARD Model updated international benchmarks (Method II) to move the benchmarks higher.

Our estimate assumes that the previous manufacturer reporting would reduce the level of total GUARD Model rebates by 30 percent by the end of the model test period. This assumption is informed by the average difference between lowest reference country price and prices averaged over all reference countries (after GDP (PPP) adjustments) for GUARD Model drugs. Table C2 shows an example of how this response was measured for the pricing of a hypothetical drug.

TABLE C2: EXAMPLE OF MANUFACTURER RESPONSE FOR A HYPOTHETICAL DRUG

NDC Code	GUARD Model Default International Benchmark (Method I)	GDP (PPP) Adjusted Average of all Reference Countries
XXXXX-YYYY	\$100	\$130

Notes: NDC stands for national drug code; PPP stands for purchasing power parity; GDP (PPP) stands for gross domestic product based on purchasing power parity.

Manufacturers that increase international prices in response to the model will likely need time to implement changes to the international prices. Accordingly, we phased this adjustment into our analysis, beginning with a 10 percent change to 2026

international price data and reaching 30 percent in the 2029 international price data. These factors are applied at an aggregate level to the rebates calculated under the GUARD Model default international benchmarks. For example, the total GUARD rebate paid based on

2027 utilization using the default international benchmark is reduced by 10 percent in our impacts to reflect this manufacturer response. Table C3 shows the percentage adjustment by performance year:

TABLE C3: PERCENTAGE ADJUSTMENT BY PERFORMANCE YEAR

	2026	2027	2028	2029	2030	2031
Phase-in of GUARD Model Updated International Benchmark (Method II) Adjustment	-10%	-20%	-30%	-30%	-30%	-30%

We anticipate that there will be some collaboration between manufacturers and providers to incentivize the

increased use of brown-bagging, where drug utilization would be shifted to the office or facility setting and would be

reimbursed under the Part B benefit, allowing the manufacturer to avoid owing a GUARD Model rebate amount

¹⁹⁹Dickson, S., et al. (2023). Trends in Proportion of Medicare Part D Claims Subject to 340B

Discounts, 2013–2020. *JAMA Health Forum*, 4(11),

e234091. <https://doi.org/10.1001/jamahealthforum.2023.4091>.

for those units. We compared current total Part D drug spending for GUARD Model drugs to comparable Healthcare Common Procedure Coding System (HCPCS) codes in the Part B program to identify drugs that have a high potential to be moved to the Part D benefit. Combined with assumptions about how much utilization would move, we estimate that this effect would further reduce the total GUARD Model rebate amounts by an additional 5 to 8 percent (dependent on year).

The GUARD Model does not make any adjustments to the Part D benefit design and GUARD rebates would not be reflected at the point of sale; so, we do not expect any induced utilization effect for GUARD Model drugs.

In addition to the manufacturer responses described previously, we considered other manufacturer reactions. Manufacturers could opt to change list prices in response to the model, but this will impact their pricing across the entire domestic market and would have unfavorable implications for inflation rebates outside of the model. Alternatively, manufacturers could increase rebates for Part D plan sponsors. This would reduce their liability for GUARD Model rebates, and perhaps enhance formulary positions for more utilization. However, these rebates

would be expected both inside and outside of the model in negotiations with large plan sponsors and would be difficult to remove once the model is over. Lastly, we considered whether manufacturers could negotiate more aggressively for drugs selected for negotiation under the IRA. Because this response could be more proportional to the model, would be more flexible in response to actual GUARD impacts, and would be less obvious to stakeholders, we considered it the most likely option.

We worked under the assumption that the manufacturers will negotiate more aggressively for upcoming selected drugs in the IRA's Medicare Drug Price Negotiation Program, so that the maximum fair prices would be closer to the ceiling prices specified under the IRA than assumed absent the model. We determined how this will impact the Part D benefit. Because not all manufacturers will be able to respond for a particular years' selected drugs, and because responses may vary, we assumed that 60 percent of the incremental GUARD rebate would be offset by the change in the OACT projection of negotiated prices. This 60 percent assumption is based off similar situations OACT has encountered albeit in different rules and different contexts. Lowering this assumption to 50 percent

would result in approximately 8 percent more federal savings. We invite stakeholder response on the most appropriate percentage for this.

Once the total GUARD Model rebate is estimated as a percentage of gross drug costs, we apply those percentages to the estimated gross drug costs for each relevant year to obtain the aggregate GUARD Model rebate under the baseline gross drug costs. This amount is then reduced by the projected Part D inflation rebate amount attributable to the GUARD Model geography. The result is the estimated incremental GUARD rebate by year.

We expect manufacturers to respond to the anticipated GUARD rebates beginning in the initial price applicability year 2028 negotiation cycle, moving the MFP closer to the ceiling prices defined in the IRA. Because of the timing requirements for the GUARD rebate, this means that the manufacturer response will take effect before the first expected GUARD rebate payment, which is expected to be paid in fiscal year 2029.

This change in negotiated prices flows through the Part D benefit with impacts to Part D federal cost and beneficiary cost. The results are shown in Table C4 on a fiscal year cash basis in billions.

TABLE C4: IMPACTS TO PART D FEDERAL COST (\$ BILLIONS)

Fiscal Year	2028	2029	2030	2031	2032	2033	Total 2028-2033
Benefit Cost	2.9	(5.3)	(4.1)	(2.4)	(2.0)	(2.6)	(13.6)
Premium Offset	(\$0.0)	(\$0.0)	\$0.2	\$0.2	\$0.2	\$0.0	\$0.6
Federal Cost	2.9	(5.3)	(4.3)	(2.6)	(2.1)	(2.7)	(14.1)

Note: All estimates presented in billions of dollars.

2. Estimated Impacts to Medicare Part D Enrollees

As mentioned previously, we do not expect the GUARD rebates to be visible to beneficiaries at the point of sale. However, the assumed change in

manufacturer negotiations for the IRA's Medicare Drug Price Negotiation Program will impact beneficiaries' cost sharing due to higher point of sale prices for initial price applicability year 2028 and subsequent years. The change

in manufacturer negotiations will also impact beneficiary premiums after the end of the IRA premium stabilization provisions. These impacts are shown in Table C5, on a calendar year basis in billions.

TABLE C5: IMPACTS TO MEDICARE PART D ENROLLEES (\$ BILLIONS)

Calendar Year	2028	2029	2030	2031	2032	2033	Total 2028-2033
Beneficiary Cost Sharing	1.0	0.8	0.5	0.4	0.4	0.0	3.0
Beneficiary Premium	(0.0)	(0.0)	0.2	0.2	0.2	0.0	0.6
Total Beneficiary Impact	1.0	0.7	0.7	0.6	0.5	0.0	3.6

Note: All estimates presented in billions of dollars.

3. Other Potential Responses

We also considered the following responses but either determined their impact would be small or that we lacked sufficient data to properly quantify the

level of impact they would have on GUARD Model rebates:

- As a change in list prices for model drugs will shift the balance between the GUARD Model rebate amount and the

inflation rebate amount, there are incentives for manufacturers to raise list prices across all payers to counteract the lost revenue from the model. This reaction could create additional effects

on Medicaid or Federal Marketplace spending. The likelihood of this response increases when the spending for a given drug outside of Medicare is higher. We welcome comments on the probability and magnitude of this response to inform future analysis.

- There also exists the possibility for manufacturers to increase DIR payments to plans in exchange for more favorable formulary placement and potential increased volume. This response would reduce GUARD unit rebates, but would be difficult to align with the GUARD Model structure. We would welcome comments on the probability and magnitude of this response to inform future analysis.
- Since drugs selected for negotiation would be excluded from the model, we might expect manufacturers would try to change their pricing to become eligible for the Medicare Drug Price

Negotiation Program if they see it being more favorable for their reimbursement. Given the criteria for drug selection under the Medicare Drug Price Negotiation Program, we believe it would be difficult for manufacturers to achieve this. Additionally, the model does not impact reimbursement for all Part D beneficiaries as negotiations would, so this response would require dramatic pricing differences to be favorable to manufacturers.

We seek feedback on the assumptions used for this analysis, including anticipated stakeholder reactions, to inform future analysis.

d. Collection of Information and Paperwork Cost

As discussed in section V.A. of this proposed rule, as specified at section 1115A(d)(3) of the Act, models are exempt from the requirements of the Paperwork Reduction Act of 1995 (44

U.S.C. 3501 through 3521). Nevertheless, and for discussional purposes only, we briefly review the main paperwork burden of this proposed rule and show it is negligible. The main information burden arises from voluntary manufacturer-reported submission of international net pricing information. The analysis of cost is summarized in Tables C6 and C7 with line items explained afterwards. Table C7 presents an analysis of items for which we have an experience basis for quantification. Table C8 discusses other items affecting the cost of submission requirements for which CMS has no prior experience on which to base quantification. To meaningfully deal with this lack of prior experience, we assume each item will increase the total quantifiable burden by some factor; a range of factors is presented to account for our lack of precise quantification.

TABLE C6: DISCUSSION OF QUANTIFIABLE BURDEN FOR SUBMISSION

Line Identification	Period	2027	2028-2031
(1)	Number of unique manufacturers	91	91
(2)	Payments per year	1	1
(3)	Hours/Preparation	20	10
(4)	Hours/Submission	6	3
(5)=(2)*((3)+(4))	Total Hours per period per Manufacturer	26	13
(6)=(1)*(5)	Total Unadjusted Aggregate hours for full period	2366	1183
(7)	Percent applied for period	1	1
(8)=(6)*(7)	Total Aggregate hours for period	2366	1183
(9a)	Mean Wage (Administrative assistants)(43-6014)	\$22.90	\$22.90
(9b)	Mean Wage (Health Service managers)(11-9111)	\$66.22	\$66.22
(9c)	Mean Wage (Software Developers, Programmers, Testers) (15-1250)	\$65.34	\$65.34
(9d)	Mean Wage (Lawyers) (23-1011)	\$87.86	\$87.86
(9e)	Mean Wage (Pharmacists)(29-1051)	\$65.97	\$65.97
(9f)=2/13*((9a - (9e)) +3/13*(9a)	Average weighted hourly wage for five professions	\$52.71	\$52.71
(10)	Factor for Fringe Benefits/Overtime	2	2
(11)=(9)*(10)	Adjusted mean wage	\$105.43	\$105.43
(12)=(11)*(8)	Total Estimated Cost	\$249,442	\$124,721
(13)=sum of row (12) with a weight of 4 for years 2028-2031	Total Cost 5 Years	\$748,326	\$748,326

We next explain the various line items in sequential order.

(1): We performed analysis on manufacturers of rebatable GUARD drugs based on two sources of manufacturers, FDA data sources (National Drug Code (NDC) Directory, Orange Book, and Purple Book) and Medi-Span.²⁰⁰ There were 91 unique manufacturers. Although some of these manufacturers are owned by the same parent company, we used the higher 91 figure because our goals are to show the negligibility of burden.

(2), (3), and (4): The hours required for submission are split between

²⁰⁰ Medi-Span Electronic Drug File (MED-File) v2, Medi-Span, Wolters Kluwer, 2025, Available at <https://www.wolterskluwer.com/en/solutions/medi-span/about> (last accessed Oct. 5, 2025).

preparation, including reading rules, gathering data, and so forth, and actual submission. We used similar estimates of submission to CMS from a Supporting Statement of the Manufacturer Submission of Average Sales Price (ASP) for Medicare Part B Drugs and Biologicals and Supporting Regulations in 42 CFR 414.800 through 806 (CMS–10110, OMB 0938–0921) from 2023. The supporting document listed 10 hours for preparation and three hours for submission per submission. In contrast to OMB 0938–0921 which required four submissions per year, for GUARD there is only one submission per year. However, we believe that extra hours would be required for the first year, and in the absence of more reliable

data we simply doubled the 10 and three.

(7): The GUARD Model performance period, for which manufacturers could choose to report international drug net pricing data, is proposed to last from January 2027 through December 2031.

(9a–9f): The \$21.90 is the mean wage obtained from the Bureau of Labor Statistics website for Secretaries and Administrative Assistants, Occupational Code 43–6014, for the latest year available at this time, 2024. Note that CMS still uses mean wages even though many agencies use median wages. However, replacing the mean by the median would not change the conclusion of negligibility. 43–6014, is the same occupational title used for estimates in OMB 0938–0921. However,

we believe that this approach (using only administrative assistants) was overly simplified. While administrative assistants are appropriate staff for the 3 hours submission, we believe the preparation would involve a team of administrative assistants, health care managers, software engineers, lawyers, and pharmacists. The mean hourly wages of these staff for 2024 are displayed along with their occupational titles and code. The wages of these five staff are combined to produce a single mean hourly wage for the team. In the absence of further data, the weights assume that all five staff work equally in the 10 hours of preparation resulting in 2 hours per staff. The administrative staff exclusively work during the three hours of submission. Thus, the weights are five-thirteenths for administrative staff and two-thirteenths for each of the other staff.

(10): Per HHS guidance,²⁰¹ CMS uses a factor of two to account for overtime and fringe benefits.

We next turn to items for which we have no basis on which to quantify. The total analysis is presented in Table C7. As noted in the table there are two non-

quantifiable issues that have to be addressed.

New and Departing participants: Each year, the group of GUARD Model participants may change based on whether their drug meets the criteria for inclusion in GUARD. We have no way of estimating with accuracy whether a given manufacturer would be included or excluded in GUARD. If we assume nine new manufacturers, then bottom line estimates from Table C7 would increase 10 percent (9/91). This is a low estimate. In a worst-case scenario, the number of participants might increase as much as 50 percent corresponding to a factor of 1.5; though this is unlikely, it helps define a range of possible costs.

19 Countries: If a manufacturer were to opt to report manufacturer-submitted data, they would do so for up to 19 countries. The 10 hours preparation assumed in Table C6 provides time for each GUARD participant to address marketing, pricing, and licensing requirements. But likely, this is different for different countries. We do not have enough information to quantify this. We approach the extra time as a factor by which we increase cost. For example,

assuming that half the countries require the same preparation time, we would multiply the bottom line cost burden by a factor of 9.5 (19/2). On the other hand, if charts are readily available of licensing, marketing, and pricing for each individual country, it might only require an extra 2 hours of work resulting in an increase of 1.15 (2/13). We take these as the low and high estimates and insert an intermediate estimate.

To obtain a range of adjusted bottom line estimates we multiply the factors together. For example, as just discussed previously, if half the countries require the same amount of work (resulting in a factor of 9.5) and if the number of participants increases 50 percent (resulting in a factor of 1.5) then we multiply the bottom line number from Table C6, \$748,326, by 14.25 (1.5 * 9.5) and obtain a high cost burden of \$10.7 million, as shown in Table C7. As shown on the bottom line of Table C7, the resulting range of estimates of cost burden is between roughly \$1 million and \$10.5 million.

TABLE C7: ADJUSTING COST BURDEN TO ACCOUNT FOR NON-QUANTIFIABLE ISSUES

Line Identification	Issue	Low Factor	Intermediate Factor	High Factor
(1)	19 countries	1.16	5	9.5
(2)	New and departing participants to GUARD Model	1.1	1.3	1.5
(3)=(1)*(2)	Product of factors	1.276	6.5	14.25
(4) (From Table C4)	Quantifiable Burden	\$748,326	\$748,326	\$748,326
(5)=(4)*(3)	Range of Possible Adjusted Burdens	\$954,864	\$4,864,117	\$10,663,642

Notes: (1) The GUARD Model will involve 19 countries. For a discussion of the low and high factor or for a discussion of new and departing participants see the paragraph immediately preceding Table C5.

E. Initial Regulatory Flexibility Act Analysis

The RFA requires agencies to analyze options for regulatory relief for small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and states are not included in the definition of a small entity. The RFA requires that CMS analyze regulatory options for small businesses and other entities unless CMS certifies that a rule will not have a significant economic

impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the proposed rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

HHS considers a significant impact on a substantial number of small entities to be one with a three percent revenue effect on 5 percent of small entities.²⁰² As discussed in the preamble of this proposed rule, manufacturers that are

GUARD Model participants would pay GUARD Model rebates to the Medicare Part D account in the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund. If the Medicare net price determined under proposed § 514.510(b)(1) for GUARD Model drugs exceeds a GUARD Model applicable international benchmark (as described in section IV.F. of this proposed rule), our analysis shows that the proposed rule would impact 26 percent of small entities, and the annual impact is estimated to be between 3.5 and 5

²⁰¹ Office of the Assistant Secretary for Planning and Evaluation. (2016). *Guidelines for Regulatory Impact Analysis*. https://aspe.hhs.gov/sites/default/files/private/pdf/242926/HHS_RIAGuidance.pdf (Accessed: 10 December 2025).

²⁰² U.S. Department of Health and Human Services. (2003). *Guidance on Proper Consideration of Small Entities in Rulemaking of the U.S. Department of Health and Human Services*. [https://aspe.hhs.gov/reports/proper-consideration-small-](https://aspe.hhs.gov/reports/proper-consideration-small-entities-rulemakings-us-dhhs)

[entities-rulemakings-us-dhhs and https://aspe.hhs.gov/sites/default/files/documents/dd6288d1b8db19ee8a1f37b3ce775003/guidance-proper-consideration-hhs-2003-rulemaking.pdf](https://aspe.hhs.gov/sites/default/files/documents/dd6288d1b8db19ee8a1f37b3ce775003/guidance-proper-consideration-hhs-2003-rulemaking.pdf) (Accessed: 10 December 2025).

percent of the small entities’ annual revenue in the United States. Given the uncertainty, CMS concludes that this proposed rule, if finalized as proposed, will have significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this proposed rule, serves as the Initial Regulatory Flexibility Analysis, as required by the RFA.

F. Description and Number of Affected Small Entities

We use the North American Industry Classification System (NAICS) to identify the industry potentially affected by the proposed rule. We also use the Small Business Administration (SBA) size standards to identify small

entities,²⁰³ as codified at 13 CFR 121.201 and explained at Title 13 part 121. The SBA considers any “Pharmaceutical Preparation Manufacturing” firm (NAICS code 325412) with fewer than 1,300 employees as a small business.

We use financial and employment information publicly available on annual reports published on companies’ websites or submitted to the Securities and Exchange Commission (SEC) for 2024. Most companies self-identified as “global” and provided information separately for their global consolidated business and for the United States. We used the Internal Revenue Service’s yearly average currency exchange rates for 2024 to convert revenue information

into U.S. dollars when this information was provided in a foreign currency.²⁰⁴ We identified 91 unique manufacturers belonging to 69 unique parent companies that would be associated with 542 unique NDC–9 codes for GUARD Model drugs.²⁰⁵ For purposes of this analysis, we consider the impact on the 69 unique parent companies. Table C8 shows that 26 percent of the affected manufacturers would be considered small based on the SBA definition. In 2024, the total company revenue in the United States for these small companies exceeded \$6 billion. These companies accounted for about 0.6 percent (6,261/1,065,917) of the total U.S. revenue among all the 69 affected entities.

TABLE C8: NUMBER OF ENTITIES BY EMPLOYMENT SIZE AND REVENUE, 2024

Company Size	Total Number of Either Global or U.S. Employees*	Percent of Unique Parent Companies	Total Global Revenue (\$million)	Total US Revenue (\$million)
Small	1,300 or fewer	26%	\$10,317	\$6,261
Large	1,301 or more	74%	\$1,734,565	\$1,065,917
Total	-	100%	\$1,744,882	\$1,072,178

Notes: *There was only one company with more than 1301 global employees and less than 1,300 U.S. employees. Since the global employees exceeded 10,000 we classified this company as large.

1. Description of the Potential Impacts on Small Entities

We anticipate that payments to CMS in the form of rebate amounts would represent the largest impact to small entities. Table C9 presents the estimated, annual aggregate projected GUARD rebate amounts for small companies using the 2024 experience, adjusted for projected changes to GUARD eligibility and benchmarks by drug and by year. We categorized NDCs

by the size of the parent manufacturer and summed the rebates for NDCs associated with manufacturers with 1300 or fewer employees. Our analysis estimates that for small companies, the total GUARD rebates will comprise approximately 3.6 to 5 percent of total revenue, which, by HHS standards is considered significant. We note that these estimates are based on available data which could change in the future and as such, the estimated impacts could vary. Specifically, the estimates

are based on the current status of rebatable drugs and employment and revenue information using 2024 (or other available data) as of the publication of this proposed rule. Given this uncertainty, we conclude that the proposed rule, if finalized as proposed, will have a significant impact on a substantial number of small entities. We welcome comments on our conclusion, approach, assumptions, and data used to estimate these impacts.

TABLE C9: ESTIMATED IMPACT ON SMALL ENTITIES

Company Size	Total U.S. Revenue (\$million)	Estimated aggregate projected GUARD Rebate Amount as Percent of Revenue for 2027 GUARD Eligible Drugs	Estimated aggregate projected GUARD Rebate Amount as Percent of Revenue for 2028 GUARD Eligible Drugs	Estimated aggregate projected GUARD Rebate Amount as Percent of Revenue for 2029 GUARD Eligible Drugs	Estimated aggregate projected GUARD Rebate Amount as Percent of Revenue for 2030 GUARD Eligible Drugs	Estimated aggregate projected GUARD Rebate Amount as Percent of Revenue for 2031 GUARD Eligible Drugs
Small	6,261	5.0%	4.6%	3.4%	3.6%	3.6%

²⁰³ U.S. Small Business Administration. (2023). *Table of Size Standards*. <https://www.sba.gov/document/support-table-size-standards> (Accessed: 10 December 2025).

²⁰⁴ Internal Revenue Service. (2025). *Yearly average currency exchange rates*. <https://www.irs.gov/individuals/international-taxpayers/yearly-average-currency-exchange-rates> (Accessed: 10 December 2025).

²⁰⁵ Based on the preliminary list of Part D rebatable drugs for 2024 as of October 1, 2025.

As explained, there is significant uncertainty around the assumptions for these estimates. We welcome comments on our estimate of significantly affected small manufacturers and the magnitude of estimated effects. We also welcome comments on adjustments to the GUARD Model that could be considered while preserving the innovative alternative payment approach tested under the GUARD Model.

2. Alternatives To Minimize the Impact on Small Entities

We considered the following alternatives to minimize the impact on small entities: (1) establishing a different spending threshold; (2) establishing an exemption process; and (3) establishing different compliance dates.

- **Spending threshold:** CMS is excluding from the GUARD Model, GUARD Model drugs when their associated application-level total gross covered prescription drug costs are below the “GUARD Model minimum spend threshold” which for performance year one is proposed to be \$69 million. This GUARD Model minimum spend threshold applies to all manufacturers irrespective of size. While lowering the GUARD Model minimum spend threshold increases the number of drugs that could be included in GUARD, it also increases the number of small manufacturers that could potentially be impacted. For this reason and others as discussed in section IV.B.2. of this proposed rule, CMS proposes not to select a higher threshold. Further, increasing the threshold reduces both the number of small and large manufacturers and the number of drugs in GUARD.

- **Exempting small entities:** As discussed in section IV.B.2. of this proposed rule, to avoid interactions with other initiatives and programs that focus on manufacturers of Medicare Part D drugs, CMS would exclude drugs when there is an active price applicability period and the price of the drug is based on a negotiated MFP. Because small and large manufacturers could potentially be eligible for this proposed exclusion, we do not believe that additional processes for exemptions are needed. CMS seeks comments on other factors or considerations regarding exemptions for small entities.

- **Compliance dates:** CMS also considered the flexibility of providing different compliance dates to small manufacturers. While creating significantly different compliance dates could provide more time for small manufacturers to comply, it could interfere with the statutory requirement

of evaluating the model annually to determine whether the GUARD Model is reducing Medicare spending while preserving or increasing quality of care for Medicare Part D enrollees.

In summary, the purpose of the GUARD Model is to test an innovative payment model that modifies the inflation rebate calculations for GUARD Model drugs using international drug pricing information. CMS expects would reduce program expenditures for Medicare Part D while preserving or enhancing beneficiaries’ quality of care. For this reason, CMS declined to propose the alternatives considered. We welcome comments on the alternatives considered as well as other factors that could be considered to mitigate the impact on small manufacturers.

G. Effects on Small Rural Hospitals

Section 1102(b) of the Act requires CMS 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 a Metropolitan Statistical Area 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 final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

H. Unfunded Mandates Reform Act

Section 202 of the UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of \$100 million in 1995 dollars, updated annually for inflation. In 2025, that threshold is approximately \$187 million. The analysis of impacts on the GUARD Model does not report an estimate of any unfunded effect on State, local, or Tribal governments, in the aggregate, or on the private sector that exceeds the \$187 million threshold. However, this proposed rule, if finalized as proposed, would result in additional impacts associated with changes in behavior; these are not quantified. Therefore, the Secretary has concluded that the requirements of section 202 of the UMRA have been met for the GUARD Model. We request comments, including on the potential magnitude of this impact

I. Federalism

Executive Order 13132 establishes certain requirements that an agency

must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this proposed rule does not impose any substantial costs on State or local governments, preempt State law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

J. Unleashing Prosperity Through Deregulation

E.O. 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.”

VI. Response to Comments

Because of the large number of public comments we normally receive on 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 December 10, 2025.

List of Subjects for 42 CFR 514

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV, subchapter H as set forth below:

■ 1. Subchapter H is amended by adding and reserving part 513 and adding part 514 to read as follows:

SUBCHAPTER H—HEALTH CARE INFRASTRUCTURE AND MODEL PROGRAMS

PART 513 [Reserved]

PART 514—GUARD MODEL

Sec.

Subpart A—General Provisions

514.1 Basis, scope and duration.
514.5 Definitions.

Subpart B—Inclusion in the GUARD Model

- 514.100 Definitions.
- 514.110 GUARD Model participation.
- 514.120 Identification of GUARD Model drugs.
- 514.125 GUARD Model drug units.
- 514.130 Defined population, inclusion and exclusion criteria.

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Authority: 42 U.S.C.1302, 1315(a), and 1395hh.

PART 514—GUARDING U.S. MEDICARE AGAINST RISING DRUG COSTS (GUARD) MODEL**Subpart A—General Provisions****§ 514.1 Basis, scope, and duration.**

(a) *Basis.* This part implements the test of the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model under section 1115A(b) of the Act. Except as specifically noted in this part, the regulations under this subpart do not affect payment, coverage, program integrity, or any other requirements that otherwise apply to providers of services, suppliers, and manufacturers under this chapter.

(b) *Scope.* This part sets forth the following:

- (1) GUARD Model participants.
- (2) The beneficiaries included in the GUARD Model.
- (3) The Part D rebatable drugs included in the GUARD Model.
- (4) The methodologies for establishing the GUARD Model Rebate amount.
- (5) GUARD Model rebate payment calculations.
- (6) Rebate reports.
- (7) Payment reconciliation.
- (8) Beneficiary protections.

(c) *Duration.* The GUARD Model has a 7-year test period consisting of a 5-year performance period and a 7-year payment period. The first performance year (performance year 1) begins on January 1, 2027, and the final performance year (performance year 5) ends on December 31, 2031, unless sooner terminated in accordance with § 514.910. The first payment year begins on January 1, 2027, and the final payment year ends on December 31, 2033.

(d) *Severability.* Were any provision of this part to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, the provisions would be severable from this part and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 514.5 Definitions.

For the purpose of this part, the following definitions are applicable unless otherwise stated:

Across-country average net price means the weighted average net price (excluding price concessions) for all international products sold across all reference countries that are part of GUARD Model drug's set of international analogs during a

submission's corresponding performance year, where the weights are the corresponding volumes of the international product sold in National Council for Prescription Drug Programs (NCPDP) units, each price is adjusted using the reference country specific gross domestic product (GDP) based on purchasing power parity (GDP PPP) adjuster, converted into U.S. dollars using the exchange rate for currency conversion as described at § 514.310(e), and expressed as a per unit price, where the units are the GUARD Model drug's NCPDP units.

Applicable submission means a voluntary manufacturer submission that CMS determines fulfils the data requirements, which include verification of the submission for completeness and validity, and therefore is suitable for determination of the GUARD Model updated international benchmark per § 514.310(b).

AMP stands for average manufacturer price.

ANDA stands for abbreviated new drug application.

Biosimilar biological product means for the United States a marketed biological product submitted in a biologics license application (BLA) under section 351(k) of the Public Health Services Act (PHS Act).

BLA stands for biologics license application.

Country-level average price means the average or weighted-average price for all international products sold in a reference country that are part of a GUARD Model drug's set of international analogs, where, if available, the weights are the corresponding volumes of international product sold expressed in NCPDP units, and expressed as a per unit price, where the units are the GUARD Model drug's NCPDP units.

Covered Part D drug has the same meaning set forth in section 1860D–2(e) of the Act and § 423.100 of this chapter.

DIR stands for direct and indirect remuneration.

EGWP stands for Employer Group Waiver Plan.

Exchange rate for currency conversion means the conversion rate used to convert from the currency of each reference country, identified in § 514.220(d), to U.S. dollars corresponding to the submission's performance year.

FDA stands for Food and Drug Administration.

FD&C Act stands for the Food, Drug and Cosmetics Act.

GDP stands for gross domestic product.

GDP (PPP) stands for GDP based on purchasing power parity.

GDP (PPP) adjuster means for a reference country, the U.S. GDP (PPP) per capita divided by the reference country's GDP (PPP) per capita rounded to the third decimal place, where—

(1) The GDP (PPP) per capita for the reference country is the most recent estimate of GDP (PPP) per capita for that reference country available in the Central Intelligence Agency (CIA) World Factbook at the end of the corresponding performance year.

(2) The reference country's GDP (PPP) per capita and U.S. GDP (PPP) per capita must be for the same calendar year. The GDP (PPP) adjuster has a lower bound of 1.000, thus if the resulting GDP (PPP) adjuster is lower than 1.000, it is set to 1.000.

Generic means for the United States, a drug submitted in an ANDA and approved under section 505(j) of the FD&C Act.

GUARD Model applicable international benchmark means, per § 514.410(b), for each GUARD Model drug, the greater of the default international benchmark and, if available, the updated international benchmark; and for which an *applicable adjustment factor*, according to § 514.410(e), has been applied.

GUARD Model beneficiary means an individual who is enrolled in a Part D plan, either in a standalone prescription drug plan (PDP) or Medicare Advantage prescription drug (MA-PD) plan, but not in an EGWP, and who resides in a GUARD Model geographic area as determined by the beneficiary's address of record with Medicare.

GUARD Model beneficiary population means all Part D enrollees (with the exception of those who are enrolled in an EGWP) who are furnished with a GUARD Model drug as identified in Medicare Part D prescription drug event (PDE) data within the GUARD Model performance period and who reside within a GUARD Model geographic area.

GUARD Model default international benchmark, which is also referred to as the Method I benchmark, means for each GUARD Model drug, the lowest price in a set of country-level average prices calculated, using the steps proposed at § 514.410(c), for each reference country identified at § 514.220(d), where international drug pricing data is available from selected data sources per § 514.210 for at least one reference country and at least one reference country-level price can be calculated.

GUARD Model drug means, subject to the exclusions set forth in § 514.120(c)

a Part D rebatable drug, as defined in 42 CFR 428.20 and determined in 42 CFR 428.101, that is a sole-source drug or sole-source biological product as defined in § 514.100, has a United States Pharmacopeia (USP) category classification that includes at least one of the USP selected categories, as defined in § 514.120(e), and is identifiable by a unique National Drug Code (NDC) 9 code for which a payment was made under Medicare Part D.

GUARD Model drug unit means, with some exceptions, as described in § 514.125(a), units dispensed based on Part D PDE records for GUARD Model drugs that are furnished to Part D enrollees who reside in GUARD Model geographic areas and are part of the GUARD Model beneficiary population.

GUARD Model geographic area means the geographic areas, defined by Zonal Improvement Plan Code Tabulation Areas (ZCTAs), selected for participation in the GUARD Model in accordance with § 514.110(d).

GUARD Model participant means a manufacturer of a GUARD Model drug that receives a Part D inflation rebate report for an applicable period that overlaps with the GUARD Model performance period.

GUARD Model payment period means the 7-year period beginning on January 1, 2027, through December 31, 2033, as specified in § 514.1(c).

GUARD Model performance period means the 5-year period beginning on January 1, 2027, through December 31, 2031, as specified in § 514.1(c).

GUARD Model updated international benchmark, which is also referred to as the Method II benchmark, means for each GUARD Model drug, the across-country average net price, which is a volume-weighted average across all reference countries, identified at § 514.220(d), where an international product that is part of the set of international analogs is sold, and includes GDP (PPP) adjustments; the across-country average net price is part of an applicable submission of international drug net pricing data by manufacturers according to § 514.310.

International biosimilar biological product means for a reference country identified in § 514.220(d), a biological product approved and licensed in a reference country under that reference country's regulatory framework under a pathway similar to section 351(k) of the PHS Act in the United States.

International generic means for a reference country identified in § 514.220(d), a drug approved and marketed in a reference country under that reference country's regulatory framework under a pathway similar to

section 505(j) of the FD&C Act in the United States.

International product means a drug or biological product sold in a reference country as identified in § 514.220(d) that is aligned across its identifying characteristics with a GUARD Model drug. The identifying characteristics are specific to each GUARD Model drug (which in accordance with § 514.120(a), is identified at the NDC-9 level) and include active ingredient(s), route of administration, dosage form, and strength. Alignment across identifying characteristics, as according to § 514.410, allows for adjustments that do not materially modify the nature of the drug but account for country-specific differences such as differences due to language, units of measurement, labeling standards, or differences in dosage form or strength.

Manufacturer has the meaning set forth in section 1927(k)(5) of the Act and § 428.20 of this chapter.

MFP stands for maximum fair price.

National Drug Code (NDC) has the same meaning as the meaning set forth in § 428.20 of this chapter.

NCPDP stands for National Council for Prescription Drug Programs.

NDA stands for new drug application.

Part D rebatable drug has the meaning set forth in section 1860D-14B(g)(1) of the Act and § 428.20 of this chapter.

Payment year means a 12-month period beginning on January 1 and ending on December 31 during the GUARD Model payment period.

Performance year means a 12-month period beginning with January 1 of a year (beginning with January 1, 2027) and ending on December 31 during the GUARD Model performance period.

Performance year Medicare net price means a per unit net price for the GUARD Model drug during the performance year, expressed in terms of NCPDP units, calculated according to § 514.510(b) using the wholesale acquisition cost (WAC), manufacturer direct and indirect remuneration (DIR), discounts from the Manufacturer Discount Program, and quantity dispensed across all PDE records associated with the GUARD Model drug during a performance year.

PHS Act stands for Public Health Services Act.

Prescription drug event (PDE) data means records submitted by a Part D plan to CMS each time a beneficiary fills a prescription under Medicare Part D. A PDE record is data summarizing the final adjudication of a Part D dispensing event that is reported to CMS by the Part D sponsor using a CMS-defined file layout.

Reference country means the countries CMS identified in § 514.220(d).

Set of international analogs means for each GUARD Model drug, the set of international products sold across all reference countries identified at § 514.220(d).

Submission means manufacturer international drug net pricing data voluntarily submitted to CMS to consider for use for the performance year for which it was submitted.

Subsequent performance year means every performance year after the first. There are four, starting January 1st and ending on December 31st of 2028, 2029, 2030, and 2031.

U.S. stands for United States.

USP stands for United States Pharmacopeia.

USPS stands for the United States Postal Service.

WAC stands for Wholesale Acquisition Cost.

Subpart B—Inclusion in the GUARD Model

§ 514.100 Definitions.

For the purpose of this subpart the following definitions are applicable unless otherwise stated:

Application-level total gross covered prescription drug costs means the sum of total gross covered prescription drug costs, as defined in 42 CFR 428.100, from Medicare Part D PDE data for all rebatable Part D drugs belonging to the same FDA application.

CPI-U has the same meaning set forth in section 1927 of the Act and § 428.20 of this chapter.

Gross covered prescription drug costs have the same meaning set forth in section 1860D–2(b)(3) of the Act and § 423.308 of this chapter.

GUARD Model minimum spend threshold means—

(1) For the performance year beginning on January 1, 2027, an amount equal to \$69 million;

(2) For the performance year beginning January 1, 2028, an amount equal to \$69 million increased by the percentage increase in CPI-U for the 12-month period beginning January 1, 2027;

(3) For subsequent performance years, the minimum spend threshold is equal to the minimum spend threshold for the prior performance year increased by the percentage increase in the CPI-U for the 12-month period beginning with January of the previous performance year; and

(4) If the resulting amount is not a multiple of \$10, CMS rounds that amount to the nearest multiple of \$10.

MA–PD stands for Medicare Advantage prescription drug.

PDP stands for prescription drug plan.

Resides within the GUARD Model geographic area means the beneficiary's home address as recorded in CMS's Medicare Enrollment Database is within the GUARD Model geographic areas as determined by CMS in § 514.110(d).

Sole-source biological product means a biological product licensed by the FDA under a BLA under section 351(a) of the PHS Act, that is not the reference biological product, as defined at 42 U.S.C. 262(i)(4), for a biosimilar biological product licensed by FDA in a BLA under section 351(k) of the PHS Act. The biosimilar biological product must have the biological product as its reference product in the FDA's Purple Book and be identified as marketed in the FDA's NDC Directory.

Sole-source drug means a drug approved by the FDA under a NDA under section 505 of the FD&C Act for which there are no generic(s), as defined at § 514.5, rated as therapeutically equivalent (under the FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations"). The generic rated as therapeutically equivalent to the drug must be recognized as a therapeutic equivalent in the FDA's Orange Book and be identified as marketed in the FDA's NDC Directory.

Zonal Improvement Plan (ZIP) Code means a trademark of the USPS created to coordinate mail handling and delivery. The USPS assigns ZIP Code ranges to regional post offices, which in turn assign ZIP Codes to delivery routes.

ZIP Code Tabulation Areas (ZCTAs) means approximate area representations of USPS 5-digit ZIP Code service routes that the U.S. Census Bureau creates using whole blocks to present statistical data from censuses and surveys.

§ 514.110 GUARD Model participation.

(a) *GUARD Model participants.* The GUARD Model requires participation by all manufacturers of GUARD Model drugs that receive a Part D inflation rebate report during an applicable period that overlaps with the GUARD Model performance period.

(b) *GUARD Model participant requirements during the GUARD Model performance period and payment period.* During the GUARD Model performance period and payment period described in § 514.1(c), GUARD Model participants must do all of the following:

(1) Adhere to the GUARD Model rebate invoicing and payment instructions in subpart G of this part and as established by CMS and its

contractors responsible for providing GUARD Model rebate invoices, and processing GUARD Model rebates, including without limitation to ensure appropriate and accurate GUARD Model rebate payments; and

(2) Participate in GUARD Model monitoring and evaluation activities in accordance with § 403.1110(b), including collecting and reporting of information as the Secretary determines is necessary to monitor and evaluate the GUARD Model.

(3) If electing to submit international net drug pricing data, adhere to the requirements set forth in § 514.310 and the GUARD Model data agreement.

(c) *GUARD Model participant requirements after the GUARD Model performance period and payment period conclude.* GUARD Model participants must do all of the following:

(1) Adhere to the GUARD Model rebate invoicing and payment instructions in subpart G of this part and as established by CMS and its contractors responsible for providing GUARD Model rebate reports and invoices, and processing GUARD Model rebates, including without limitation to ensure appropriate and accurate GUARD Model rebate payments.

(2) Participate in GUARD Model monitoring and evaluation activities in accordance with 42 CFR 403.1110(b), including collecting and reporting of information as the Secretary determines is necessary to monitor and evaluate the GUARD Model during the GUARD Model performance period.

(3) Continue the GUARD Model reconciliation activities as described in § 514.610.

(4) If electing to submit international net drug pricing data, adhere to the requirements set forth in § 514.310 and the GUARD Model data agreement.

(d) *Model geographic scope.*

(1) CMS will determine the geographic scope of the GUARD Model no later than 60 calendar days before the beginning of the GUARD Model performance period by selecting a simple random sample of ZCTAs that would enable a representative sample of Medicare Part D enrollees and Medicare expenditures, including Part D expenditures.

(2) ZCTAs are the geographic unit of selection.

(i) The GUARD Model geographic areas are identified by ZIP codes that are aligned with ZCTAs.

(ii) During the model performance period, if a ZIP Code that is within the GUARD Model geographic area is split or redesignated, that ZIP Code will not

get reassigned to a GUARD Model geographic area.

(iii) Beneficiaries already assigned to the GUARD Model geographic area remain assigned to the GUARD Model geographic area regardless of any subsequent changes to their Zip Code.

(iv) Newly enrolled beneficiaries in a split or redesignated ZIP Code are not assigned to a GUARD Model geographic area.

(3) The identified GUARD Model geographic areas must include approximately 25 percent of the United States, excluding U.S. territories.

(4) The identified GUARD Model geographic areas are not subject to administrative or judicial review.

§ 514.120 Identification of GUARD Model drugs.

(a) *GUARD Model drugs.* Subject to the limitations specified in paragraph (c) of this section, GUARD Model drugs include Part D rebatable drugs as defined in 42 CFR 428.20 and determined in 42 CFR 428.101, identified at the NDC-9 level—

(1) Are sole-source drugs and sole-source biological products, as defined in § 514.100, in accordance with paragraph (b) of this section; and

(2) Have a USP category classification identified according to paragraph (d) of this section that includes at least one of the USP selected categories according to paragraph (e) of this section.

(b) *Sole-source condition.* Sole-source drugs or sole-source biological products that during a performance year no longer fulfill the definition of sole-source drug or sole-source biological product proposed at § 514.100 will be subject to the GUARD Model for the period of the performance year during which the drug or biological product did fulfill the definition.

(c) *Exclusions.* All of the following are excluded from the GUARD Model:

(1) Generics and biosimilar biological products as defined in § 514.5.

(2) A drug with application-level total gross covered prescription drug costs as defined in § 514.100 below the GUARD Model minimum spend threshold as defined in § 514.100 for the corresponding performance year. If a GUARD Model drug exceeds the GUARD Model minimum spend threshold for a performance year during the GUARD Model performance period, the GUARD Model drug is no longer subject to exclusion for subsequent performance years.

(3) A drug that is a selected drug (as defined in section 1192(c) of the Act) with an MFP that is in effect.

(d) *USP category classification.* For a GUARD Model drug, its USP category

classification is the category or categories identified for the GUARD Model drug in the USP Medicare Model Guidelines.

(1) At time of consideration for inclusion into the GUARD Model, the most recently published version of the USP Medicare Model Guidelines will be utilized to identify the categories.

(2) Identification is done using the GUARD Model drug's NDC-9, RxNorm Concept Unique Identifier, active ingredient(s), or FDA approved indication(s), and matching all USP categories in the USP Medicare Model Guidelines associated with the GUARD Model drug.

(3) Once a category or categories are assigned it remains the GUARD Model's drug category or categories for the entire performance period.

(e) *USP selected categories.* From the most recent USP Medicare Model Guidelines available (according to paragraph (d)(1) of this section) as follows:

(1) USP categories corresponding to Medicare Protected Classes, as defined in Chapter 6 section 30.2.5 from the Medicare Prescription Drug Benefit Manual.

(i) Any change to the definition of Medicare Protected Classes in Chapter 6 section 30.2.5 from the Medicare Prescription Drug Benefit Manual is carried over.

(ii) The current USP categories that correspond to Medicare Protected Classes are Anticonvulsants, Antidepressants, Antineoplastics, Antipsychotics, Antivirals, Bipolar Agents, and Immunological Agents.

(2) USP categories of Analgesics, Antimigraine Agents, Blood Glucose Regulators, Cardiovascular Agents, Central Nervous System Agents, Gastrointestinal Agents, Genetic or Enzyme or Protein Disorder Replacement or Modifiers or Treatment, Metabolic Bone Disease Agents, Ophthalmic Agents, and Respiratory Tract/Pulmonary Agents.

(f) *Carry over of changes to definitions.* Any changes to the definition of applicable threshold and Part D rebatable drug in 42 CFR 428.20 and the determination of Part D rebatable drugs in 42 CFR 428.101 are carried over.

§ 514.125 GUARD Model drug units.

(a) *Inclusion.* All GUARD Model drug units dispensed to GUARD Model beneficiaries who reside in GUARD Model geographic areas during the performance period, identified using Medicare Part D PDE records.

(b) *Exclusions.* CMS will exclude drug units covered under 340B.

§ 514.130 Defined population, inclusion and exclusion criteria.

(a) *Beneficiary eligibility criteria.* An individual is eligible to be a GUARD Model beneficiary if the individual meets all of the following criteria:

(1) Is enrolled in a standalone PDP or MA-PD plan under Medicare Part D that is not an EGWP;

(2) Resides within a GUARD Model geographic area, as determined by the beneficiary's address recorded in CMS's Medicare Beneficiary Database (MBD), System No. 09-70-0536; and

(3) Is not excluded from GUARD Model participation under paragraph (d) of this section.

(b) *Initial model cohort and comparison group.* Subject to the paragraph (d) of this section, approximately 30 calendar days prior to GUARD Model start, using available Medicare program administrative information as determined by CMS, CMS will identify the—

(1) Initial model cohort consisting of Medicare beneficiaries who meet the beneficiary eligibility criteria under paragraph (a) of this section for inclusion in the model at model start (as identified by CMS under § 514.1(c)) and add such beneficiaries to the model cohort.

(2) Comparison group consisting of Medicare beneficiaries enrolled in Medicare Part D who do not have an address of record within the GUARD Model geographic areas selected for inclusion in the model, and add such beneficiaries to the comparison group.

(c) *Updated cohort.* Subject to the paragraph (d) of this section, periodically (not more frequently than weekly), using available Medicare program administrative information as determined by CMS will update the model cohort.

(1) CMS will add the Medicare beneficiaries who meet all the following criteria to the model cohort:

(i) Are enrolled in a standalone PDP or MA-PD plan under Medicare Part D (but not an EGWP).

(ii) That have Medicare as their primary payer.

(iii) That have an address of record within the GUARD Model geographic areas selected for inclusion (as identified by CMS under § 514.110(c)).

(iv) That are not yet included in the model cohort.

(v) That are not also in the comparison group.

(2) Beneficiaries in the model cohort who no longer are enrolled in the standalone PDP or MA-PD plan under Medicare Part D, no longer have Medicare as their primary payer, or are enrolled in an EGWP will be removed

from the model cohort at the next update.

(d) *Exclusions.* The following individuals are excluded from being model beneficiaries.

(1) Beneficiaries who do not have Medicare as their primary payer.

(2) Beneficiaries who are not enrolled in the standalone PDP or MA–PD plan under Medicare Part D.

(3) Beneficiaries who are enrolled in an EGWP.

(e) *Review.* The identification of included GUARD Model beneficiaries and the timing of such identification, as well as the identification of the beneficiaries in the comparison group are not subject to administrative and judicial review.

Subpart C—Existing International Data Sources and Reference Countries

§ 514.210 Existing data sources of international drug pricing data.

(a) *General.* Subject to requirements in paragraph (b) of this section and selection criteria outlined in paragraph (c) of this section, CMS will select a data source of international drug pricing data for each GUARD Model drug's set of international analogs that are sold in the reference countries determined in § 514.220(d). CMS does the following prior to the GUARD Model rebate payment calculation:

(1) For the first performance year, identifies available data sources of international drug pricing data.

(2) For each subsequent performance year, identifies available data sources of international drug pricing data for any GUARD Model drug that was not a GUARD Model drug in a previous performance year or did not have a GUARD Model default international benchmark in a previous performance year.

(b) *Requirements for data sources of international drug pricing data.* Data sources, as determined by CMS, must do all the following:

(1) Utilize a standardized method for identifying drugs across countries within that data source, such as using internationally recognized scientific and nonproprietary product names.

(2) Utilize a standard method for identifying a drug's route of administration and dosage form across countries within that data source, such as using an internationally recognized nomenclature for pharmaceutical forms like the New Form Code classification.

(3) Utilize a standard method for identifying a drug's strengths across countries within that data source, and they are expressed in internationally recognized measures such as milligrams or milliliters.

(4) Utilize a standard method to identify a drug's regulatory approval pathway across countries within that data source, that at a minimum distinguishes international generics and international biosimilar biological products, as defined at § 514.5.

(5) Contain at a minimum one of the following forms of drug pricing data and utilizes a standard method across countries within that data source to record the pricing data:

(i) Coordinated sales and volume data, meaning a sales amount corresponding to a volume recorded in a standardized currency across countries within that data source, and which corresponds to actual or calculated transaction amount between a seller and a purchaser of a drug or biological product, and its corresponding volume, meaning the quantity of units—recorded in a standardized unit measure across countries within that data source—where the lowest dispensable amount is or can be converted into NCPDP units that correspond to the GUARD Model drug.

(ii) Coordinated price and volume data, meaning a price recorded in a standardized currency across countries within that data source, and which corresponds to the price for an actual or calculated transaction between a seller and a purchaser of a drug or biological product, and its corresponding volume, meaning the quantity of units—recorded in a standardized unit measure across countries within that data source—where the lowest dispensable amount is or can be converted into NCPDP units that correspond to the GUARD Model drug.

(iii) Price data, meaning a price recorded in a standardized currency across countries within that data source, and which corresponds to the price for an actual or calculated transaction between a seller and a purchaser of a drug or biological product.

(6) Have mechanisms in place to maintain, update, validate, and correct, if necessary, the information on international drug pricing in the data source on at least a quarterly basis.

(7) Be maintained by an organization that seeks to limit the lag inherent in data to no more than 90 calendar days from the end of the calendar quarter for which drug pricing information is compiled to the time that the organization makes the updates available to users of the data source.

(c) *Selection of data source.* Subject to paragraphs (c)(1) and (2) of this section, for each GUARD Model drug, CMS selects a data source that CMS has access to that fulfills the requirements from paragraph (b) of this section, and,

if available, obtains the data, to then calculate the GUARD Model default international benchmark for each GUARD Model drug as described in § 514.410(c).

(1) If there is more than one data source for a GUARD Model drug, CMS selects the data source at the highest level of the hierarchy described in paragraph (c)(2) of this section and if there is still more than one data source for a GUARD Model drug at the same level, CMS selects a single data source based on an assessment of the relative reliability and generalizability of the data from each available data source.

(2) *Data selection hierarchy.*

(i) For each GUARD Model drug included in the first performance year, the following hierarchy is used to select the data source of international drug pricing information:

(A) The data source contains coordinated sales and volume data for the set of international analogs in the highest number of reference countries, identified in § 514.220(d), for—

(1) Any duration of the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year; or

(2) If data for the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year is not available, data for any duration of the most recent available prior 12-month period beginning on or after January 1, 2024, is used.

(B) The data source contains coordinated prices and volume data the set of international analogs in the highest number of reference countries, identified in § 514.220(d), for—

(1) Any duration of the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year; or

(2) If data for the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year is not available, data for any duration of the most recent available prior 12-month period beginning on or after January 1, 2024, is used.

(C) The data source contains price data for the set of international analogs in the highest number of reference countries, identified in § 514.220, for—

(1) Any duration of the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year; or

(2) If data for the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year is not available, data for any duration of the most recent

available prior 12-month period beginning on or after January 1, 2024, is used.

(ii) For each GUARD Model drug included in a subsequent performance year, and not in any prior performance year, or that did not have a GUARD Model default international benchmark in a previous performance year, the same hierarchy described in paragraph (c)(2)(i) of this section is used, but it would read “subsequent performance year” instead of “first performance year.”

§ 514.220 Identifying reference countries.

(a) *General.* For the GUARD Model performance period, CMS will determine reference countries in accordance with paragraph (d) of this section using criteria in paragraph (b) of this section and GDP data as characterized in paragraph (c) of this section.

(b) *Reference country identification criteria.* CMS identifies countries that meet all of the following:

(1) Were non-U.S. Organization for Economic Co-operation and Development (OECD) member countries as of October 1, 2025.

(2) Had an aggregate GDP (PPP) of at least \$400 billion U.S. dollars as of October 1, 2025.

(3) Had a per capita GDP (PPP) that is at least 60 percent of the U.S. GDP per capita as of October 1, 2025.

(c) *GDP data.* GDP data used in paragraph (b) of this section—

(1) Corresponds to the most recent country data available in the U.S. CIA World Factbook as of October 1, 2025; and

(2) The country's per capita GDP (PPP) for that country and U.S. GDP per capita are for the same calendar year.

(d) *Reference countries.* Subject to paragraph (b) of this section, CMS determines the set of reference countries for the GUARD Model performance period are as follows:

- (1) Australia.
- (2) Austria.
- (3) Belgium.
- (4) Canada.
- (5) Czech Republic.
- (6) Denmark.
- (7) France.
- (8) Germany.
- (9) Ireland.
- (10) Israel.
- (11) Italy.
- (12) Japan.
- (13) The Netherlands.
- (14) Norway.
- (15) South Korea.
- (16) Spain.
- (17) Sweden.
- (18) Switzerland.

(19) United Kingdom.

Subpart D—Manufacturer Submitted Data

§ 514.300 Definitions.

For the purpose of this subpart the following definitions are applicable unless otherwise stated:

Authorized representative means an individual, designated by a manufacturer, as responsible for submitting international drug net pricing data, and who is also responsible for managing all communications related to the submission on behalf of the manufacturer.

Average net-to-gross ratio means for a reference country, the total net sales for international products that are part of a GUARD Model drug's set of international analogs in a reference country divided by the corresponding total gross sales for the corresponding international products.

Country-level net price means a weighted average net price, that excludes price concessions, for all international products sold in a reference country that are part of a GUARD Model drug's set of international analogs during a submission's corresponding performance year, where the weights are the corresponding volumes of international products sold, expressed as a per unit price, where the units are the GUARD Model drug's NCPDP units.

Gross sales amount means the amount of money paid, inclusive of any price concessions, for the purchase of an international product in a reference country.

International regulatory approval status means any information relevant and sufficient for CMS to determine whether each international product's approval or licensing status according to the reference country's regulatory framework would make it an international generic, international biosimilar biological product, or neither.

Net price level means, with respect to sales of international products, all sales of an international product in a reference country at the same price and price concession.

Net sales amount means the amount of money paid, exclusive of any price concessions, for the purchase of an international product in a reference country.

Price concession means any discounts, rebates, or other concessions offered by the manufacturer that lowers the amount paid for purchase of an international product in a reference country.

§ 514.310 Manufacturer submission of international drug net pricing data.

(a) *General.*

(1) *Voluntary submission.*

Manufacturers may voluntarily elect to submit manufacturer international drug net pricing data, henceforth the *submission*, to CMS in accordance with the data requirements of this section.

(2) *Purpose.* CMS uses applicable submissions, determined in accordance with paragraph (b) of this section, to determine the GUARD Model updated international benchmark per § 514.410(d) for the performance year corresponding to the submission.

(b) *Data requirements.*

(1) *Data agreement.* 90 calendar days prior to the submission, the manufacturer must execute a data agreement with CMS that establishes the terms, conditions, and requirements related to the international drug net pricing data under this section.

(i) The data agreement is only applied for the performance year for which there is a submission.

(ii) A new data agreement is required for every performance year for which the manufacturer elects to submit international drug net pricing data for a GUARD Model Part D rebatable drug.

(2) *Timing of submission.* The submission must be received by CMS no later than 180 calendar days after the end of the performance year for which the manufacturer is making the submission.

(3) *Scope of submission.*

Manufacturers may make a submission for one or more GUARD Model drugs. For each GUARD Model drug, the submission must—

(i) Include all international products that are part of the GUARD Model drug's set of international analogs with sales in the reference countries identified in § 514.220(d) that occur during the performance year for which they are making the submission;

(ii) Ensure alignment is consistent with the alignment approach to identify the set of international analogs at § 514.410(c); and

(iii) Ensure that allocation and calculations be done in a manner consistent with the generally acceptable accounting principles (GAAP), international financial reporting standards (IFRS), or other internationally recognized accounting approaches.

(4) *Verification of manufacturer submissions.* CMS will conduct a review of all submissions for completeness and validity, and may request additional data or information before finalizing its review and making a determination of applicability.

(i) *Completeness.* To be verified for completeness, the submission must include all basic data elements as described in paragraph (c) of this section and all net pricing data elements as described in paragraph (d) of this section, unless explained in an acceptable manner according to paragraph (e) of this section, as well as fulfill the following requirements:

(A) Proper and full execution of the manufacturer data agreement.

(B) Proper and full attestation by the manufacturer's authorized representative as described in paragraph (e) of this section.

(C) The submission was done using the proper portal and all security requirements within.

(D) The submission was executed in the manner and form required by CMS.

(E) The submission will include supporting documentation that explains how each of the elements of the submission were compiled or calculated and any reasonable assumptions that were applied.

(F) If for any element of the basic data elements in paragraph (c) of this section and net pricing data elements in paragraph (d) of this section, third-party individuals and organizations were relied upon to gather, analyze, or submit data, this must be specified for each element and the third-party individual or organization identified.

(ii) *Validity.* CMS will utilize all available data sources and information to assess the extent to which the submission reflects international drug net pricing in the reference countries. CMS may choose to request additional supporting information from manufacturers before completing assessment of validity of the submission.

(A) CMS will conduct some or all of the following checks, as appropriate:

(1) Cross reference against existing international pricing data for the set of international analogs.

(2) Check submitted data elements for internal consistency.

(3) Conduct cross-validation using external publicly available data.

(4) Conduct technical data quality checks.

(5) Any other appropriate checks as determined by CMS.

(B) *Request for additional information.* If CMS requests additional supporting information from manufacturers before completing its assessment of a submission's validity, the manufacturer must respond within 15 calendar days. Failure to respond within 15 calendar days will result in CMS being unable to confirm the

validity of the submission, and the submission will not be deemed valid.

(5) *Applicable submission.* CMS will determine that a submission is an applicable submission only if the submission is satisfactorily verified per paragraph (b) of this section.

(c) *Basic data elements required.*

(1) A submission must include all the following basic data elements:

(i) GUARD Model drug brand name, nonproprietary name, and NDC-9.

(ii) For every reference country where at least one international product that is part of a GUARD Model drug's set of international analogs was sold during the submission performance year—

(A) Reference country name; and

(B) For every international product part of the GUARD Model drug's set of international analogs sold in the reference country, all of the following:

(1) Scientific name and active ingredient(s).

(2) Brand name(s) (all variations if there are more than one in the reference country) and nonproprietary name.

(3) Names of manufacturers, marketers, licensees, or other entities responsible for selling the international product in the reference country.

(4) International regulatory approval status.

(5) Route of administration and dosage form as they are expressed in the reference country and in equivalent terms to what is expressed in the NDC directory for the GUARD Model drug.

(6) Dosage strength and dosing units as they are expressed in the reference country and in NCPDP equivalent units according to the GUARD Model drug's NCPDP unit.

(7) All package forms and sizes available.

(d) *Net pricing data elements required.* A submission must include net pricing elements in complete fulfillment of one of the net pricing data submission options that follow:

(1) *Streamlined option.*

(i) For every reference country where at least one international product part of a GUARD Model drug's set of international analogs was sold during the performance year corresponding to the submission—

(A) For every sale involving an international analog aggregated at the net price level—

(1) Gross sales amount in the reference country currency and U.S. dollars;

(2) Net sales amount in the reference country currency and U.S. dollars; and

(3) Sales volume—in NCPDP units corresponding to the GUARD Model drug's NCPDP unit;

(B) Average net-to-gross ratio;

(C) Exchange rate for currency conversion, as defined at § 514.5 and according to the requirements at § 514.310(e);

(D) Country-level average net price in the reference country currency and U.S. dollars; and

(E) GDP (PPP) adjuster (as defined at § 514.5).

(ii) Across-country average price in U.S. dollars.

(2) *Limited option.*

(i) For every reference country where at least one international product part of a GUARD Model drug's set of international analogs was sold during the performance year corresponding to the submission of all of the following:

(A) Total gross sales amount meaning the sum of all gross sales amounts in the reference country currency and U.S. dollars.

(B) Total net sales amount meaning the sum of all net sales amounts in the reference country currency and U.S. dollars.

(C) Total sales volume—in NCPDP units corresponding to the GUARD Model drug's NCPDP unit—meaning the corresponding volume for the total net sales amount from paragraph (d)(2)(i)(B) of this section.

(D) Average net-to-gross ratio.

(E) Exchange rate for currency conversion, as defined at § 514.5 and according to the requirements at § 514.310(e).

(F) Country-level average net price in the reference country currency and U.S. dollars.

(G) GDP (PPP) adjuster (as defined at § 514.5).

(ii) Across-country average price in U.S. dollars.

(e) *Exchange rate for currency conversion.* The exchange rate used in the submission for currency conversion for the currency of the reference country to U.S. dollars will come from the World Bank Atlas.

(1) The exchange rate must correspond to the submission's corresponding performance year.

(2) The exchange rate must be applied to all data elements requiring currency conversion in the submission.

(f) *Explanation of non-inclusion.* If a manufacturer is unable to include every data element as required (described in paragraphs (c) and (d) of this section) for all international products to be in scope per paragraph (b) of this section, CMS will require a detailed explanation to justify the non-inclusion of for every data element for each international product not included.

(1) CMS will waive the data element requirements for each data element not included if CMS determines the

explanation is sufficient to justify non-inclusion.

(2) CMS will consider the submission for a GUARD Model drug to be in scope if CMS determines the explanation is sufficient to justify the non-inclusion of the excluded international products.

(g) *Data integrity and quality assurance*—(1) *Corrections and restatements*. Manufacturers may submit corrections and restatements of applicable submissions, provided the corrections and restatements are made in accordance with the requirements in paragraphs (b) through (f) of this section and are submitted within—

(i) 30 calendar days after the submission deadline; or

(ii) If responding to a CMS request, within 15 calendar days of the request.

(2) *Attestation requirements*. Each submission must include an attestation by the authorized representative certifying the completeness and validity of the data submission on behalf of the manufacturer and any third-party entities relied upon for gathering, analyzing, or submitting the manufacturer net pricing data. The attestation requires the authorized representative to—

(i) Provide contact information; and

(ii) Attest that—

(A) The submission is accurate and complete to the best of the manufacturer's knowledge;

(B) The submission is prepared in full compliance with all requirements of this section; and

(C) The authorized representative has the authority to make the attestation on behalf of the manufacturer.

(h) *Confidentiality and data protections*. CMS will maintain the confidentiality of information submitted under this section to the extent permitted by law and in accordance with applicable privacy and security requirements.

(i) *Submission platform and security requirements*. The authorized representative must gain access to the Health Plan Management System (HPMS) or other CMS system that will be used for submission, comply with all encryption and submission requirements established by CMS, and submit using the appropriate system and in the manner and form as determined by CMS.

Subpart E—Determination of the GUARD Model Applicable International Benchmark

§ 514.410 Determination of the GUARD Model Applicable International Benchmark

(a) *General*. For each GUARD Model drug, according to paragraph (b) of this

section, CMS will designate a GUARD Model applicable international benchmark.

(b) *Determination of the GUARD Model applicable international benchmark*—

(1) CMS will identify the greater of the following for a GUARD Model drug for a performance year—

(i) The GUARD Model default international benchmark (as determined in § 514.410(c)), as available; or

(ii) The GUARD Model updated international benchmark (as determined in § 514.410(d)), as available.

(2) CMS will multiply the identified benchmark from paragraph (b)(1) of this section by the applicable adjustment factor (as determined in paragraph (e) of this section) and designate the result as the GUARD Model applicable international benchmark.

(c) *Determination of the GUARD default international benchmark*. (1) The GUARD Model default international benchmark is calculated for every GUARD Model drug using the selected data source according to § 514.210 prior to the GUARD Model rebate payment amount determination for the first performance year, according to the calculation steps in paragraph (c)(3) of this section, and this will be the default international benchmark for the performance period.

(2) For any GUARD Model drug included in a subsequent performance year that was not part of the first performance year, or that did not have a GUARD Model default international benchmark in a previous performance year, the GUARD Model default international benchmark is calculated prior to the GUARD Model rebate payment amount determination for the corresponding subsequent performance year, and in accordance with paragraph (c)(3) of this section, and this is the default international benchmark for the remainder of the performance period.

(3) *Steps in determining the GUARD Model default international benchmark*. CMS will calculate the GUARD Model default international benchmark for each GUARD Model drug when there is available international drug pricing data from the selected data sources described in § 514.210 for at least one reference country among those identified in § 514.220(d).

(i) *Identification of records from international drug pricing data*. CMS will identify records for every international product that is part of a GUARD Model drug's set of international analogs in the available 12-months of international drug pricing data.

(A) CMS will find records for international products that align with the GUARD Model drug's active ingredient, route of administration, dosage form, and strength using the data sources' standardized method for identifying scientific names or nonproprietary names, route of administration, dosage forms, and strengths, and CMS will make any necessary adjustments to the records to ensure alignment.

(B) If CMS does not identify any records in paragraph (c)(3)(i)(A) of this section for a reference country, CMS will find records for said reference country for any international products that align with the GUARD Model drug's active ingredient, route of administration, and dosage form using the data sources' standardized method for identifying scientific names or nonproprietary names, route of administration, and dosage forms, and CMS will make any necessary adjustments to the records to ensure alignment. If CMS identifies—

(1) Only one international product, then its records are retained.

(2) More than one international product, and the relative difference in terms of strength between the two closest (in absolute terms) international product's strengths and the GUARD Model drug's strength compared to the relative difference in prices for those same two strength-misaligned international products is—

(i) Equal to or greater than half of the relative strength difference, then CMS will retain the records for the international product whose strength is closest in magnitude to the strength of the GUARD Model drug.

(ii) If the relative price difference is less than half of the relative strength difference, then CMS will retain records for both international products with the closest strengths in absolute terms to the GUARD Model drug.

(iii) In the case of ties, CMS will default to retaining records for the lower-strength international product.

(C) CMS will identify among the records retained from paragraph (c)(3)(i)(A) and (B) of this section, records for international products that the data source reports as an international generic or an international biosimilar biological product according to the reference country's regulatory framework. CMS will exclude these records from the calculation of the GUARD Model default international benchmark.

(D) CMS will identify among the records retained from paragraph (c)(3)(i)(A) and (B) of this section, records for international products where

the data source reports pricing information with a value of zero or less than zero.

(ii) *Data sufficiency for GUARD Model default international benchmark calculation.* If the data resulting from paragraph (c)(3)(i) of this section—

(A) Has records for at least one international product in any reference country, CMS will proceed to the calculation in paragraph (c)(3)(iii) of this section.

(B) Has no records for any international product in any reference country, the GUARD Model drug does not have a GUARD Model default international benchmark and therefore no GUARD Model rebate payment is calculated for that performance year.

(iii) *Steps for calculation of the GUARD Model default international benchmark—(A) Calculation of the country-level average price.* For each reference country with records identified per paragraph (c)(3)(i) of this section, CMS will calculate an average price per NCPDP unit of the GUARD Model drug using all records for that reference country.

(1) If the data source contains coordinated sales and volume or coordinated prices and volume, for each record of selected data for a reference country, CMS will—

(i) If contained in the data source and appropriate, CMS will convert sales amounts so that the sales amount is expressed in terms of the GUARD Model drug's NCPDP unit;

(ii) If contained in the data source and appropriate, CMS will multiply prices by the corresponding volume, where the volume is expressed in terms of the GUARD Model drug's NCPDP unit;

(iii) If the resulting amounts from paragraph (c)(3)(iii)(A)(1)(i) or (ii) are not in U.S. dollars, CMS will convert the local currency to U.S. dollars using the exchange rate for currency conversion from the selected data source.

(iv) CMS will multiply the results from paragraph (c)(3)(iii)(A)(1)(iii) by the GDP (PPP) adjuster as defined at § 514.5.

(v) CMS will calculate the total volume as a sum of all the volumes for each record of selected data for a reference country, converted if needed to be expressed in terms of the GUARD Model drug's NCPDP unit.

(vi) CMS will calculate the total volume-weighted price as a sum of all the volume-weighted prices from paragraph (c)(3)(iii)(A)(1)(iv) of this section.

(vii) CMS will divide the total volume-weighted prices from paragraph (c)(3)(iii)(A)(1)(vi) of this section by the

total volume described in paragraph (c)(3)(iii)(A)(1)(v) of this section to obtain a country-level average price.

(2) If the data source contains only prices, for each record of selected data for a reference country, CMS will do all of the following:

(i) Sum of all the prices for each record of selected data for a reference country, converted if needed to be expressed in terms of the GUARD Model drug's NCPDP unit, converting if needed from a local currency to U.S. dollars using the exchange rate for currency conversion from the selected data source.

(ii) Multiply the results from paragraph (c)(3)(iii)(A)(2)(i) of this section by the GDP (PPP) adjuster as defined at § 514.5.

(iii) Divide the result from paragraph (c)(3)(iii)(A)(2)(ii) of this section by the number of records used in from paragraph (c)(3)(iii)(A)(2)(i) to obtain the country-level average price.

(B) *Selection of the GUARD Model default international benchmark.*

Among all the country-level average prices obtained from paragraph (c)(3)(iii)(A) of this section, the lowest amount, in absolute terms, is designated as the GUARD Model default international benchmark.

(d) *Determination of the GUARD Model updated international benchmark.*

(1) CMS determines the GUARD Model updated international benchmark for each GUARD Model drug, when there is an applicable submission per § 514.310, prior to the GUARD Model rebate payment amount determination for a performance year.

(2) The across-country average net price data element from the net pricing data elements of an applicable submission as described in § 514.310, is the GUARD Model updated international benchmark.

(e) *Applicable adjustment factor.* When the GUARD Model applicable international benchmark is based on the—

(1) GUARD Model default international benchmark, the applicable adjustment factor is 102 percent.

(2) GUARD Model updated international benchmark, the applicable adjustment factor is 105 percent.

Subpart F—Determination of the GUARD Model Rebate Payment Amount

§ 514.500 Definitions.

For the purpose of this part, the following definitions are applicable unless otherwise stated:

Applicable drug has the meaning set forth in section 1860D–14C(g)(2) of the Act.

Applicable period has the meaning set forth in 42 CFR 428.20.

Currently in shortage has the same meaning set forth in 42 CFR 428.300.

Drug shortage or shortage has the same meaning set forth in 42 CFR 428.300.

Line extension has the meaning set forth in 42 CFR 428.200.

Medicare Part D Manufacturer Discount Program has the meaning set forth in section 1860D–14C of the Act.

Part D rebatable drug has the meaning set forth in 42 CFR 428.20.

Performance year per unit Part D inflation rebate amount means the per unit Part D inflation rebate amount determined under 42 CFR 428.202(a) and 428.204(c), expressed as a performance year amount and converted from per-AMP unit terms to per-NCPDP unit terms, calculated as follows:

(1) Subject to paragraph (3) of this definition, for a GUARD Model drug that is not a line extension as defined in this subpart, the performance year per unit Part D inflation rebate amount is equal to the sum of the following:

(i) The product of—

(A) The per unit Part D inflation rebate amount associated with the applicable period beginning October of the calendar year prior to the performance year as set forth in 42 CFR 428.202(a);

(B) 0.75; and

(C) NCPDP unit conversion factor.

(ii) The product of—

(A) The per unit Part D inflation rebate amount associated with the applicable period beginning October of the performance year, as set forth in 42 CFR 428.202(a);

(B) 0.25; and

(C) NCPDP conversion factor.

(2) Subject to paragraph (4) of this definition, for a GUARD Model drug that is a line extension as defined in this subpart, the performance year per unit Part D inflation rebate amount is equal to the sum of the following:

(i) The product of—

(A) The greater of the per unit Part D inflation rebate amount associated with the applicable period beginning October of the calendar year prior to the performance year, as set forth in 42 CFR 428.202(a), or the product of the amounts determined under 42 CFR 428.204(c)(1) and (2) for the applicable period;

(B) 0.75; and

(C) NCPDP unit conversion factor.

(ii) The product of—

(A) The greater of the per unit Part D inflation rebate amount associated with

the applicable period beginning October of the performance year, as set forth in 42 CFR 428.202(a), or the product of the amounts determined under 42 CFR 428.204(c)(1) and (2) for the applicable period;

(B) 0.25; and

(C) NCPDP conversion factor.

(3) Notwithstanding paragraph (1) of this definition, for a GUARD Model drug that is not a line extension as defined in this subpart, for which the GUARD Model drug is a Part D rebatable drug only during the months in which one of the applicable periods overlaps with the performance year, the performance year per unit Part D inflation rebate amount is equal to the per unit Part D inflation rebate amount associated with the applicable period and expressed in NCPDP units (that is, multiplied by the NCPDP conversion factor) in which the GUARD Model drug is a Part D rebatable drug, as set forth in 42 CFR 428.202(a).

(4) Notwithstanding paragraph (2) of this definition, for a GUARD Model drug that is a line extension as defined in this subpart, for which the GUARD Model drug is a Part D rebatable drug only during the months in which one of the applicable periods overlaps with the performance year, the performance year per unit Part D inflation rebate amount is equal to the greater of the per unit Part D inflation rebate amount associated with the applicable period in which the GUARD Model drug is a Part D rebatable drug, as set forth in 42 CFR 428.202(a), or the product of the amounts determined under 42 CFR 428.204(c)(1) and (2) for the applicable period.

§ 514.510 Determination of the GUARD Model Rebate Amount for GUARD Model Drugs.

(a) *Calculation of the total GUARD Model rebate payment amount.* The total GUARD Model rebate for a GUARD Model drug, identified as set forth in § 514.120, for a performance year is equal to the product of the per unit GUARD Model rebate amount for the drug, as determined under paragraph (b) of this section, and the total units of the GUARD Model drug dispensed under Part D for GUARD Model beneficiaries, as determined under paragraph (d) of this section.

(b) *Formula for calculating the per unit GUARD Model rebate amount.* Subject to paragraph (b)(2) of this section, CMS will calculate the per unit GUARD Model rebate payment amount for a GUARD Model drug by determining the amount by which the performance year Medicare net price for the drug, as calculated in accordance

with paragraph (b)(1) of this section, exceeds the applicable international benchmark.

(1) *Calculation of the performance year Medicare net price.* CMS will calculate the performance year Medicare net price by using WAC to calculate the performance year aggregate gross price, subtracting certain manufacturer rebates (from DIR) and discounts (from the Manufacturer Discount Program) from that aggregate price to produce the performance year aggregate net price, and dividing that net price by the quantity dispensed to produce a per unit price.

(i) *Performance year aggregate gross price.* For each GUARD Model drug, CMS will identify all PDE records for all NDC-11s associated with the NDC-9 of the GUARD Model drug with dates of service during the performance year. The performance year aggregate gross price is equal to the WAC for the GUARD Model drug, multiplied by the quantity dispensed reported on the PDE record, summed across all PDE records identified.

(A) For each PDE record, CMS will use third party sources to identify the WAC using the NDC-11. If there was no WAC available for an NDC-11, but there is an available WAC for another NDC-11 associated with the NDC-9 of the GUARD Model drug, CMS will use this available WAC.

(B) For each PDE record, CMS will identify the WAC in effect on the date of service reported on the PDE record.

(1) If there is not an effective WAC as of the date of service for any PDE records during the performance year, CMS will use the most recently effective WAC available.

(2) If the GUARD Model drug has some PDE records during the performance year for which there is an effective WAC as of the date of service, but other PDE records during the performance year for which there is not an effective WAC as of the date of service, CMS will impute a WAC for the latter category of PDE records based on the available WAC that was in effect most recently before the date of service on the PDE record.

(3) If there was no WAC in effect before the date of service on the PDE record, but there was a WAC in effect after the date of service, CMS will use the WAC that was in effect after the date of service and this would be applied to that PDE record.

(C) If there is no WAC available for any NDC-11 associated with the NDC-9 of the GUARD Model drug, CMS will not calculate a performance year aggregate gross price or issue a GUARD

Model Rebate Report for that performance year.

(ii) *Performance year aggregate net price.* The performance year aggregate net price is equal to the performance year aggregate gross price determined under paragraph (i) of this section, minus the following amounts:

(A) The sum of manufacturer rebates found in the Detailed DIR Report for the performance year across all plans for all NDC-11s associated with the NDC-9 of a GUARD Model Part D rebatable drug.

(B) Manufacturer discounts provided under the Medicare Part D Manufacturer Discount Program and obtained from the amounts reported on PDE records for the GUARD Model drug for the performance year. For a GUARD Model drug eligible for the phase-in under section 1860D-14C(g)(4)(B) or 1860D-14C(g)(4)(C) of the Act, the amount determined under this paragraph is equal to the amount the manufacturer would have paid in discounts under the Medicare Part D Manufacturer Discount Program during the performance year if the GUARD Model Part D rebatable drug had not been eligible for the phase-in.

(iii) *Convert to a per unit price.* The performance year Medicare net price is equal to the amount determined under paragraph (b)(1)(ii) of this section, divided by the sum of the amounts reported in the quantity dispensed field across all PDE records identified in paragraph (d) of this section.

(2) *Exception.* In instances when the applicable international benchmark set forth at § 514.410 is equal to zero, the per unit GUARD Model rebate payment amount is equal to zero.

(c) *Calculation of the incremental per unit GUARD Model rebate amount and the Total Incremental GUARD Model rebate amount—(1) Incremental per unit GUARD Model rebate amount.* (i) Subject to paragraph (c)(1)(ii) of this section, the incremental per unit GUARD Model rebate amount is equal to the per unit GUARD Model rebate payment amount, as set forth in paragraph (b) of this section, minus the performance year per unit Part D inflation rebate amount, as set forth at § 514.500 for the GUARD Model drug.

(ii) To the extent the amount determined under paragraph (c)(1)(i) of this section is less than or equal to zero, the incremental per unit GUARD Model rebate amount is equal to zero.

(2) *Total Incremental GUARD Model rebate amount.* (i) The Total Incremental GUARD Model rebate amount is equal to the product of the incremental per unit GUARD Model rebate amount determined under paragraph (c)(1) of this section and the total units of the GUARD Model drug

dispensed under Part D for GUARD Model beneficiaries determined under paragraph (d) of this section.

(ii) The Total Incremental total GUARD Model rebate amount for the GUARD Model drug may be reduced in accordance with § 514.520 or adjusted in accordance with subpart G of this part.

(d) *Determination of the total units of the GUARD Model drug dispensed under Part D for GUARD Model beneficiaries.* For each GUARD Model drug, CMS will determine the total number of units as follows:

(1) CMS will apply the methodology set forth at 42 CFR 428.203, inclusive of the removal of certain units as set forth at 42 CFR 428.203(b) and subject to the following adjustments:

(i) The methodology applies as if references to “applicable period” are references to “performance year.”

(ii) The methodology does not apply as set forth at 42 CFR 428.203(a)(2) to crosswalk to AMP units.

(2) From the total units identified in paragraph (d)(1) of this section, CMS will remove units for PDE records that are not associated with a GUARD Model beneficiary.

§ 514.520 Reducing the Total Incremental GUARD Model rebate amount for GUARD Model drugs in shortage or when there is a severe supply chain disruption or likely shortage.

(a) *Reducing the Total Incremental GUARD Model rebate amount for GUARD Model drugs currently in shortage.* (1) *General.* CMS will reduce the Total Incremental GUARD Model rebate amount determined under § 514.510(c)(2), if any is owed, for a GUARD Model drug that is currently in shortage, as set forth in 42 CFR 428.300, at any point during the performance year.

(2) *Calculation of reduction.* The reduced Total Incremental GUARD Model rebate amount is equal to the following:

(i) For a GUARD Model drug that was a Part D rebatable drug during both applicable periods that overlap with the performance year, the sum of—

(A) The product of—

(1) The Total Incremental GUARD Model rebate amount;

(2) 0.75;

(3) 1 minus the product of—

(i) The applicable percent reduction determined under 42 CFR 428.301(b)(2) for the applicable period that overlaps with the first three quarters of the performance year; and

(ii) The percentage of time the GUARD Model drug was currently in shortage during the first three quarters

of the performance year determined by CMS under 42 CFR 428.301(b)(3).

(B) The product of—

(1) The Total Incremental GUARD Model rebate amount;

(2) 0.25;

(3) One minus the product of—

(i) The applicable percent reduction determined under 42 CFR 428.301(b)(2) for the applicable period that overlaps with the last quarter of the performance year; and

(ii) The percentage of time the GUARD Model drug was currently in shortage during the last quarter of the performance year determined by CMS under 42 CFR 428.301(b)(3).

(ii) For a GUARD Model drug that was a Part D rebatable drug during only one of the applicable periods that overlap with the performance year, the product of—

(A) The Total Incremental GUARD Model rebate amount;

(B) One minus the product of—

(1) The applicable percent reduction determined under 42 CFR 428.301(b)(2) for the applicable period that overlaps with the performance year and during which the GUARD Model drug was a Part D rebatable drug; and

(2) The percentage of time the GUARD Model drug was currently in shortage during that applicable period determined by CMS under 42 CFR 428.301(b)(3).

(3) *Application of reduction.* CMS will apply a reduction of the Total Incremental GUARD Model rebate amount as determined under paragraph (a)(2) of this section to the GUARD Model drug at the NDC-9 level.

(b) *Reducing the Total Incremental GUARD Model rebate amount for certain GUARD Model drugs when there is a severe supply chain disruption—*(1) *General.* CMS will reduce the Total Incremental GUARD Model rebate amount determined under § 514.510(c)(2) for a generic GUARD Model drug or biosimilar biological product if CMS determines that a severe supply chain disruption occurred during an applicable period that overlaps with the performance year. A severe supply chain disruption includes disruptions caused by a natural disaster or other unique or unexpected event as set forth in § 428.300.

(2) *Calculation of reduction.* For a GUARD Model drug that is a generic or biosimilar biological product as described at 42 CFR 428.300, the reduced Total Incremental GUARD Model rebate amount is equal to the following:

(i) For a GUARD Model drug that was a Part D rebatable drug during both

applicable periods that overlap with the performance year, the sum of—

(A) The product of—

(1) The Total Incremental GUARD Model rebate amount;

(2) The percentage reduction applied under 42 CFR 428.302 for the applicable period that overlaps with the first three quarters of the performance year; and

(3) 0.75.

(B) The product of—

(1) The Total Incremental GUARD Model rebate amount;

(2) The percentage reduction applied under 42 CFR 428.302 for the applicable period that overlaps with the last quarter of the performance year; and

(3) 0.25.

(ii) For a GUARD Model drug that was a Part D rebatable drug during only one of the applicable periods that overlap with the performance year, the product of—

(A) The Total Incremental GUARD Model rebate amount;

(B) The percentage reduction applied under 42 CFR 428.302 for the applicable period that overlaps with the performance year and during which the GUARD Model drug was a Part D rebatable drug.

(3) *Limitation on GUARD Model rebate reductions.* The limitations set forth in 42 CFR 428.302(b)(4) on multiple rebate reductions for the same GUARD Model drug and performance year apply to this subpart.

(c) *Reducing the Total Incremental GUARD Model rebate amount for generic GUARD Model drugs likely to be in shortage—*(1) *General.* CMS will reduce the Total Incremental GUARD Model rebate amount determined under § 514.510(c)(2) for a generic GUARD Model drug when CMS determines that the generic GUARD Model drug is likely to be in shortage during an applicable period that overlaps with the performance year. CMS will make likely to be in shortage determinations in accordance with the criteria set forth in 42 CFR 428.300 and 428.303.

(2) *Calculation of reduction.* For a GUARD Model drug that is a generic Part D rebatable drug as described at 42 CFR 428.300, the reduced Total Incremental GUARD Model rebate amount is equal to the following:

(i) For a GUARD Model drug that was a Part D rebatable drug during both applicable periods that overlap with the performance year, the sum of—

(A) The product of—

(1) The Total Incremental GUARD Model rebate amount;

(2) The percentage reduction applied under 42 CFR 428.303 for the applicable period that overlaps with the first three quarters of the performance year; and

(3) 0.75.

(B) The product of—

(1) The Total Incremental GUARD Model rebate amount;

(2) The percentage reduction applied under 42 CFR 428.303 for the applicable period that overlaps with the last quarter of the performance year; and

(3) 0.25.

(ii) For a GUARD Model drug that was a Part D rebatable drug during only one of the applicable periods that overlaps with the performance year, the product of—

(A) The Total Incremental GUARD Model rebate amount; and

(B) The percentage reduction applied under 42 CFR 428.303 for the applicable period that overlaps with the performance year and during which the GUARD Model drug was a Part D rebatable drug.

(3) *Limitation on GUARD Model rebate reductions.* The limitations set forth in 42 CFR 428.303(b)(4) on multiple rebate reductions for the same GUARD Model drug and performance year apply to this subpart.

Subpart G—Reports of Total Rebate Payment Amounts, Reconciliation, Suggestion of Error, and Payments

§ 514.600 Definitions.

For the purpose of this part, the following definitions are applicable unless otherwise stated:

Date of receipt is the calendar day following the day in which a report of a Total Incremental GUARD Model rebate amount (as set forth in § 514.610) is made available to the manufacturer of a GUARD Model drug by CMS.

§ 514.610 Rebate report and suggestion of error.

(a) *General.* This section applies to GUARD Model drugs for all GUARD Model performance years and payment years.

(b) *Preliminary GUARD Model rebate report.* (1) A preliminary GUARD Model rebate report is provided to each manufacturer of a GUARD Model drug not later than 20 months after the end of a performance year.

(2) The preliminary GUARD Model rebate report for each GUARD Model drug includes the following information:

(i) Information related to the Part D inflation rebate amount for quarters corresponding to the relevant performance year.

(ii) The NDC(s) for the GUARD Model drug as defined under § 514.120(a).

(iii) The total number of units dispensed under Part D for the GUARD Model drug for the performance year as determined in § 514.510(d).

(iv) The GUARD Model applicable international benchmark as described in § 514.42(d).

(v) The performance year Medicare net price for the GUARD Model drug as determined in § 514.510(b)(1).

(vi) The total GUARD Model rebate amount as determined in proposed § 514.510(a).

(vii) The per unit GUARD Model rebate amount for the GUARD Model drug for the performance year as determined in § 514.510(b).

(viii) The performance year per unit Part D inflation rebate amount as described in § 514.500.

(ix) The incremental per unit GUARD Model rebate amount as determined in § 514.510(c)(1).

(x) Any applied reductions as described in § 514.520.

(xi) The total Part D inflation rebate amount as determined in 42 CFR 428.201(a).

(xii) The Total Incremental GUARD Model rebate amount due as determined in § 514.510(c)(2).

(c) *GUARD Model rebate report.* A GUARD Model rebate report will be provided to each manufacturer of a GUARD Model drug not later than 22 months after the end of each performance year.

(1) The GUARD Model rebate report will include the following:

(i) The information described in paragraph (b)(2) of this section, if applicable.

(ii) Any revisions to the information in paragraph (c)(1)(i) of this section resulting from CMS' review of a suggestion of error as set forth in § 514.620, if applicable.

(iii) Any CMS-determined recalculations from paragraph (d)(2) of this section.

(2) The GUARD Model rebate report is the invoice of a manufacturer's Total Incremental GUARD Model rebate amount due as calculated in § 514.510(c)(2), if any, for a GUARD Model drug for a performance year.

(3) The GUARD Model rebate amount due will be reported as a dollar amount that is rounded to the nearest cent.

(d) *Reconciliation of the Total Incremental GUARD Model rebate amount.* CMS will perform reconciliation of the Total Incremental GUARD Model rebate amount provided in a GUARD Model rebate report specified in paragraph (c) of this section for a performance year in the following circumstances:

(1) *Regular reconciliation.* CMS will perform a reconciliation of the Total Incremental GUARD Model rebate amount not later than 12 months after the date of receipt of the GUARD Model

Rebate Report for a performance year and a second reconciliation not later than 36 months after the date of receipt of the GUARD Model rebate report for a performance year to include revisions to the information used to calculate the Total Incremental GUARD Model rebate amount as specified in paragraph (c)(1) of this section.

(i) *Preliminary reconciliation.* Not more than 60 calendar days prior to the issuance of a report with the reconciled Total Incremental GUARD Model rebate amount for a performance year specified in paragraph (d)(1)(ii) of this section, CMS will conduct a preliminary reconciliation of the Total Incremental GUARD Model rebate amount for a performance year based on the information specified in paragraphs (d)(1)(i)(A) through (H) of this section, and CMS will provide the information specified in paragraphs (d)(1)(i)(A) through (H) of this section to the manufacturer of a GUARD Model drug for the performance year, if applicable—

(A) Updated total number of rebatable units, including updates submitted by a PDP or MA–PD plan sponsor and updates to 340B units and updates to units excluded as specified in § 514.510(d);

(B) Updated WAC for the performance year;

(C) The reconciled per unit GUARD Model rebate amount as determined in § 514.510(b);

(D) The reconciled incremental per unit GUARD Model rebate amount for the performance year as determined in § 514.510(c)(1);

(E) The reconciled Total Incremental GUARD Model rebate amount as determined in § 514.510(c)(2);

(F) The reconciled total GUARD Model rebate amount as determined in proposed § 514.510(a);

(G) The difference between the Total Incremental GUARD Model rebate amount due as specified on the GUARD Model rebate report set forth at § 514.510(c)(2) and the reconciled Total Incremental GUARD Model rebate amount as set forth in paragraph (d)(1)(i) of this section; and

(H) Any other data elements that may be updated as a result of manufacturer misreporting.

(ii) *Report with a reconciled rebate amount.* With the inclusion of any additional revisions to the information resulting from CMS' review of a suggestion of error as set forth in § 514.620, if applicable, a report with the reconciled Total Incremental GUARD Model rebate amount is provided to each manufacturer of a GUARD Model drug within 12 months and 36 months after receipt of the

GUARD Model rebate report described in paragraph (c) of this section.

(2) *CMS identification of an error or manufacturer misreporting.* CMS may recalculate a Total Incremental GUARD Model rebate amount and provide the manufacturer of a GUARD Model drug with a report of a reconciled Total Incremental GUARD Model rebate amount if—

(i) CMS identifies an error in the information specified in paragraphs (c) and (d)(1) of this section, including reporting system or coding errors, not later than 5 years from the date of receipt by a manufacturer of a GUARD Model rebate report for the performance year; or

(ii) CMS determines at any time that the information used by CMS to calculate the Total Incremental GUARD Model rebate amount was inaccurate due to manufacturer misreporting.

(3) *Impact of reconciliation on rebate amount.* A reconciliation as set forth in paragraph (d) of this section may result in an increase, decrease, or no change to the Total Incremental GUARD Model rebate amount as calculated under § 514.510(c)(2) owed by a manufacturer for the performance year for the GUARD Model drug.

(i) A report with a reconciled Total Incremental GUARD Model rebate amount that is an increase to the Total Incremental GUARD Model rebate amount is the invoice for the additional amount due on the manufacturer's Total Incremental GUARD Model rebate amount as set forth in § 514.510(c)(2) for a GUARD Model drug for a performance year.

(ii) [Reserved]

(4) *Drugs included in a reconciliation.* A drug covered under Part D that does not meet the requirements of a GUARD Model drug specified in § 514.120(a) for performance year is not included in a reconciliation under paragraph (d) of this section.

§ 514.620 Suggestion of error.

(a) *General.* Manufacturers of GUARD Model drugs may submit to CMS a request to correct errors in the preliminary GUARD Model rebate report (suggestion of error) or the report detailing the preliminary reconciliation of the Total Incremental GUARD Model rebate amount if the manufacturer believes that there is a mathematical error or errors to be corrected before the GUARD Model Rebate Report or a subsequent reconciliation, as applicable, is finalized. CMS will consider such request at its discretion before finalizing the GUARD Model rebate report or subsequent reconciliation.

(1) Section 1860D–14B(f) of the Act applies to preclude administrative or judicial review of the following:

(i) The determination of units as set forth in § 514.510(d).

(ii) The calculation of the Total Incremental GUARD Model rebate amount as set forth in § 514.510(c)(2) inclusive of any reconciled Total Incremental GUARD Model rebate amount.

(2) Section 1115A(d)(2) of the Act precludes administrative or judicial review of CMS' determination of whether a drug is a GUARD Model drug, as set forth in § 514.510(c)(2).

(b) *Process of submission.* Subject to the scope and timing requirements specified in paragraphs (a) and (c) of this section, manufacturers may submit the suggestion of error and provide supporting documentation (if applicable).

(c) *Timing.* A manufacturer must submit its suggestion of error for the performance year within 10 calendar days from the date of receipt of a preliminary GUARD Model rebate report or a preliminary reconciliation of a Total Incremental GUARD Model rebate amount using the method and process established by CMS in paragraph (b) of this section.

(d) *Notice.* CMS will—

(1) Include any revisions to the calculation of the Total Incremental GUARD Model rebate amount, if determined necessary by CMS based on the suggestion of error submitted under this section prior to issuance of the GUARD Model rebate report as set forth in § 514.610 as well as any report of a reconciled Total Incremental GUARD Model rebate amount as set forth in § 514.610.

(2) Notify the manufacturer whether CMS revises its calculation of the Total Incremental GUARD Model rebate amount based on the suggestion of error.

§ 514.630 Manufacturer access to rebate reports.

(a) *General.* CMS will establish a method and process for a manufacturer of the GUARD Model drug to do the following:

(1) Access the GUARD Model rebate report as set forth in § 514.610 including any report of a reconciled Total Incremental GUARD Model rebate amount as set forth in § 514.610;

(2) Submit a suggestion of error as set forth in § 514.620; and

(3) Pay a Total Incremental GUARD Model rebate amount as set forth in § 514.510(c)(2).

(b) [Reserved.]

§ 514.640 Deadline and process for payment of rebate amount.

(a) *Total Incremental GUARD Model Rebate amounts owed by a manufacturer.* For payment of a Total Incremental GUARD Model rebate amount owed by a manufacturer:

(1) Upon receipt of a Total Incremental GUARD Model rebate amount, payment is due no later than 11:59 p.m. Pacific Time on the 30th calendar day after the date of receipt of information regarding the Total Incremental GUARD Model rebate amount on—

(i) A rebate report specified in § 514.610; or

(ii) A report of a reconciled Total Incremental GUARD Model rebate amount specified in § 514.610.

(2) Failure to pay a Total Incremental GUARD Model rebate amount timely and in full may result in an enforcement action as described in § 514.650 and subpart H of this part.

(b) *Refund to the manufacturer.* If a GUARD Model reconciled Total Incremental GUARD Model rebate amount for a performance year as specified in § 514.610 is less than what the manufacturer paid for that performance year, CMS will initiate the process to provide a refund equal to the excess amount paid within 60 calendar days of the date of receipt of the report with the reconciled Total Incremental GUARD Model rebate amount.

§ 514.650 Civil money penalty notice and appeals procedures.

General. The provisions of 42 CFR 428.500 regarding the imposition of civil money penalties also apply with respect to this subchapter to the same extent as they are applicable with respect to part 428, except that, in applying such provisions with respect to this part, any reference therein to the rebate amount determined in § 428.201(a) shall be considered a reference to the Total Incremental GUARD Model rebate amount calculated pursuant to § 514.510(c).

Subpart H—Beneficiary Protections, Quality Strategy, and Monitoring and Compliance Activities

§ 514.710 Beneficiary protections.

(a) *General.* The requirements set forth in 42 CFR part 512, including those related to beneficiary protections, monitoring, and compliance shall apply to this model.

(b) *Reporting and analysis of issues.*

(1) For tracking purposes, CMS will utilize the existing Complaints Tracking Module so that beneficiaries and other stakeholders can report access or other issues related to GUARD Model drugs.

(2) CMS will utilize 1–800–MEDICARE for beneficiaries, providers, or other stakeholders to submit reports that a GUARD Model drug has been harder to source or obtain after the implementation of the GUARD Model.

(3) CMS will analyze information from the Complaints Tracking Module System and 1–800–MEDICARE to identify any complaints or issues related to the GUARD Model drugs. CMS may conduct investigations to verify and assess the reported access issues and implement appropriate remedial measures, as set forth at § 514.750(a), based on investigation findings to ensure beneficiary access to GUARD Model drugs.

§ 514.720 Quality of care.

(a) *General.* Consistent with section 1115A(b)(4) of the Act, CMS will monitor and evaluate the impact of the GUARD Model on quality of care. CMS may examine, at least annually or more frequently, as deemed appropriate by CMS, multiple domains of quality, including but not limited to beneficiary out-of-pocket costs, enrollment trends, drug utilization, health care utilization, access to GUARD Model drugs, patient experience, and other quality measures and other quality measures.

(1) Model rebate payment amounts are not adjusted based on quality of care.

(2) [Reserved].

(b) *Collection or analyses of measures.* CMS may collect or analyze any of the following data to monitor changes in quality of care associated with the GUARD Model:

(1) Existing administrative claims-based measures.

(2) Existing information on Part D, including but not limited to the Part D formulary reference files.

(3) Existing patient experience surveys, such as the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey or the Medicare Current Beneficiary Survey

(MCBS), from a sample of beneficiaries who receive a GUARD Model drug.

(4) Survey(s) to a sample of GUARD Model stakeholders administered by CMS.

(5) Manufacturer sales data available to CMS from existing or submitted data sources.

(6) Other data sources or information deemed appropriate by CMS.

§ 514.730 Monitoring and compliance.

The GUARD Model manufacturers must comply with all applicable Federal laws and regulations, including requirements set forth at § 512.130 and § 512.150.

§ 514.740 Audits and record retention.

The audit rights, access requirements, and record retention requirements set forth in § 512.135 shall apply to the GUARD Model.

§ 514.750 Enforcement authority and remediation.

(a) *Remedial action.* As stated in § 512.160, CMS may take one or more remedial actions described in § 512.160(b) if CMS determines that a GUARD Model participant has done any of the actions described in § 512.160(a).

(b) *Notice.* A manufacturer of a GUARD Model drug must notify CMS within 15 calendar days after becoming aware that the manufacturer is subject to investigation or sanction by the federal, state, or local government, or any licensing authority.

Subpart I—Waivers

§ 514.800 Waiver of Medicare Program requirements for purposes of testing the GUARD Model.

CMS waives the Medicare program requirements in the following provisions to the extent necessary solely for the purposes of testing the GUARD Model:

(a) *Waiving the Part D inflation rebate calculation to the extent necessary.*

Section 1860D–14B(b)(1) of the Act regarding the Medicare Part D inflation rebate calculation to the extent necessary, in order to permit testing of an alternative rebate calculation and rebate amount for GUARD Model drugs.

(b) *Waiver of invoice timing requirements to the extent necessary.* Section 1860D–14B(a)(1) of the Act regarding invoicing timing requirements to the extent necessary to establish deadlines, effective dates, and time period requirements for invoicing of the Total Incremental GUARD Rebate Amount.

Subpart J—Severability and Model Terminations

§ 514.900 Severability

If any provision of this part to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, that provision is severable from this part. The invalidity or unenforceability will not affect the remainder of this part or any other part of this subchapter, or the application of the provision to other persons not similarly situated or to other dissimilar circumstances.

§ 514.910 Termination of the GUARD Model.

(a) *Termination.* CMS may terminate the GUARD Model for the reasons as set forth in § 512.165(a). CMS will comply with the notification requirements as set forth in § 512.165(b).

(b) *Review.* Consistent with section 1115A(d)(2) of the Act, termination of the GUARD Model is not subject to administrative or judicial review.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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Part IV

Department of the Treasury

Internal Revenue Service

26 CFR Part 54

Department of Labor

Employee Benefits Security Administration

29 CFR Part 2590

Department of Health and Human Services

45 CFR Part 147

Transparency in Coverage; Proposed Rule

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

[REG–107111–25]

RIN 1545–BQ55

DEPARTMENT OF LABOR**Employee Benefits Security Administration****29 CFR Part 2590**

RIN 1210–AC30

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Part 147**

[CMS–9882–P]

RIN 0938–AV64

Transparency in Coverage

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Proposed rule.

SUMMARY: These proposed rules set forth proposed requirements that would amend the regulations under the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code regarding price transparency reporting requirements for non-grandfathered group health plans and health insurance issuers offering non-grandfathered group and individual health insurance coverage. Specifically, these proposed rules would improve the standardization, accuracy, and accessibility of public pricing disclosures in line with the goals of the Executive Order 14221. With respect to the in-network rate and out-of-network allowed amount machine-readable files, these proposed rules would achieve these goals by adding new contextual files and additional data elements like product type, network name, and enrollment counts; changing the reporting level for aggregation of data; removing in-network rates for unlikely provider-to-service mappings; increasing the reporting period and lowering the claims threshold for out-of-network historical data; and reducing the reporting cadence. These proposed rules would also improve the findability of all of the publicly disclosed machine-

readable files required under the Transparency in Coverage rules, including the prescription drug file, by requiring a text file and footer with website URLs and contact information for the files. These proposed rules would also require pricing information that is made available through an online consumer tool and paper (upon request), to also be made available by phone, and establish that the satisfaction of such requirement also satisfies the requirements of section 114 of the No Surprises Act (including for grandfathered group health plans and health insurance issuers offering grandfathered group and individual health insurance coverage that are not otherwise subject to these proposed rules).

DATES: To be assured consideration, comments must be received at one of the addresses provided below by February 23, 2026.

ADDRESSES: Written comments may be submitted to the addresses specified below. Any comment that is submitted will be shared among the Department of the Treasury, the Department of Labor, the Department of Health and Human Services (the Departments), and the Office of Personnel Management. Please do not submit duplicates.

Comments will be made available to the public. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. Comments are posted on the internet exactly as received and can be retrieved by most internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

In commenting, please refer to file code CMS–9882–P. Because of staff and resource limitations, the Departments 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 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–9882–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9882–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: Kendra May or Jeremy Rotner, Centers for Medicare and Medicaid Services, (301) 492–4293.

Elizabeth Schumacher or Sharon Aguirre, Employee Benefits Security Administration, (202) 693–8335.

Alexander Krupnick, Internal Revenue Service, Department of the Treasury, (202) 317–5500.

Individuals interested in obtaining information from the Department of Labor (DOL) concerning employment-based health coverage laws may call the Employee Benefits Security Administration (EBSA) Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the DOL’s website (www.dol.gov/agencies/ebsa). In addition, information from the Department of Health and Human Services (HHS) on private health insurance coverage and coverage provided by non-Federal governmental group health plans can be found on the Centers for Medicare & Medicaid Services (CMS) website (<http://www.cms.gov/marketplace>), information on health care reform can be found at <http://www.healthcare.gov>, and information on surprise medical bills can be found at <http://www.cms.gov/nosurprises>.

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. The Departments post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments. The Departments 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. The Departments continue to encourage individuals not to submit duplicative comments. The

Departments will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments. The Departments encourage commenters to include supporting facts, research, and evidence in their comments. When doing so, commenters are encouraged to provide citations to the materials referenced, including active hyperlinks. Likewise, commenters who reference materials that have not been published are encouraged to upload relevant data collection instruments, data sets, and detailed findings as a part of their comment. Providing such citations and documentation will assist the Departments in analyzing the 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/>.

I. Executive Summary

A. Purpose

The Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments) issued proposed requirements in the 2019 Transparency in Coverage proposed rules (2019 proposed rules)¹ and finalized the rules in 2020 (the 2020 final rules).² The rules aimed to provide consumers with price and benefit information that would enable them to better evaluate health care options and make cost-conscious decisions; reduce surprises in consumers' out-of-pocket costs for health care services; create a competitive dynamic that would begin to narrow price differences for the same services in the same health care markets; foster innovation by providing industry the information necessary to support informed, price-conscious consumers in the health care market; and, over time, potentially lower overall health care costs.³

The public disclosures made pursuant to the 2020 final rules led to the release of an enormous amount of previously hidden pricing data. However, post-implementation, the Departments continue to receive feedback from users of the machine-readable files emphasizing the need to address certain gaps in reporting and shrink file size by reducing duplication and removing unnecessary data. Since the finalization of the 2020 final rules, the Departments have also received feedback from many interested parties about the myriad ways

in which plans and issuers contract with providers for items and services that impact the usability of the data disclosed under the rules.

On February 25, 2025, President Trump issued Executive Order 14221, "Making America Healthy Again by Empowering Patients With Clear, Accurate, and Actionable Healthcare Pricing Information" (Executive Order 14221).⁴ Among other things, Executive Order 14221 directs the Departments to take all necessary and appropriate action, including issuing proposed regulatory action to promote more transparency in health care pricing information. In line with the goals of Executive Order 14221, the Departments propose several amendments to the 2020 final rules to improve the standardization, accuracy, and accessibility of pricing information.

Based on internal assessment and external feedback from interested parties, the Departments have identified three main barriers to fully achieving the goals of the 2020 final rules: inaccessibility due to the size of the machine-readable files, ambiguity regarding some of the data disclosures due to a lack of contextual information alongside the raw data, and misalignment with the "2019 Medicare and Medicaid Programs: CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates. Price Transparency Requirements for Hospitals To Make Standard Charges Public" rule⁵ (2019 Hospital Price Transparency rule) that makes comparing data across disclosures challenging.

The Departments understand that the large size of many of the required machine-readable files, particularly the in-network rate machine-readable file (In-network Rate File), is the most prominent challenge with working with the machine-readable files. Academics and researchers,⁶ data engineers,⁷ health

plans and health insurance issuers,⁸ and members of Congress⁹ have stated that these large file sizes create several problems for file users seeking to open and analyze the files, as well as for health plans and health insurance issuers reporting that amount of data. For file users, the amount of data to sift through monthly requires significant resources and time. Smaller datasets are easier to analyze and cheaper to maintain. For plans and issuers, large files have large data storage, maintenance, and bandwidth costs. The amount of data being generated monthly can also lead to increased errors in the files, making it difficult for plans and issuers to ensure they are compliant with the disclosure requirements and for file users to be confident in the integrity of the data being reported. Reducing the collective burden from large file sizes and making it easier for all users to work with the data in the machine-readable files are among the driving goals of these proposed rules.

With the 2020 final rules, the Departments expected the public disclosure of pricing information related to health care items and services to help both uninsured and insured individuals in their health care and health coverage purchasing decisions. As stated in the preamble to the 2020 final rules, research indicates that having access to pricing information can increase consumers' overall satisfaction and provide opportunities for education and engagement on health care pricing.¹⁰

Price transparency enables consumers to evaluate health care options and make cost-conscious decisions, allowing for the possibility of a competitive dynamic that may narrow price dispersion for the same items and services in the same health care markets and put downward pressure on prices and potentially lower overall health care costs.¹¹ Since the publication of the 2020 final rules, researchers have continued to analyze price transparency in health care with the benefit of access to the data provided largely by the machine-readable files.

⁴ Exec. Order No. 14221, 90 FR 11005 (February 28, 2025).

⁵ 84 FR 65524 (November 27, 2019).

⁶ Christopher Whaley, Neeraj Radhakrishnan, Michael Richards, Kosali Simon, et al., *Understanding Health Care Price Variation: Evidence from Transparency-in-Coverage Data*, 3 Health Affairs Scholar 2 (2025), <https://doi.org/10.1093/haschl/qxaf011>;

Michael E. Cherner, Sabrina Corlette, Kelly Davenport, François de Brantes, et al., *Transparency in Coverage: Recommendations for Improving Access to and Usability of Health Plan Price Data* (2022), Georgetown University, <https://georgetown.app.box.com/s/1ezsgg21c7smaexr8rht15sokgusl>.

⁷ Adam Geitgey, *A Petabyte of Health Insurance Prices per Month*, *Turquoise Health* (July 11, 2023),

<https://blog.turquoise.health/a-petabyte-of-health-insurance-rates-a-month/>.

⁸ United Health Care, *Transparency in coverage*, <https://transparency-in-coverage.uhc.com/> (last visited Dec. 8, 2025). ("Files are in a JSON format and may contain millions of lines of data and be up to 1 terabyte (TB) in size. Please consider your system's capacity and memory when downloading these files.")

⁹ Maggie Hassan & Michael Braun, *Letter to CMS Administrator Chiquita Brooks-LaSure* (Mar. 6, 2023), <https://www.hassan.senate.gov/imo/media/doc/tic.pdf>.

¹⁰ 85 FR 72158 (November 21, 2020).

¹¹ 85 FR 72158, 72159 (November 12, 2020).

¹ 84 FR 65464 (November 27, 2019).

² 85 FR 72158 (November 12, 2020).

³ 85 FR 72158, 72160 (November 12, 2020).

Some researchers have identified significant potential cost-savings across the health insurance landscape through greater use of the machine-readable file data.¹² Recent discussions extol the potential benefits of price transparency, echoing the reasons the Departments emphasized in the 2020 final rules. These include effects on the demand for health care by “guiding patients to lower-priced providers” and to the supply side by “promot[ing] price competition among providers,”¹³ as well as benefits to employers to “redesign health benefits and inform purchasing decisions.”¹⁴ One analysis emphasized a range of benefits, from “optimizing current contracts” to “increasing the accuracy of performance assumptions, market analysis, and strategic value.”¹⁵ Early analyses of the potential financial and economic impacts of the 2020 final rules show promise for fulfilling the goals the Departments articulated in the 2020 final rules of “facilitating a market-driven health care system by giving consumers of health care services data that will enable consumers to make fully informed, cost-conscious decisions when choosing health care.”¹⁶

While the machine-readable file requirements of the 2020 final rules and the 2019 Hospital Price Transparency rule do not require the exact same disclosures, they have similar goals and some overlapping data. Therefore, it can be useful to review studies of hospital machine-readable files for lessons learned and outcomes that may translate to the plan and issuer machine-readable file disclosures. One study using hospital data found that “choosing plans from the largest insurer in the local market is more likely to result in

lower negotiated rates than from other plans,” which can lead to reduced costs for the “growing number of self-insured employers engaged in direct contracts with hospitals.”¹⁷ One county government used hospital data in this manner to reduce its health costs by over 40 percent.¹⁸ Tools allowing comparison of the hospital data recently began populating the internet. The Departments are also aware of app developers conducting similar analyses of the data from plan and issuer disclosures and offering them to consumers (both individuals and employers). The Departments expect that continued analyses and development of consumer-facing tools and services will result in similar savings opportunities achieved from studying the hospital machine-readable files.

However, the success of these analyses and the effectiveness of consumer-facing tools depend on the usability of the machine-readable files. Large file sizes, lack of clarity, and data of limited use hamper efforts to build tools that can be brought to market. These proposed changes, if finalized, would contribute to making the files easier to digest and analyze, reduce challenges for existing tool developers, and open the market to additional tool and app developers.

The Departments seek to address the limitations of the machine-readable files through these proposed rules as well as through updates to the machine-readable file form and manner requirements as detailed in technical implementation guidance. As a first step towards addressing these limitations, on May 22, 2025, the Departments announced in FAQs Part 70 the intention to release schema version 2.0 (Schema 2.0), which will implement revised technical requirements for the In-network Rate File and out-of-network allowed amounts and billed charges machine-readable file (Allowed Amount File).¹⁹ However, the Departments also

recognize that more substantive requirements are needed to clarify the data being published and to give users more confidence in the data. Feedback from interested parties demonstrates that, while the raw data from the machine-readable files presents valuable information and opportunities for analysis, additional contextual information is needed to supplement the in-network rates and out-of-network allowed amounts and billed charges disclosed in the machine-readable files. Additional contextual information would allow users to understand changes in pricing over time, promote more accurate reporting, and make pricing information more meaningful and accessible overall. Therefore, the Departments are issuing these proposed rules as a next step to addressing these concerns.

The disclosure requirements under the Transparency in Coverage rules represent just one prong in a multipronged approach to promote greater transparency and understanding of costs and pricing in the health care and the health insurance market. The 2020 final rules must be viewed within the context of other regulatory and statutory changes, such as the Hospital Price Transparency initiative, as well as Title I of Division BB of the Consolidated Appropriations Act, 2021 (CAA), also known as the No Surprises Act, and its consumer protections against surprise billing, its requirements for a good faith estimate, advanced explanation of benefits, and more accurate provider directories. With respect to the Hospital Price Transparency and the Transparency in Coverage initiatives in particular, section 3(b) of Executive Order 14221 instructed the Departments to “issue updated guidance or proposed regulatory action ensuring pricing information is standardized and easily comparable across hospitals and health plans.”²⁰ The Departments received encouraging feedback that “commercial prices disclosed in the TiC [Transparency in Coverage] data are mostly comparable to those disclosed by hospitals in compliance with the hospital price transparency rule and to Marketscan [sic] claims data.”²¹

¹² Stephen T. Parente, *Estimating the Impact of New Health Price Transparency Policies*, 60 The Journal of Health Care Organization, Provision, and Financing (Feb. 17, 2023);

David N. Bernstein & John R. Crowe, *Price Transparency in United States' Health Care: A Narrative Policy Review of the Current State and Way Forward*, 61 Inquiry (2024).

¹³ Juan Carvajal, Christopher Ody, & Christopher Whaley, *The Relationship Between Pricing Transparency and Price Competition in the US Health Care Industry* (Nov. 5, 2024), https://www.analysisgroup.com/globalassets/insights/publishing/2024_aba_article_relationship_between_pricing_transparency.pdf.

¹⁴ Christopher Whaley & Austin Frakt, *If Patients Don't Use Available Health Service Pricing Information, Is Transparency Still Important?*, 24 AMA Journal of Ethics 995 (Nov. 2022).

¹⁵ Sarun Charumilind, Shubham Singhal, Oleg Bestsenny, Erica Coe, et al., *How Price Transparency Could Affect US Healthcare Markets*, McKinsey (Apr. 2, 2024), <https://www.mckinsey.com/industries/healthcare/our-insights/how-price-transparency-could-affect-us-healthcare-markets>.

¹⁶ 85 FR 72158, 72171 (November 12, 2020).

¹⁷ Yang Wang, Michael E. Chernen, Leemore S. Dafny, Maximilian J. Pany, et al., *Do Insurers with Greater Market Power Negotiate Consistently Lower Prices for Hospital Care? Evidence From Hospital Price Transparency Data*, 29 Medical Care Research & Review (Aug. 18, 2023).

¹⁸ Sara Hansard, *One County Combed Hospital Data to Slash Health Plan Costs 43 Percent* (Feb. 6, 2023), Bloomberg, <https://news.bloomberglaw.com/health-law-and-business/employer-health-plan-eyes-43-savings-from-payment-data-audits>.

¹⁹ U.S. Department of Labor, U.S. Department of Health & Human Services & U.S. Department of the Treasury, *Frequently Asked Questions About Affordable Care Act Implementation Part 70* (May 22, 2025), <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-70>.

²⁰ Exec. Order No. 14221, 90 FR 11005, 11006 (February 28, 2025).

²¹ Yang Wang, Michael Meiselbach, Gerard Anderson & Ge Bai, *Hospital Pricing Information Consistent Between Transparency-In-Coverage Data and Other Commercial Data Sources*, 42 Health Affairs (2023), <https://www.healthaffairs.org/content/forefront/hospital-pricing-information-consistent-between-transparency-coverage-data-and-other>. Information on MarketScan data can be found at <https://www.merative.com/documents/merative-marketscan-research-databases>.

However, other interested parties have noted that, despite the consistency of the raw data across hospital and plan and issuer machine-readable files, there are other challenges in comparing the information between the two sets of machine-readable files.²² Therefore, the Departments intend in these proposed rules, along with Schema 2.0, to help align the Hospital Price Transparency reporting requirements and the 2020 final rules, as well as to fulfill the directive under Executive Order 14221.

Additionally, to better inform a response to Executive Order 14221, on June 2, 2025, the Departments published a Request for Information (RFI) seeking the public's input on ways to effectively implement or amend the prescription drug machine-readable file requirement in the 2020 final rules.²³

Building off of the 2020 final rules, the Departments propose these rules pursuant to the authority under Section 2715A of the Public Health Service (PHS) Act, incorporated into section 715 of the Employee Retirement Income Security Act (ERISA) and section 9815 of the Internal Revenue Code (Code), which provide that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage must comply with section 1311(e)(3) of the Patient Protection and Affordable Care Act (Affordable Care Act). This section of the Affordable Care Act addresses transparency in health coverage and imposes certain reporting and disclosure requirements on health plans that are seeking certification as qualified health plans (QHPs) that may be offered on an Exchange (as defined by section 1311(b)(1) of the Affordable Care Act).

The Departments also propose these rules pursuant to the authority under the No Surprises Act, which amended chapter 100 of the Code, Part 7 of ERISA, and title XXVII of the PHS Act. Among other protections, the No Surprises Act provides Federal protections against surprise billing by limiting out-of-network cost sharing and prohibiting balance billing in many of the circumstances in which surprise bills most frequently arise. Section 114 of the No Surprises Act added Code section 9819, ERISA section 719, and

PHS Act section 2799A–4, which require plans and issuers to offer price comparison guidance by telephone and make a “price comparison tool” available on the plan’s or issuer’s website.

B. Summary of the Major Provisions

1. Transparency in Coverage—Definitions

The 2020 final rules include definitions at 26 CFR 54.9815–2715A1(a)(2); 29 CFR 2590.715–2715A1(a)(2); and 45 CFR 147.210(a)(2). These proposed rules, if finalized, would add a definition of the term health insurance market for purposes of amendments to 26 CFR 54.9815–2715A3(b)(1)(ii), 29 CFR 2590.715–2715A3(b)(1)(ii), and 45 CFR 147.212(b)(1)(ii) that would require group health plans and health insurance issuers offering group or individual health insurance coverage to make an out-of-network allowed amount machine-readable file available for each health insurance market in which the plan or issuer offers a plan or coverage. Under 26 CFR 54.9815–2715A1 and 45 CFR 147.210, the Departments propose to redesignate paragraphs (a)(2)(xi) through (xxii) as paragraphs (a)(2)(xii) through (xxiii), respectively, and add a new paragraph (a)(2)(xi) with the new definition. Under 29 CFR 2590.715–2715A1, the Departments propose to redesignate paragraphs (a)(2)(x) through (xxi) as paragraphs (a)(2)(xi) through (xxii) and add a new paragraph (a)(2)(x) with the new definition.

2. Transparency in Coverage—Required Disclosures to Participants, Beneficiaries, or Enrollees

The 2020 final rules at 26 CFR 54.9815–2715A2; 29 CFR 2590.715–2715A2; and 45 CFR 147.211 require non-grandfathered group health plans and health insurance issuers offering non-grandfathered coverage in the group and individual markets to make cost-sharing information available to participants, beneficiaries, and enrollees through an internet-based self-service tool (self-service tool), and in paper form, upon request.

The Departments propose to amend paragraph (b)(1)(vii)(A) of this section to require the disclaimer, described in that paragraph, to state that the cost-sharing information does not account for potential additional amounts in situations where applicable State and Federal law allow out-of-network providers to balance bill participants, beneficiaries, and enrollees. This proposed amendment reflects the existence of the Federal balance billing

protections set forth in the No Surprises Act, which was not in effect when (b)(1)(vii)(A) was finalized in the 2020 final rules. The Departments also propose to clarify that the disclaimer is not required if the State in which the item or service was furnished prohibits all out-of-network providers from balance billing for all items and services payable by the plan or issuer.

In addition, the Departments propose to add a new paragraph at (b)(2)(iii) under this section to require plans and issuers to make available to participants, beneficiaries, and enrollees the cost-sharing estimates and other disclosures required under paragraph (b)(1) via a telephone number to implement requirements under section 9819 of the Code, section 719 of ERISA, and PHS Act Section 2799A–4, as added by section 114 of the No Surprises Act.²⁴ The Departments propose to require a telephone number through which a consumer may seek customer assistance which would be required to be the same number that Code section 9816(e), ERISA section 716(e), and PHS Act section 2799A–1(e), as added by section 107 of the No Surprises Act requires be indicated on any physical or electronic plan or insurance identification card issued to a participant, beneficiary, or enrollee. The Departments also propose to redesignate paragraph (b)(2)(ii)(D) as new paragraph (b)(2)(iv) and amend redesignated paragraph (b)(2)(iv) to remove phone as an alternative means by which a participant, beneficiary, or enrollee can request the disclosures required under paragraph (b)(1).

The Departments also propose to add a new paragraph (c)(7) stating that plans and issuers satisfy the requirements set forth in Code section 9819, ERISA section 719, and PHS Act section 2799A–4 regarding the price comparison tool by providing the information to participants, beneficiaries, and enrollees set forth in paragraph (b)(1) as amended in accordance with the method and format requirements set forth in paragraph (b)(2), as amended.²⁵

²⁴ 42 U.S.C. 300gg–111(e)(3); 29 U.S.C. 1185e(e)(3); 26 U.S.C. 9819. U.S. Department of Labor, U.S. Department of Health & Human Services & U.S. Department of the Treasury, *FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49* (August 20, 2021), <https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/downloads/faqs-part-49.pdf> and <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf>.

²⁵ While PHS Act section 2715A does not apply to grandfathered health plans and health insurance issuers offering grandfathered individual and group health insurance coverage, section 9819 of the Code, section 719 of ERISA, and section 2799A–4

²² Nikki Tong, *Price Transparency Proposal Leaves Room for Improvement, Experts Say*, *Fierce Healthcare* (Aug. 1, 2023), <https://www.fiercehealthcare.com/providers/price-transparency-proposal-leaves-room-improvement>; Jing Jiang, Mengqi Jiang & Ge Bai, *Enforcing Hospital Price Transparency: Lessons from CMS Actions*, *Health Affairs Forefront* (Dec. 3, 2024), <https://www.healthaffairs.org/content/forefront/enforcing-hospital-price-transparency-lessons-cms-actions>.

²³ 90 FR 23303 (June 2, 2025).

3. Transparency in Coverage— Requirements for Public Disclosure

The Transparency in Coverage final rules at 26 CFR 54.9815–2715A3; 29 CFR 2590.715–2715A3; and 45 CFR 147.212 require non-grandfathered group health plans and health insurance issuers offering non-grandfathered group and individual health insurance coverage to disclose on a public website, in the format of machine-readable files, information regarding in-network provider rates for covered items and services, out-of-network allowed amounts and billed charges for covered items and services, and negotiated rates and historical net prices for covered prescription drugs.

The Departments propose a number of amendments that would apply to the disclosure of information required under paragraphs (b)(1) and (b)(2). First, the Departments propose to amend the introductory paragraph of (b) to reference new requirements for the public disclosure of contextual information and to redesignate paragraphs (b)(2) through (b)(3) as paragraphs (b)(3) through (b)(4), respectively, and add a new paragraph (b)(2) describing the proposed contextual information disclosure requirements for the In-network Rate File. The Departments also propose to add two new paragraphs, (b)(2)(iv) and (b)(3)(iii), to help users more easily locate the public disclosures made pursuant to these proposed rules by requiring plans and issuers to post a plain text file in a .txt format (Text File) in the root folder of the plan or issuer's website and a specific internet domain as a link in the footer on the home page of the plan's or issuer's website. The Departments are also considering a standardized file format for all machine-readable files. The Departments also propose to amend the required information at redesignated paragraph (b)(1)(i)(B) and paragraph (b)(1)(ii)(A) to remove the requirement to report a specific number of digits of the Health Insurance Oversight System (HIOS) identifier (ID) that are required for each coverage option and to add a requirement to disclose the product type associated with the plan or policy in the In-network Rate Files and the Allowed Amount Files. The Departments also propose to amend the special rules to prevent unnecessary duplication in current paragraph (b)(4) by redesignating paragraph (b)(4)(i) as paragraph (b)(5)(i), redesignating paragraph (b)(4)(ii) as paragraph

(b)(5)(ii), redesignating paragraph (b)(4)(iii) as paragraph (b)(5)(iv), and adding paragraph (b)(5)(iii). In new paragraph (b)(5)(iii), the Departments propose to permit self-insured group health plans under certain circumstances to allow another party, such as a service provider, with which they have an agreement as described in paragraph (b)(5)(ii), to make available in a single In-network Rate File as required under paragraph (b)(1)(i), the information required under paragraph (b)(1)(i) for more than one plan, insurance policy, or contract (including those offered by different plan sponsors with which the other party has an agreement) and across different health insurance markets. The Departments also propose to amend newly redesignated paragraph (b)(5)(iv) to permit self-insured group health plans under certain circumstances to allow another party with which they have an agreement to aggregate the Allowed Amount Files required under paragraph (b)(1)(ii) for more than one self-insured group health plan, including those offered by different plan sponsors.

Finally, the Departments propose to amend newly redesignated paragraph (b)(4) by adding new paragraphs to specify the timing requirements for each machine-readable file required as proposed under these rules. As related to the public disclosures generally, proposed paragraph (b)(4)(i) would amend the required reporting frequency for the In-network Rate and Allowed Amount Files under paragraphs (b)(1)(i) and (b)(1)(ii) from monthly to quarterly but would not propose any changes to the monthly reporting frequency for the prescription drug file required under paragraph (b)(1)(iii). Newly redesignated paragraph (b)(4)(vi) proposes to require the Text File proposed under new paragraph (b)(2)(iv) to be posted beginning on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1) and updated and posted as soon as practicable but no later than 7 calendar days following a change in any of the information required under redesignated paragraph (b)(2)(iv).

The amendments contained in these proposed rules generally modify requirements related to the In-network Rate Files and the Allowed Amount Files. However, several proposed amendments would amend requirements related to the prescription drug machine-readable files, specifically: the requirement that plans and issuers must include a Text File in the root folder of a plan's or issuer's website as described in proposed paragraphs (b)(2)(iv) (section III.C.7.d. of

this preamble) and the requirements related to the method and format for disclosing information to the public as described in proposed redesignated paragraph (b)(3) (section III.C.9. of this preamble). The Departments note in each applicable section when a proposal would modify requirements related to the prescription drug machine-readable files.

4. Public Disclosure of In-Network Rates

With respect to the disclosure of in-network rates specifically, to reduce duplicate in-network rate data, the Departments propose to amend 26 CFR 54.9815–2715A3(b)(1)(i), 29 CFR 2590.715–2715A3(b)(1)(i), and 45 CFR 147.212(b)(1)(i) to require plans and issuers to make an In-network Rate File available for each provider network maintained or contracted by the plan or issuer. As part of this proposal, the Departments propose to redesignate paragraphs (b)(1)(i)(A) through (C) as paragraphs (b)(1)(i)(B) through (D), respectively, and add a new paragraph (b)(1)(i)(A) requiring each In-network Rate File to include the common provider network name for which negotiated rate information is included in that file.

The Departments also propose to amend redesignated paragraph (b)(1)(i)(D)(1) to require in-network rates to be reflected as a dollar amount except for contractual arrangements under which plans and issuers agree to pay an in-network provider a percentage of billed charges and are not able to assign a dollar amount to an item or service prior to a bill being generated. The Departments also propose to add new paragraph (b)(1)(i)(E), requiring each In-network Rate File to include current enrollment totals, as of the date the file is posted, for each plan or coverage option offered by a plan or issuer that uses that file's provider network.

The Departments also propose in new paragraph (b)(1)(i)(F) to require plans and issuers to exclude any provider and their negotiated rate (provider-rate combination) for an item or service, if the provider is unlikely to be reimbursed for the item or service given that provider's area of specialty, according to the plan's or issuer's internal provider taxonomy used during the claims adjudication process. The Departments also propose to amend newly redesignated paragraph (b)(1)(i)(D)(2) to account for this proposed required exclusion.

The Departments also propose to require plans and issuers to post several contextual machine-readable files under new paragraph (b)(2) that would help file users better understand the public

of the PHS Act do apply to grandfathered health plans and issuers offering grandfathered health insurance coverage.

disclosures required in the In-network Rate Files under paragraph (b)(1)(i). This proposal would mean plans and issuers would be required to prepare new contextual files for each In-network Rate File prepared pursuant to these proposed rules. In particular, the Departments propose to require a change-log file (“Change-log File”) at new paragraph (b)(2)(i), which would identify any changes made to the required information described in paragraph (b)(1)(i) in the In-network Rate File since the last posted In-network Rate File.

The Departments also propose to require a utilization file (“Utilization File”) at new paragraph (b)(2)(ii), which would document, for the 12-month period that ends 6 months prior to the publication date of each Utilization File, all items and services covered under the plans or policies represented in the In-network Rate File prepared pursuant to proposed amended paragraph (b)(1)(i) for which a claim has been submitted and reimbursed. The Utilization File would also include each in-network provider identified by the National Provider Identifier (NPI), Tax Identification Number (TIN), and Place of Service Code who was reimbursed, in whole or in part, for a claim for each covered item or service included in such file.

The Departments also propose to require plans and issuers to publish a taxonomy file (“Taxonomy File”) at new paragraph (b)(2)(iii) which would include their internal provider taxonomy that matches items and services (represented by a billing code) with provider specialties (represented by specialty codes that are derived from the Health Care Provider Taxonomy²⁶ code set established by the National Uniform Claim Committee (NUCC)) to determine if the plan or issuer should deny reimbursement for an item or service because it was not furnished by a provider in an appropriate specialty.

Finally, the Departments propose to add timing requirements for the proposed new contextual files under redesignated paragraph (b)(4). With respect to the contextual files that related to the In-network Rate Files

under paragraph (b)(1)(i), under proposed paragraph (b)(4)(iii), the Change-log File proposed at paragraph (b)(2)(i) would be required to be posted beginning on the first day of the calendar-year quarter following the date on which the first In-network Rate File is required to be posted under paragraph (b)(4)(i), and updated and posted quarterly whether or not there are changes to that file since it was last posted. Under proposed paragraph (b)(4)(iv), the Utilization File proposed at paragraph (b)(2)(ii) would be required to be posted beginning on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1) and updated annually after the initial posting. Lastly, under proposed paragraph (b)(4)(v), the Taxonomy File proposed at paragraph (b)(2)(iii) would be required to be posted beginning on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1) and updated and posted quarterly if changes to the internal provider taxonomy impact the information required in the machine-readable file required under paragraph (b)(1)(i).

5. Public Disclosure of Out-of-Network Allowed Amounts

The Departments propose to make several amendments to 26 CFR 54.9815–2715A3(b)(1)(ii), 29 CFR 2590.715–2715A3(b)(1)(ii), and 45 CFR 147.212(b)(1)(ii) to increase the amount of historical claims data available in the Allowed Amount Files. These amendments would require plans and issuers to report out-of-network allowed amounts and billed charges at the health insurance market level, rather than the plan or policy level, lower the threshold for including claims in the Allowed Amount File from 20 to 11 different claims per item or service, and increase the reporting period from 90 days to 6 months and the lookback period from 180 days to 9 months.

6. Severability

The 2020 final rules included severability clauses to emphasize the Departments’ intent that, to the extent a reviewing court holds that any provision of the final rules is unlawful, the remaining rules should take effect and be given the maximum effect permitted by law. The 2020 final rules provide that any provision held to be

invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from the relevant section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances. The Departments are not modifying this language in the 2020 final rules and clarify that these clauses continue to apply and would extend to the amendments proposed in these rules, if finalized.

7. Technical Amendments

The Departments propose a series of technical amendments to the way group health plans and health insurance issuers offering group or individual health insurance coverage are referenced in 26 CFR 54.9815–2715A2 and 54.9815–2715A3, 29 CFR 2590.715–2715A2 and 2590.715–2715A3, and 45 CFR 147.211 and 147.212. In the 2020 final rules, the Departments generally adopted the convention of referring to those entities using the terms “group health plan” and “health insurance issuer” throughout the regulations, except that where the Departments refer to those entities more than once in the same paragraph, the terms “plan” and “issuer” are used after the initial instance. However, that convention was not applied evenly.

Therefore, in the internet-based self-service tool disclosure requirements in 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211, the Departments propose technical amendments to paragraphs (b)(1)(i)(A), (b)(1)(i)(B), (b)(2)(ii), (b)(3)(i), and (b)(3)(ii) that would bring the terms used to describe those entities in line with that convention. In the machine-readable file disclosure requirements in 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212, the Departments propose amendments to redesignated paragraph (b)(1)(i)(D), (b)(5)(i), and (b)(5)(ii) that would bring the terms used to describe those entities in line with that convention. These paragraphs are otherwise unchanged. These proposed changes are technical in nature and would not affect the rights or obligations of any plan, issuer, or other entity.

C. Summary of Costs and Benefits

²⁶ National Uniform Claim Committee, *Health Care Provider Taxonomy*, <https://www.nucc.org/index.php/code-sets-mainmenu-41/provider-taxonomy-mainmenu-40> (last visited Dec. 8, 2025).

TABLE 1a: Summary of Annual Costs

Provision Description	Annual Cost (\$)
Information Collection Requests (ICRs) Regarding Requirements for Disclosures to Participants, Beneficiaries, or Enrollees Under 26 CFR 54.9815-2715A2, 29 CFR 2590.715-2715A2, and 45 CFR 147.211*	\$52,000,000
ICRs Regarding Requirements to Implement the Disclosures Required for the Utilization File (26 CFR 54.9815-2715A3(b)(2)(ii), 29 CFR 2590.715-2715A3(b)(2)(ii), and 45 CFR 147.212(b)(2)(ii))	\$9,186,120
ICRs Regarding Requirements to Respond to Machine-Readable File Inquiries (26 CFR 54.9815-2715A3(b)(2)(iv), 29 CFR 2590.715-2715A3(b)(2)(iv), and 45 CFR 147.212(b)(2)(iv))	\$7,015,200
Total	\$68,201,320

* High-end 3-year estimated values are represented in the table and used to determine the overall estimated 3-year average.

TABLE 1b: Summary of One-time Costs

Provision Description	Total Cost (\$)
ICRs Regarding Requirements to Update Cost-Sharing Disclosure Reflecting Federal Balance Billing Protections (26 CFR 54.9815-2715A2, 29 CFR 2590.715-2715A2, and 45 CFR 147.211)	\$37,657
To Train Customer Service Representatives and Supervisors to Provide Cost-Sharing Information for ICRs Regarding Requirements for Disclosures to Participants, Beneficiaries, or Enrollees to Provide Pricing Information via Phone (26 CFR 54.9815-2715A2, 29 CFR 2590.715-2715A2, and 45 CFR 147.211*)	\$13,727,040
ICRs Regarding Requirements to Organize Files by Provider Network, Allow Service Providers or Other Parties to Organize by Provider Network across Multiple Self-insured Group Health Plans (26 CFR 54.9815-2715A3(b)(1)(i) and (b)(5)(iii), 29 CFR 2590.715-2715A3(b)(1)(i) and (b)(5)(iii), and 45 CFR 147.212(b)(1)(i) and (b)(5)(iii))	\$43,810,240
ICRs Regarding Requirements to Include Product Type in Both In-network Rate and Allowed Amount Files (26 CFR 54.9815-2715A3(b)(1)(i)(B) and (b)(1)(ii)(A), 29 CFR 2590.715-2715A3(b)(1)(i)(B), and (b)(1)(ii)(A), and 45 CFR 147.212(b)(1)(i)(B) and (b)(1)(ii)(A))	\$7,141,600
ICRs Regarding Requirements to Report Dollar Amounts Except for Only “Percentage-of-Billed Charges” Payments (26 CFR 54.9815-2715A3(b)(1)(i)(D)(I), 29 CFR 2590.715-2715A3(b)(1)(i)(D)(I), and 45 CFR 147.212(b)(1)(i)(D)(I)) *	\$7,141,600
ICRs Regarding Requirements to Report Required Enrollment Data (26 CFR 54.9815-2715A3(b)(1)(i)(E), 29 CFR 2590.715-2715A3(b)(1)(i)(E), and 45 CFR 147.212(b)(1)(i)(E))	\$7,141,600
ICRs Regarding Requirements to Exclude Certain Providers from In-network Rate Files (26 CFR 54.9815-2715A3(b)(1)(i)(F), 29 CFR 2590.715-2715A3(b)(1)(i)(F) and 45 CFR 147.212(b)(1)(i)(F))	\$42,849,600
ICRs Regarding Requirements to Aggregate Allowed Amount Files by Market Type and Allow Service Providers or Other Parties to Aggregate by Market Type across Multiple Self-insured Group Health Plans (26 CFR 54.9815-2715A3(b)(1)(ii), 29 CFR 2590.715-2715A3(b)(1)(ii), and 45 CFR 147.212(b)(1)(ii) and Permit Such Aggregation at the Third-Party Administrator (TPA) Level (26 CFR 54.9815-2715A3(b)(5)(iv), 29 CFR 2590.715-2715A3(b)(5)(iv), and 45 CFR 147.212(b)(5)(iv))	\$14,283,200
ICRs Regarding Requirements to Add a Change-log File Related to the In-network Rate File Disclosures (26 CFR 54.9815-2715A3(b)(2)(i), 29 CFR 2590.715-2715A3(b)(2)(i), and 45 CFR 147.212(b)(2)(i))	\$133,361,480
ICRs Regarding Requirements to Implement the Utilization File (26 CFR 54.9815-2715A3(b)(2)(ii), 29 CFR 2590.715-2715A3(b)(2)(ii), and 45 CFR 147.212(b)(2)(ii))	\$638,958,320
ICRs Regarding Requirements to Add a Text File and Identify Point-of-Contact for Inquiries to Improve Discoverability and Accessibility of Machine-Readable Files (26 CFR 54.9815-2715A3(b)(2)(iv), 29 CFR 2590.715-2715A3(b)(2)(iv), and 45 CFR 147.212(b)(2)(iv))	\$5,258,240
Total	\$913,710,577

* High-end 3-year estimated values are represented in the table and used to determine the overall estimated 3-year average.

TABLE 1c: Summary of Annual Benefits

Provision Description	Annual Benefits (\$)
For third-party developers and other file users: ICRs Regarding (1) Requirements to Reduce Data Cleaning Computational Costs (26 CFR 54.9815-2715A3(b)(1)(i)(F), 29 CFR 2590.715-2715A3(b)(1)(i)(F) and 45 CFR 147.212(b)(1)(i)(F)), and (2) Changing Timing Requirements for Machine-Readable Files Reporting from Monthly to Quarterly (26 CFR 54.9815-2715A3(b)(4), 29 CFR 2590.715-2715A3(b)(4), and 45 CFR 147.212(b)(4))	\$11,162,400
For plans, issuers, third-party developers, and other file users: ICRs Regarding (1) Requirements to Reduce Storage Costs (26 CFR 54.9815-2715A3(b)(1)(i)(F), 29 CFR 2590.715-2715A3(b)(1)(i)(F) and 45 CFR 147.212(b)(1)(i)(F)), and (2) Changing Timing Requirements for Machine-Readable Files Reporting from Monthly to Quarterly (26 CFR 54.9815-2715A3(b)(4), 29 CFR 2590.715-2715A3(b)(4), and 45 CFR 147.212(b)(4))	\$73,317,600
For plans and issuers: ICRs Regarding (1) Requirements to Reduce Network Egress Costs (26 CFR 54.9815-2715A3(b)(1)(i)(F), 29 CFR 2590.715-2715A3(b)(1)(i)(F) and 45 CFR 147.212(b)(1)(i)(F)), and (2) Changing Timing Requirements for Machine-Readable Files Reporting from Monthly to Quarterly (26 CFR 54.9815-2715A3(b)(4), 29 CFR 2590.715-2715A3(b)(4), and 45 CFR 147.212(b)(4))	\$171,126,000
For third-party developers and other file users: ICRs Regarding Requirements to Reduce Time Locating Files by Requiring a Text File and Footer Links to Quickly Find Machine-Readable Files (26 CFR 54.9815-2715A2(b)(2)(iv) and (b)(3)(iii), 29 CFR 2590.715-2715A2(b)(2)(iv) and (b)(3)(iii), and 45 CFR 147.212(b)(2)(iv) and (b)(3)(iii))	\$1,440,000
Total	\$257,046,000

II. Background

A. Executive Orders

On June 24, 2019, President Trump issued Executive Order 13877, “Improving Price and Quality Transparency in American Healthcare to Put Patients First.”²⁷ Executive Order 13877 sought to improve transparency in health care and empower patients to make fully informed decisions about their health care. As Executive Order 13877 noted, “patients often lack both access to useful price and quality information and the incentives to find low-cost, high-quality care.” The lack of this information is widely understood to be one of the root problems causing dysfunction within America’s health care system, “generally leav[ing] patients and taxpayers worse off than would a more transparent system.”

Executive Order 13877 directed the Departments to take action that would combat this issue by making meaningful price and quality information more broadly available to more Americans, thereby increasing competition, innovation, and value in the health care system. Specifically, section 3(b) of Executive Order 13877 directed the Secretaries of the Departments to issue

an advance notice of proposed rulemaking, consistent with applicable law, soliciting comment on a proposal to require health care providers, health insurance issuers, and self-insured group health plans to provide or facilitate access to information about expected out-of-pocket costs for items or services to patients before they receive care.

To fulfill their responsibility under Executive Order 13877, the Departments proposed²⁸ and subsequently finalized the Transparency in Coverage rules in the 2020 final rules.²⁹ The 2020 final rules published by the Departments on November 12, 2020, implemented section 2715A of the PHS Act, which requires group health plans and health insurance issuers offering group or individual health insurance coverage to comply with section 1311(e)(3) of the Affordable Care Act. As described more fully elsewhere in this preamble, these provisions address transparency in health coverage and require plans and issuers to make certain information available to the public.

On February 25, 2025, President Trump issued Executive Order 14221,³⁰

“Making America Healthy Again by Empowering Patients With Clear, Accurate, and Actionable Healthcare Pricing Information.” Executive Order 14221 stated that “[m]aking America healthy again will require empowering individuals with the best information possible to inform their life and healthcare choices” with the goal to “make more meaningful price information available to patients to support a more competitive, innovative, affordable, and higher quality healthcare system.” To that end, the Executive Order directs the Departments to “promote universal access to clear and accurate healthcare prices[;] . . . to improve existing price transparency requirements; increase enforcement of price transparency requirements; and identify opportunities to further empower patients with meaningful price information, potentially including through the expansion of existing price transparency requirements.”³¹

Section 3 of Executive Order 14221 directs the Secretaries of the Departments to rapidly implement and enforce the health care price transparency regulations issued pursuant to Executive Order 13877,³²

²⁷ Exec. Order No. 13877, 84 FR 30849 (June 27, 2019).

²⁸ 84 FR 65464 (November 27, 2019).

²⁹ 85 FR 72158 (November 12, 2020).

³⁰ Exec. Order No. 14221, 90 FR 11005 (February 28, 2025).

³¹ *Id.*

³² Exec. Order No. 13877, 84 FR 30849 (June 27, 2019).

including action to: “(a) require the disclosure of the actual prices of items and services, not estimates; (b) issue updated guidance or proposed regulatory action ensuring pricing information is standardized and easily comparable across hospitals and health plans; and (c) issue guidance or proposed regulatory action updating enforcement policies designed to ensure compliance with the transparent reporting of complete, accurate, and meaningful data.”³³ In line with these directives, the Departments are publishing these proposed rules with amendments to the regulations issued under the 2020 final rules.³⁴

B. Statutory Background and Enactment of the Affordable Care Act and the No Surprises Act

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) was enacted on March 30, 2010 (collectively the Affordable Care Act). As relevant here, the Affordable Care Act reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to health coverage requirements for group health plans and health insurance issuers. The term group health plan includes both insured and self-insured group health plans.

The Affordable Care Act also added section 715 to ERISA and section 9815 to the Code to incorporate the provisions of part A of title XXVII of the PHS Act, PHS Act sections 2701 through 2728, into ERISA and the Code, making them applicable to group health plans and health insurance issuers providing coverage in connection with group health plans.

Section 2715A of the PHS Act, incorporated into section 715 of ERISA and section 9815 of the Code, provides that plans and issuers must comply with section 1311(e)(3) of the Affordable Care Act, which addresses transparency in health coverage and imposes certain reporting and disclosure requirements for health plans that are seeking certification as QHPs that may be offered on an Exchange. A plan or coverage that is not offered through an Exchange (as defined by section 1311(b)(1) of the Affordable Care Act) is required to submit the information required to the relevant Secretary and the relevant State’s insurance commissioner, and to make that information available to the public.

The 2020 final rules require non-grandfathered health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to disclose cost-sharing information for all covered items and services to participants, beneficiaries, and enrollees through an internet-based self-service tool or, if requested by the individual, on paper. These provisions of the 2020 final rules implement paragraph (C) of section 1311(e)(3) of the Affordable Care Act.

The 2020 final rules also require non-grandfathered plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to disclose on a public website three separate machine-readable files containing certain information regarding health care pricing under the plan or coverage. The machine-readable file disclosure requirements are intended to make health care pricing information accessible and useful to consumers and other interested parties (including employers, and other purchasers of health care),³⁵ support efforts to lower health care costs by driving competition,³⁶ and to supplement State transparency efforts.³⁷ These provisions of the 2020 final rules requiring plans and issuers to disclose in-network negotiated rates, out-of-network allowed amounts and the associated billed charges, and negotiated rates and historical net prices for prescription drugs implement paragraph (A) of section 1311(e)(3) of the Affordable Care Act. In particular, the provisions requiring the disclosure of out-of-network allowed amounts specifically implement the requirement in section 1311(e)(3)(A)(vii) of the Affordable Care Act to provide information on “payments with respect to any out-of-network coverage.” In addition, the Secretary of HHS determined that requiring disclosure of payment information on in-network rates and prescription drugs is appropriate under section 1311(e)(3)(A)(ix) of the Affordable Care Act.

The No Surprises Act added new provisions applicable to plans and issuers in Subchapter B of chapter 100 of the Code, Part 7 of ERISA, and Parts D and E of title XXVII of the PHS Act. As relevant here, the No Surprises Act added new sections 9816(a)–(b) and 9817(a) of the Code, sections 716(a)–(b) and 717(a) of ERISA, and sections 2799A–1, 2799A–2, 2799B–1, 2799B–2, 2799B–3, and 2799B–5 of the PHS Act,

which protect participants, beneficiaries, and enrollees in group health plans and group and individual health insurance coverage from balance bills by prohibiting nonparticipating providers, facilities, and providers of air ambulance services from billing or holding liable individuals for an amount that exceeds in-network cost sharing determined in accordance with the No Surprises Act’s cost-sharing limitations in circumstances where the cost-sharing limitations apply. The No Surprises Act also added new section 9816(e) of the Code, section 716(e) of ERISA, and sections 2799A–1(e) of the PHS Act, which contain requirements for applicable group health plans or issuers to include certain information, in clear writing, on any physical or electronic plan or insurance identification card issued to the participants or beneficiaries in the plan or coverage. This information includes any deductible applicable to such plan or coverage, any out-of-pocket maximum limitation applicable to such plan or coverage, and a telephone number and internet website address through which such individual may seek consumer assistance information.

Further, section 114 of the No Surprises Act added section 2799A–4 of the PHS Act, section 9819 of the Code, and section 719 of ERISA, which require plans and issuers to: offer price comparison guidance by telephone and make available on the internet website of the plan or issuer a price comparison tool that (to the extent practicable) allows an individual enrolled under such plan or coverage, with respect to such plan year, such geographic region, and participating providers with respect to such plan or coverage, to compare the amount of cost sharing that the individual would be responsible for paying under such plan or coverage with respect to the furnishing of a specific item or service by any such provider.

C. Statutory Background for Enforcement With Regards to the Affordable Care Act and the CAA of 2021

The enforcement responsibilities of HHS and the States with respect to oversight of health insurance issuer compliance with the Federal insurance market reforms are set forth in the PHS Act. Pursuant to section 2723(a)(1) of the PHS Act, as amended by the No Surprises Act, states have primary enforcement authority over health insurance issuers regarding the provisions of Parts A and D of title XXVII of the PHS Act. Under this framework, HHS has enforcement

³³ Exec. Order No. 14221, 90 FR 11005 (February 28, 2025).

³⁴ 85 FR 72158 (November 12, 2020).

³⁵ 85 FR 72158, 72160–61 (November 12, 2020).

³⁶ 85 FR 72158, 72161–62 (November 12, 2020).

³⁷ 85 FR 72158, 72162–63 (November 12, 2020).

authority over issuers in a State if the Secretary of HHS makes a determination that the State is failing to substantially enforce a provision (or provisions) of Part A or D of title XXVII of the PHS Act.³⁸

The Departments of Labor and the Treasury generally have primary enforcement authority over private sector employment-based group health plans. The Internal Revenue Service (IRS) has jurisdiction over certain church plans. HHS also has primary enforcement authority over non-Federal governmental plans, such as those sponsored by state and local government employers.³⁹

The Departments will generally use existing processes to ensure compliance with the Code, ERISA, and PHS Act requirements that apply to group health plans and health insurance issuers. HHS's enforcement procedures related to the PHS Act Federal insurance market reforms are set forth in section 2723 of the PHS Act and 45 CFR 150.101 *et seq.*, including bases for initiating investigations, performing market conduct examinations, and imposing civil money penalties. Section 504 of ERISA provides DOL with investigatory authority to determine whether any person has violated or is about to violate any provision of ERISA or any regulation or order thereunder.

D. Consultation With and Input From Interested Parties

The Departments have been in regular consultation with interested parties since publishing the 2019 proposed rules. In addition to the thousands of comments received on the 2019 proposed rules, following the publication of the 2020 final rules, the Departments continued to engage in consultation with interested parties and collaboration about implementation of the 2020 final rules through technical implementation discussions on GitHub (an online hosting platform for development and source code management that permits version control), webinars, emails, and an inquiry management system, as well as other informal compliance assistance efforts and meetings with interested parties. This period of collaboration with interested parties led to the finalization of an initial technical format for disclosures (Schema 1.0) that was finalized on March 1, 2022, and became applicable on July 1, 2022. The Departments also regularly review news articles and research publications

discussing the 2020 final rules and have received written and verbal recommendations from plans and issuers, data engineers, and researchers and academics.⁴⁰

On May 22, 2025, the Departments released FAQs Part 70 on Schema 2.0, which states the Departments' intention to issue revised technical reporting requirements for the In-network Rate File and Allowed Amount File for group health plans and health insurance issuers, and the applicability date for implementation.⁴¹ FAQs Part 70 requested interested parties to provide feedback through GitHub on how best to address the revised technical reporting requirements. These improvements respond to feedback from interested parties and are designed to reduce unnecessary or duplicative data fields and make cost information easier for consumers to understand and use.

Additionally, on June 2, 2025, the Departments issued an RFI⁴² regarding the prescription drug machine-readable file requirement seeking comment and recommendations on the prescription drug price disclosure requirements. More specifically, the RFI requested comments and recommendations to help inform implementation of the prescription drug file disclosure requirements, including information on existing prescription drug file data elements, the ability of health plans to access necessary data for reporting, as well as state approaches and innovation.⁴³

The Departments considered all public input received as they developed the policies in these proposed rules, with the exception of prescription drug RFI comments. However, the Departments received these prescription drug RFI comments and are separately taking them into consideration to evaluate how to implement the Transparency in Coverage prescription drug disclosure requirements in technical implementation guidance or future rulemaking.

III. Provisions of the Proposed Regulations

A. Definitions

The Departments propose to define the term health insurance market for purposes of proposed amendments to

the Allowed Amount File provision at 26 CFR 54.9815–2715A3(b)(1)(ii), 29 CFR 2590.715–2715A3(b)(1)(ii), and 45 CFR 147.212(b)(1)(ii) (discussed in more detail in section III.C.6. of this preamble), which would require group health plans and health insurance issuers offering group or individual health insurance coverage to make an out-of-network allowed amount machine-readable file available for each health insurance market in which plans and issuers offer a plan or coverage. Establishing a standardized definition of the term health insurance market for this purpose would promote consistent data organization across plans and issuers in these market-level Allowed Amount Files.

The Departments propose to redesignate paragraphs (a)(2)(xi) through (xxii) as paragraphs (a)(2)(xii) through (xxiii) under 26 CFR 54.9815–2715A1 and 45 CFR 147.210, respectively, and add a new paragraph (a)(2)(xi) with the new definition. The Departments also propose to redesignate paragraphs (a)(2)(x) through (xxi) as paragraphs (a)(2)(xi) through (xxii) under 29 CFR 2590.715–2715A1, and to add a new paragraph (a)(2)(x) with the new definition. Under this proposal, health insurance market would mean, irrespective of the State, one of the following:

- The individual market, as defined in 45 CFR 144.103 (other than short-term, limited-duration insurance or individual health insurance coverage that consists solely of excepted benefits).
- The large group market, as defined in 45 CFR 144.103 (other than coverage that consists solely of excepted benefits).
- The small group market, as defined in 45 CFR 144.103 (other than coverage that consists solely of excepted benefits).
- For purposes of self-insured group health plans (other than account-based plans, as defined in 26 CFR 54.9815–2711(d)(6)(i), 29 CFR 2590.715–2711(d)(6)(i), and 45 CFR 147.126(d)(6)(i), and plans that consist solely of excepted benefits), all self-insured group health plans maintained by the plan sponsor.

For consistency, this definition would largely align with the definition of the term “insurance market” for the purposes of the methodology for calculating the qualifying payment amount (QPA) at 26 CFR 54.9816–6(a)(8), 29 CFR 2590.716–6(a)(8), and 45 CFR 149.140(a)(8). As background, Code section 9816(a)(3)(E), ERISA section 716(a)(3)(E), and PHS Act 2799A–1(a)(3)(E), as added by section 103 of the

⁴⁰ *Supra* note 8, 9, 10, and 11.

⁴¹ U.S. Department of Labor, U.S. Department of Health & Human Services & U.S. Department of the Treasury, *FAQs About Affordable Care Act Implementation Part 70* (May 22, 2025), <https://www.cms.gov/files/document/aca-faqs-part-70.pdf> and <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-70>.

⁴² See 90 FR 23303 (June 2, 2025).

⁴³ *Id.*

³⁸ See section 2723(a)(2) and (b)(1)(A) of the PHS Act; 45 CFR 150.203.

³⁹ Section 2723(b)(1)(B) of the PHS Act.

No Surprises Act, generally defines the QPA as “the median of the contracted rates recognized by the plan or issuer, respectively (determined with respect to all such plans of such sponsor or all such coverage offered by such issuer that are offered within the same insurance market (specified in subclause (I), (II), (III), or (IV) of clause (iv)) as the plan or coverage) . . . under such plans or coverage, respectively, on January 31, 2019,” subject to other criteria and increased for inflation. Paragraph (a)(3)(E)(iv)(III) of the Code and ERISA and paragraph (a)(3)(E)(iv)(IV) of the PHS Act, provide that in the case of a self-insured group health plan, a health insurance market is “other self-insured group health plans.”

When interpreting the definition of QPA for purposes of establishing a methodology for calculating the QPA, the Departments defined “insurance market” with respect to self-insured group health plans to include, “at the option of the plan sponsor, all self-insured group health plans administered by the same entity (including a third party administrator (TPA) contracted by the plan), to the extent otherwise permitted by law, that is responsible for calculating the qualifying payment amount on behalf of the plan.”⁴⁴ In other words, the interim final rules permitted plan sponsors to use either rates from only their own plans or rates from all plans administered by their TPA to calculate QPAs. However, this language has been vacated by the United States District Court for the Eastern District of Texas on the basis that the No Surprises Act specifies that QPAs must be calculated using the rates of “all such plans of such sponsor.”⁴⁵ Therefore, the United States

District Court for the Eastern District of Texas interpreted the No Surprises Act to restrict aggregation in that manner for the purpose of calculating the QPA.

In contrast, the language of PHS Act section 2715A neither requires nor prohibits disclosure of information described in the Affordable Care Act section 1311(e)(3) to be aggregated by any specific market. Therefore, in order to avoid confusion between the insurance market applicable to the Allowed Amount File and the insurance market applicable to the definition of QPA, which is subject to the holding of *TMA III*, the Departments propose to use the term “health insurance market,” rather than “insurance market,” for purposes of organizing the Allowed Amount File. The Departments note that to the extent self-insured group health plans use an entity to administer the plan, the aggregation rules described in proposed 26 CFR 54.9815–2715A3(b)(5)(iv), 29 CFR 2590.715–2715A3(b)(5)(iv), and 45 CFR 147.212(b)(5)(iv) would allow the entity to aggregate out-of-network allowed amounts for more than one plan offered by a self-insured group health plan sponsor the entity administers, including those offered by self-insured group health plan sponsors. For clarity, the Departments also propose to include cross-references to the market-wide definitions in 45 CFR 144.103 where applicable.

The Departments understand that the term health insurance market is not generally used to refer to self-insured group health plans. However, for purposes of uniformity in the definition, to facilitate a more streamlined and uniformed disclosure of Allowed Amount File, and for ease of reference, the Departments propose that for purposes of self-insured group health plans (other than account-based plans, as defined in 26 CFR 54.9815–2711(d)(6)(i), 29 CFR 2590.715–2711(d)(6)(i), and 45 CFR 147.126(d)(6)(i) of this subchapter, and plans that consist solely of excepted benefits), health insurance market would mean all self-insured group health plans maintained by the plan sponsor.

The Departments seek comment on this proposed definition.

B. Requirements for Disclosing Cost-Sharing Information to Participants, Beneficiaries, and Enrollees

1. Disclaimer on Balance Billing

The Departments propose to amend the balance billing protection notice that plans and issuers are currently required to include along with the required cost-

sharing information to participants, beneficiaries, and enrollees under 26 CFR 54.9815–2715A2(b)(1)(vii)(A), 29 CFR 2590.715–2715A2(b)(1)(vii)(A), and 45 CFR 147.211(b)(1)(vii)(A). These proposed amendments would require a statement that the cost-sharing information in the self-service tool does not account for potential additional amounts in situations where applicable State and Federal law allow out-of-network providers to bill participants, beneficiaries, or enrollees for the difference between a provider’s billed charges and the sum of the amount collected from the plan or issuer and the amount collected from the participant, beneficiary, or enrollee in the form of a copayment, coinsurance, or deductible amount (the difference referred to as balance billing). These changes are being proposed to reflect the existence of the Federal balance billing protections set forth in the No Surprises Act, which were not yet enacted when the current disclaimer language was finalized in the 2020 final rules. This statement would not be required if the State in which the item or service was furnished prohibits all out-of-network providers from balance billing for all items and services payable by the group health plan or health insurance issuer.

Currently, under paragraph (b)(1) of this section, plans and issuers must disclose certain cost-sharing information to participants, beneficiaries, and enrollees, including, under paragraph (b)(1)(i), an estimate of the participant’s, beneficiary’s, or enrollee’s cost-sharing liability for a requested covered item or service from a particular provider or providers. Paragraph (b)(1)(iv) requires, in part, that if the request is for cost-sharing information for an out-of-network provider, the plan or issuer must disclose an out-of-network allowed amount or any other rate that the group health plan or health insurance issuer will pay for the requested covered item or service. As discussed in the 2020 final rules,⁴⁶ because cost estimates cannot account for potential balance billing by an out-of-network provider, current rules under paragraph (b)(1)(vii) require plans and issuers to include a notice with a number of statements, including, under paragraph (b)(1)(vii)(A), that out-of-network providers may bill participants, beneficiaries, or enrollees for the difference between a provider’s billed charges and the sum of the amount collected from the plan or issuer and the amount collected from the participant, beneficiary, or enrollee in the form of a

⁴⁴ 86 FR 36954 (July 13, 2021).

⁴⁵ Texas Medical Association, a trade association representing more than 56,000 Texas physicians and medical students; Dr. Adam Corley, a Tyler, Texas physician; Tyler Regional Hospital, LLC, a hospital in Tyler, Texas; LifeNet, Inc.; East Texas Air One, LLC; Rocky Mountain Holdings, LLC; and *Air Methods Corporation v. United States Department of Health & Human Services, U.S. Department of Labor, U.S. Department of the Treasury, and the Office of Personnel Management*, No. 6:22–cv–450–JDK (E.D. Tex. August 24, 2023) (*TMA III*) (vacating portions of 26 CFR 54.9816–6T(a)(8)(iv), 29 CFR 2590.716–6(a)(8)(iv), and 45 CFR 149.140(a)(8)(iv). The Department of Justice did not appeal the vacatur of this specific provision and it remains in place. *See also FAQs About Affordable Care Act and Consolidated Act, 2021 Implementation Part 71* (July 30, 2025). <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-71> (until the Fifth Circuit issues its en banc decision, extending enforcement relief for plans and issuers that use a QPA calculated using a good faith, reasonable interpretation of the methodology in place before the district court decision, for items and services furnished before February 1, 2026).

⁴⁶ 85 FR 72158, 72201 (November 12, 2020).

copayment or coinsurance amount (the difference often referred to as balance billing) and that these estimates do not account for those potential additional amounts. Because there were existing State laws prohibiting balance billing to some extent, as discussed in the 2020 final rules,⁴⁷ the current rules only require this statement if balance billing is permitted under State law.

Shortly after the 2020 final rules were published, the CAA, 2021, which included the No Surprises Act, was signed into law on December 27, 2020. The No Surprises Act added provisions that apply to group health plans and health insurance issuers offering group or individual health insurance coverage, including certain limitations on cost sharing for emergency services and for non-emergency services provided by nonparticipating providers with respect to visits to certain participating health care facilities.⁴⁸ The No Surprises Act also added certain limitations on cost sharing for air ambulance services provided by out-of-network air ambulance providers.⁴⁹ Additionally, the No Surprises Act added that cost-sharing payments for emergency services, non-emergency services furnished by a nonparticipating provider in a participating health care facility, and air ambulance services furnished by a nonparticipating provider must be counted toward any in-network deductible or out-of-pocket maximums applied under the plan or coverage (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable), respectively (and these in-network deductibles and out-of-pocket maximums must be applied) in the same manner as if such cost-sharing payments were made with respect to services furnished by a participating provider or facility.⁵⁰

In addition to the new provisions applicable to plans and issuers, the No Surprises Act added a new Part E to title XXVII of the PHS Act establishing requirements applicable to health care providers, facilities, and providers of air ambulance services. Specifically, the No Surprises Act added new PHS Act sections 2799B–1, 2799B–2, 2799B–3, and 2799B–5, which protect participants, beneficiaries, and enrollees in group health plans and group and individual health insurance coverage

offered by health insurance issuers from balance bills by generally prohibiting nonparticipating providers, facilities, and providers of air ambulance services from billing or holding liable individuals for an amount that exceeds in-network cost sharing determined in accordance with the No Surprises Act's cost-sharing limitations in circumstances where the cost-sharing limitations apply.

Given that after the passage of the No Surprises Act, all participants, beneficiaries, and enrollees of group health plans and group and individual health insurance coverage are now protected from certain balance billing under Federal law, the Departments propose to amend the balance billing protection notice provision under paragraph (b)(1)(vii)(A) to require a statement that the cost-sharing information provided pursuant to paragraph (b)(1)(i) does not account for potential additional amounts in situations where applicable State and Federal law allow out-of-network providers to bill participants, beneficiaries, or enrollees, for the difference between a provider's billed charges and the sum of the amount collected from the plan or issuer and from the participant, beneficiary, or enrollee in the form of a copayment, coinsurance, or deductible amount (the difference referred to as balance billing). Because there are circumstances under which participants, beneficiaries, and enrollees can be balance billed under current Federal law and State balance billing laws, the Departments propose to clarify that this disclaimer is not required only if the State in which the item or service is to be furnished prohibits all out-of-network providers from balance billing for all items and services payable by the group health plan or health insurance issuer.

The Departments understand that no States currently categorically prohibit balance billing under all circumstances. Therefore, requiring plans and issuers in States without such categorical prohibitions to include this disclaimer would provide an additional layer of transparency for consumers. It would also maintain flexibility for plans and issuers to not include the notice if the State in which the plan or issuer is disclosing cost-sharing information to a participant, beneficiary, or enrollee does, subsequent to the finalization of these proposed rules, pass a law to which all providers are subject that prohibits balance billing for all items and services payable by the plan or issuer.

The Departments seek comment on this proposal.

2. New Required Method and Format for Disclosing Information to Participants, Beneficiaries, or Enrollees

The Departments propose to add new 26 CFR 54.9815–2715A2(b)(2)(iii), 29 CFR 2590.715–2715A2(b)(2)(iii), and 45 CFR 147.211(b)(2)(iii) to require plans and issuers to make available to participants, beneficiaries, and enrollees, at their request, the cost-sharing estimates and other disclosures required under 26 CFR 54.9815–2715A2(b)(1), 29 CFR 2590.715–2715A2(b)(1), and 45 CFR 147.211(b)(1) via a phone number. Under this proposal, the information required via a phone number would be required to be accurate at the time of the request and provided at the time of the request. Plans and issuers would be required to use the same telephone number that Code section 9816(e), ERISA section 716(e), and PHS Act section 2799A–1(e), as added by section 107 of the No Surprises Act,⁵¹ require be indicated on any physical or electronic plan or insurance identification (ID) card issued to participants, beneficiaries, and enrollees for obtaining customer assistance. The Departments also propose to redesignate paragraph (b)(2)(ii)(D) as new paragraph (b)(2)(iv) and amend paragraph (b)(2)(iv) to remove phone as an example of an alternative means for providing the disclosures by which a participant, beneficiary, or enrollee may request the disclosures required described in paragraph (b)(1) because providing the disclosures by a phone number would be required, as specified previously. If this new requirement is finalized as proposed, plans and issuers would be required to make available cost-sharing estimates via the internet-based self-service tool, a phone number, and paper upon request.

The 2020 final rules at paragraph (b)(2) allow plans and issuers to satisfy the disclosure requirements of paragraph (b)(1) through a self-service tool, via paper, or through an alternative means such as phone or email, provided the participant, beneficiary, or enrollee agrees that disclosure through such means is sufficient to satisfy the request and the request is fulfilled at least as rapidly as required for the paper method. However, disclosure by such alternative means is not required.

⁵¹ U.S. Department of Labor, U.S. Department of Health & Human Services & U.S. Department of the Treasury, *FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49* (August 20, 2021), <https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/downloads/faqs-part-49.pdf> and <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf>.

⁴⁷ 85 FR 72158, 72201 (November 12, 2020).

⁴⁸ Codified in Code section 9816, ERISA section 716, and PHS Act section 2799A–1.

⁴⁹ Codified in Code section 9817, ERISA section 717, and PHS Act section 2799A–2.

⁵⁰ Codified in Code sections 9816 and 9817, ERISA sections 716 and 717, and PHS Act sections 2799A–1 and 2799A–2.

While the Departments have determined that the No Surprises Act's price comparison tool (codified at Code section 9819, ERISA section 719, and the PHS Act section 2799A–4) and self-service tool required under the 2020 final rules are largely duplicative, as discussed in more detail in section III.B.3. of this preamble, the requirements of Code section 9819, ERISA section 719, and the PHS Act section 2799A–4 expand the requirements for the disclosure of cost-sharing information in the 2020 final rules in one prominent way. Specifically, Code section 9819, ERISA section 719, and the PHS Act section 2799A–4 require group health plans and health insurance issuers offering group or individual health insurance coverage to “offer price comparison guidance by telephone.”

The Departments intend for these proposed rules to satisfy the requirements of the No Surprises Act to require price comparison guidance via a telephone number, as set forth in Code section 9819, ERISA section 719, and PHS Act section 2799A–4. Further, implementing this requirement would respond to feedback the Departments have received from participants, beneficiaries, and enrollees since the publication of the 2020 final rules, indicating a limited ability to receive cost-sharing information over the phone when requested from plans and issuers. Requiring plans and issuers to provide cost-sharing information in this way would further promote the price transparency goals of providing accurate, real-time pricing to consumers, and making that information accessible to more consumers.

To achieve these goals, these proposed rules add paragraph (b)(2)(iii), proposing to require plans and issuers to make available to participants, beneficiaries, and enrollees the cost-sharing estimates and other disclosures required under paragraph (b)(1), via phone, at the time requested and accurate at the time of their request.

In addition, at paragraph (b)(2)(iii), the Departments propose to allow plans and issuers to limit the number of providers with respect to which cost-sharing information for covered items and services is provided to no fewer than 20 providers per day and, to require plans and issuers to disclose the applicable provider-per-day limit to the participant, beneficiary, or enrollee when the request for information is made. A similar 20 provider limit currently applies with respect to paper requests at 26 CFR 54.9815–2715A2(b)(2)(ii), 29 CFR 2590.715–2715A2(b)(2)(ii), and 45 CFR

147.211(b)(2)(ii). In the 2020 final rules, the Departments determined based on comments that “limiting paper request to 20 providers per request is a reasonable approach to balancing the burdens on plans and issuers with the benefits of providing consumers with enough information to be able to compare cost and provider options.”⁵² The Departments have determined that the process by which plans and issuers would generate information responsive to requests for receiving cost-sharing information over the phone should be similar to the process for generating such information to deliver via paper, given the practicalities of generating a response on paper and over the phone. Therefore, the Departments propose to adopt the limitations for paper disclosure at 26 CFR 54.9815–2715A2(b)(2)(ii), 29 CFR 2590.715–2715A2(b)(2)(ii), and 45 CFR 147.211(b)(2)(ii) for phone disclosure such that plans and issuers may limit the number of providers with respect to which cost-sharing information for covered items and services is provided to no fewer than 20 providers per day and, plans and issuers would be required to disclose the applicable provider-per-day limit to the participant, beneficiary, or enrollee when the request for information is made. This proposal is intended to balance the added burden to plans and issuers of this additional method of delivery with ensuring that participants, beneficiaries, and enrollees that opt to receive cost-sharing information over the phone have access to the same information as those that request such information via the paper method. The Departments note that nothing in these proposed rules precludes a participant, beneficiary, or enrollee from obtaining cost-sharing information from more than one method, consistent with the requirements for each method. Similarly, for consistency with the requirements for the paper method of delivery under the 2020 final rules, the Departments also propose to require plans and issuers to satisfy requests for cost-sharing information over the phone at the time of the phone call in order to ensure that participants, beneficiaries, and enrollees receive information as quickly as possible.

Accordingly, the Departments propose to require plans and issuers to make available to participants, beneficiaries, and enrollees the cost-sharing estimates and other disclosures described in paragraph (b)(1) via phone at the time of the request and accurate at the time of the request, and in

accordance with the method and format requirements in paragraphs (b)(2)(i)(A) through (C).

The Departments are also proposing to require health plans and health insurance issuers to make cost-sharing estimates and other disclosures available over the phone at a number designated on the ID card for individuals to seek assistance. Code section 9816(e), ERISA section 716(e), and PHS Act section 2799A–1(e) (insurance ID card requirements), as added by section 107 of the No Surprises Act, separately require plans and issuers to include in clear writing, on any physical or electronic plan or insurance identification card issued to participants, beneficiaries, or enrollees, certain information including a phone number and website address for individuals to seek consumer assistance. Therefore, plans and issuers are already required to have a phone number designated on any physical or electronic plan or insurance identification card and, under this proposal, plans and issuers should make available cost-sharing estimates and other disclosures at the request of the participant or beneficiary via such phone number, if finalized. These provisions apply with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.⁵³ The Departments expect that requiring plans and issuers to use an existing phone number would allow them to leverage existing workflows and would make it easier for participants, beneficiaries, and enrollees to obtain the cost information they are seeking.

The Departments request comment on whether this proposal should include phone service standards to ensure that consumers have access to timely and reliable information. In particular, the Departments request comment on what such standards should include and what parameters should be applied to each criterion. The Departments also request comment on whether there are other relevant Federal, State, or local

⁵³ U.S. Department of Labor, U.S. Department of Health & Human Services & U.S. Department of the Treasury, *FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49* (Aug. 20, 2021), <https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/downloads/faqs-part-49.pdf> and <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf>. FAQ Part 49 provided that, pending any implementing rulemaking, the Departments would not deem a plan or issuer to be out of compliance with ID card requirements where a plan or issuer includes on any ID card, among other things, a telephone number and website address for individuals to seek consumer assistance and access additional applicable deductibles and maximum out-of-pocket limits.

⁵² 85 FR 72158, 72207 (November 12, 2020).

standards for phone service quality or any industry practices that the Departments should consider.

3. Compliance With PHS Act Section 2799A–4, ERISA Section 719, and Code Section 9819

The Departments propose to add new 26 CFR 54.9815–2715A2(c)(7), 29 CFR 2590.715–2715A2(c)(7), and 45 CFR 147.211(c)(7) stating that a plan or issuer satisfies the requirements of Code section 9819, ERISA section 719, and the PHS Act section 2799A–4, as added by section 114 of the No Surprises Act by providing the information required under paragraph (b)(1) of this section to participants, beneficiaries, and enrollees in accordance with the method and format requirements specified in paragraph (b)(2) of this section.

The 2020 final rules added 26 CFR 54.9815–2715A2(b)(1) and (b)(2), 29 CFR 2590.715–2715A2(b)(1) and (b)(2), and 45 CFR 147.211(b)(1) and (b)(2), which created a comprehensive set of requirements for plan and issuer disclosure of cost-sharing information through an internet-based self-service tool, and in paper form, upon request.⁵⁴ Paragraph (b)(1) of the 2020 final rules requires the disclosure of cost-sharing information, which is accurate at the time the request is made, with respect to a participant's, beneficiary's, or enrollee's cost-sharing liability for covered items and services, and which must reflect any cost-sharing reductions the enrollee would receive.

Under paragraph (b)(2) of the 2020 final rules, disclosures must be made available through a self-service tool on an internet website that provides real-time responses based on cost-sharing information that is accurate at the time of the request, in plain language, without a fee, or in paper form, at the user's request. This paragraph requires certain functionality to make searching using the self-service tool easier, including searching by billing code or descriptive term, and refining and reordering search results based on geographic proximity of in-network providers, and the amount of the participant's, beneficiary's, or enrollee's estimated cost-sharing liability for the covered item or service, to the extent the search for cost-sharing information for covered items or services returns multiple results.⁵⁵

Code section 9819, ERISA section 719, and PHS Act section 2799A–4, as added by section 114 of the No

Surprises Act, require plans and issuers to offer price comparison guidance by telephone and make available on the plan's or issuer's website a “price comparison tool” that allows individuals enrolled under such plan or coverage offered by the plan or issuer to compare the amount of cost sharing that the individual would be responsible for paying for an item or service furnished by an in-network provider (hereinafter “No Surprises Act price comparison tool”). This requirement was applicable with respect to plan years (and in the individual market, policy years) beginning on or after January 1, 2022.

The Departments announced on August 20, 2021, in FAQs Part 49 that the price comparison methods required by the No Surprises Act price comparison tool are largely duplicative of the self-service tool component of the 2020 final rules except that the information under the No Surprises Act price comparison tool must also be provided over the telephone upon request.⁵⁶ Therefore, the Departments indicated they intended to propose rulemaking requiring that the same pricing information that is available through the self-service tool or in paper form, as described in the 2020 final rules, must also be provided over the phone upon request. The Departments also announced that, as an exercise of enforcement discretion, they would defer enforcement of the requirement that plans and issuers make available a price comparison tool by internet website, in paper form, or telephone pursuant to the No Surprises Act until plan years (or in the individual market, policy years) beginning on or after January 1, 2023, to align the enforcement date of the No Surprises Act price comparison disclosure requirements with the enforcement date of the self-service tool described in the 2020 final rules.

Further, the Departments announced their intention to propose rulemaking and seek public comment regarding whether compliance with the self-service tool requirements of the 2020 final rules should satisfy the analogous requirements set forth Code section 9819, ERISA section 719, and PHS Act section 2799A–4. Plans and issuers have built and developed tools to comply with the requirements of the 2020 final

rules and have anticipated, since the release of FAQs Part 49, that the Departments would propose in a future rulemaking that plans and issuers satisfy the No Surprises Act price comparison tool requirement by providing the required disclosures to participants, beneficiaries, and enrollees through the self-service tool as required in paragraphs (b)(1) and (2) of the 2020 final rules. Given this, the Departments have determined that requiring plans and issuers to build a second self-service tool would impose significant unnecessary burden and cause considerable confusion for consumers on the purposes of the two tools. Thus, it is appropriate that compliance with the self-service tool described in the 2020 final rules and as amended in these proposed rules should satisfy compliance with the No Surprises Act price comparison tool requirements.

Therefore, as discussed in section II.B.2. of this preamble, to align with the No Surprises Act price comparison tool requirements the Departments propose to require in new paragraph (b)(2)(iii) that plans and issuers make available to participants, beneficiaries, and enrollees the cost-sharing information and other disclosures required under paragraph (b)(1) via the same telephone number that Code section 9816(e), ERISA section 716(e), and PHS Act section 2799A–1(e), as added by section 107 of the No Surprises Act, requires be indicated on any physical or electronic plan or insurance identification card issued to a participant, beneficiary, or enrollee for obtaining customer assistance. The Departments also propose at new paragraph (c)(7) that a group plan or health insurance issuer satisfies the requirements of Code section 9819, ERISA section 719, and PHS Act section 2799A–4 by providing the information required in paragraph (b)(1) to participants, beneficiaries, and enrollees in accordance with the method and format requirements specified in paragraph (b)(2).

The Departments acknowledge that, while PHS Act section 2715A does not apply to grandfathered health plans and health insurance issuers offering grandfathered individual and group health insurance coverage, Code section 9819, ERISA section 719, and PHS Act section 2799A–4 do. The Departments have also stated that the requirements of PHS Act section 2715A are largely duplicative to those of Code section 9819, ERISA section 719, and PHS Act section 2799A–4, except that the former does not require information to be disclosed by phone. Therefore, if this rule is finalized, grandfathered health plans and issuers offering grandfathered

⁵⁴ 26 CFR 54.9815–2715A2(b)(1) and (2), 29 CFR 2590.715A2(b)(1) and (2), and 45 CFR 147.211(b)(1) and (2).

⁵⁵ 26 CFR 54.9815–2715A2(b)(2)(i), 29 CFR 2590.715A2(b)(2)(i), and 45 CFR 147.211(b)(2)(i).

⁵⁶ U.S. Department of Labor, U.S. Department of Health & Human Services & U.S. Department of the Treasury, *FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49* (Aug. 20, 2021), <https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/downloads/faqs-part-49.pdf> and <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf>.

health insurance coverage may comply with the requirements of PHS Act 2715A, as codified in 26 CFR 54.9815–2715A2, 29 CFR 2590.716–2715A2 and 45 CFR 147.211, to satisfy the requirements of Code section 9819, ERISA section 719, and PHS Act section 2799A–4. The Departments request comments on whether any additional provisions are necessary to assist grandfathered health plans and health insurance issuers in complying with the requirements of 26 CFR 54.9815–2715A2, 29 CFR 2590.716–2715A2 and 45 CFR 147.211. The Departments seek comment on all aspects of this proposal.

4. Applicability

The Departments propose to revise 26 CFR 54.9815–2715A2(c)(1), 29 CFR 2590.715–2715A2(c)(1), and 45 CFR 147.211(c)(1) to state that the proposed amendments to (b)(1)(vii)(A), and new paragraphs (b)(2)(iii), (b)(2)(iv), and (c)(7) of this section would apply for plan years (in the individual market, policy years) beginning on or after January 1, 2027. Until such time, the current provisions of paragraph (b) of this section continue to apply.

With respect to proposed provisions at new paragraph (b)(2)(iii), the Departments understand that most plans and issuers already have in place a consumer assistance telephone number for participants, beneficiaries, and enrollees to receive benefit information pursuant to Code section 9816(e), ERISA section 716(e), and PHS Act section 2799A–1(e), as added by section 107 of the No Surprises Act, and as clarified in previously issued guidance.⁵⁷ Because plans and issuers can leverage the operations of an existing consumer assistance phone number, the Departments have determined that the proposed applicability date appropriately balances the need for improved access to cost-sharing estimates for consumers who wish to access this information over the phone with the time necessary for plans and issuers to make the administrative and operational changes to implement this proposal. Similarly, because most plans are already required to disclose the balance billing disclosures under the 2020 final rules, the Departments have determined that the proposed applicability date for new paragraph

(b)(1)(vii)(A) that would amend the balance billing disclosure is appropriate and reasonable.

The Departments propose to make new paragraph (c)(7) applicable for plan years (in the individual market, policy years) beginning on or after January 1, 2027. The Departments selected this date because once plans and issuers are required to provide cost-sharing information by phone on the same date pursuant to proposed new paragraph (b)(2)(iii), it would be reasonable for the Departments to consider a plan or issuer's compliance with paragraphs (b)(1) and (2) to constitute compliance with the No Surprises Act price comparison tool as required by Code section 9819, ERISA section 719, and PHS Act section 2799A–4.

The Departments seek comment on this proposed applicability date for these proposed provisions.

C. Requirements for Public Disclosure of In-Network Rates and Historical Allowed Amount Data for Covered Items and Services From In- and Out-of-Network Providers

1. Provider Network-Level Reporting for the In-Network Rate Files

The current In-network Rate File provision at 26 CFR 54.9815–2715A3(b)(1)(i), 29 CFR 2590.715–2715A3(b)(1)(i), and 45 CFR 147.212(b)(1)(i) requires plans and issuers to make available on a public website a machine-readable file that discloses in-network provider rates for covered items and services, with the exception of prescription drugs that are subject to a fee-for-service reimbursement arrangement. The Departments propose to amend the introductory language of paragraph (b)(1)(i) to require plans and issuers to make available an In-network Rate File for each provider network maintained or contracted by the group health plan or health insurance issuer. This proposed change is intended to reduce the size and total number of In-network Rate Files, allow file users to more efficiently aggregate and analyze the data, and align reporting more closely to how data is typically reported by hospitals pursuant to the Hospital 2019 and 2023 Price Transparency rules⁵⁸ under 45 CFR part 180.

a. Reducing File Size

As discussed in section I.A. of this preamble, file size is the most common concern that the Departments have heard from interested parties regarding the current In-network Rate Files. These

files are often very large, making them challenging for users to download, analyze, and store.⁵⁹ In-network Rate File sizes often represent many terabytes of data a month for a single issuer,⁶⁰ and many exceed most local storage and processing capabilities.⁶¹ Additionally, each issuer may have hundreds of separate files for each plan or coverage it offers, making aggregation and analysis highly resource intensive.⁶²

The Departments have determined that the size of the In-network Rate File can be highly dependent on how it is organized. It is very common for multiple plans offered by the same issuer or administered by the same service provider to leverage the same provider networks with the same negotiated rates.⁶³ This means that when plans and issuers organize In-network Rate Files by plan ID, they often repeat the same negotiated rates across multiple plan files, which leads to significant duplicative data throughout the In-network Rate Files. The Departments have received consistent feedback about the challenges related to file size, and some of that feedback has suggested that the disclosure requirements be amended to organize In-network Rate Files by provider network, whereby each file would contain all rates negotiated by the reporting entity for that provider network, rather than having a file for each plan ID.⁶⁴

⁵⁹ See Fred Diamond, *Payers' Price Transparency Data Still Not User-Friendly, Say Researchers* (Feb. 7, 2023), <https://www.fiercehealthcare.com/payers/health-insurance-plans-price-transparency-data-still-not-user-friendly-say-researchers>; See also David Muhlestein, *Improving Price Transparency Data: Recommendations From Practice*, Health Affairs (Mar. 19, 2025), <https://www.healthaffairs.org/content/forefront/improving-price-transparency-data-recommendations-practice>.

⁶⁰ See David Muhlestein, *Improving Price Transparency Data: Recommendations from Practice*, Health Affairs (Mar. 19, 2025), <https://www.healthaffairs.org/content/forefront/improving-price-transparency-data-recommendations-practice>.

⁶¹ See Aileen Y. Choi, Karen Manthe-Cohen, & Robert J. Rosso, *Technical Challenges with Private Health Insurance Price Transparency Data*, Congressional Research Service (June 13, 2025), <https://www.congress.gov/crs-product/R48570>.

⁶² See Aileen Y. Choi, Karen Manthe-Cohen, & Robert J. Rosso, *Technical Challenges with Private Health Insurance Price Transparency Data*, Congressional Research Service (June 13, 2025), <https://www.congress.gov/crs-product/R48570>.

⁶³ See Lester Adler, Michael Fiedler, & Benjamin Ippolito, *Assessing Recent Health Care Proposals from the House Committee on Energy and Commerce* (May 25, 2023), <https://www.brookings.edu/articles/assessing-recent-health-care-proposals-from-the-house-committee-on-energy-and-commerce>.

⁶⁴ See Mark Robben, *Learnings from MRF Land*, Serif Health (Mar. 31, 2023), <https://www.serifhealth.com/blog/learnings-from-mrf-land>; Georgetown University, *Transparency in Coverage*:

Continued

⁵⁷ U.S. Department of Labor, U.S. Department of Health & Human Services & U.S. Department of the Treasury, *FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49* (Aug. 20, 2021), <https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-part-49.pdf> and <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/affordable-care-act-faqs-49-2021.pdf>.

⁵⁸ 84 FR 65524 (November 17, 2019) and 88 FR 81540 (November 22, 2023).

Currently, the technical implementation guidance for the In-network Rate File allows plans and issuers flexibility to leverage a Table of Contents File to combine common negotiated rates across multiple In-network Rate Files, rather than publishing negotiated rates individually for each plan ID. This allows issuers to avoid duplicating prices within and across plans by linking the files for each plan that uses a given provider network to an underlying file of in-network prices.⁶⁵ Interested parties report that this reduces the total amount of data that must be analyzed to estimate market-level prices.⁶⁶ Many plans and issuers currently leverage this optimization. The Departments conducted an internal analysis in 2024 that sampled In-network Rate Files market wide and found that 83 percent of issuers sampled were leveraging a Table of Contents to organize their files.

The Departments agree that where multiple plans share the same negotiated rates under an umbrella provider network, organizing the In-network Rate Files by provider network would decrease the size of the files, often significantly while still maintaining data integrity. Therefore, to standardize this method of organizing files across all plans and issuers, the Departments propose to amend the introductory language of paragraph (b)(1)(i) to require plans and issuers to make an In-network Rate File available for each provider network maintained or contracted by the plan or issuer. This approach would also reduce the total number of In-network Rate Files because there are far more plans and policies available than there are distinct, separately managed provider networks.⁶⁷

To make it easier for file users to determine in advance of downloading a provider network-level In-network Rate File whether it contains data of interest to them, the Departments propose to

redesignate paragraphs (b)(1)(i)(A) through (C) as paragraphs (b)(1)(i)(B) through (D), respectively, and add a new paragraph (b)(1)(i)(A) requiring each In-network Rate File to include the common provider network name for which negotiated rate information is included. The Departments seek comment on whether there is another term or code, in addition to or instead of the common provider network name, that would help producers or file users identify specific provider networks. The Departments expect plans and issuers to define what constitutes a separate provider network according to their current business practices. The Departments solicit comments on whether additional limitations on what constitutes a separate provider network should be required.

In order to maintain the connection of rates to plans under this proposal, as further discussed in section III.C.2. of this preamble, the Departments also propose to amend redesignated paragraph (b)(1)(i)(B) to require plans and issuers to identify, for each provider network for which the plan or issuer must publish an In-network Rate File, each of the plan's or issuer's coverage options that use that network. This would allow file users to cross reference the rates for a particular plan or policy of interest to its in-network rates.

The Departments also propose conforming amendments to redesignated paragraphs (b)(1)(i)(C) and (D). Specifically, the Departments propose to amend redesignated paragraph (b)(1)(i)(C) to specify that each In-network Rate File must include a billing code and a plain language description for each covered item or service included in the file, rather than under each coverage option offered by plans and issuers.⁶⁸ The Departments propose to amend redesignated paragraph (b)(1)(i)(D) to specify that all applicable rates must be included for each covered item or service included in the file, rather than for all items or services the plan or issuer covers, since not all applicable rates for items or services the plan or issuer covers are negotiated under a given provider network. Since plans and issuers would be required to make an In-network Rate File available for each provider network they maintain or contract with, they

would ultimately still be required to disclose all applicable rates for items or services they cover, but those rates may not all be reported in every In-network Rate File organized by provider network.

The Departments are also proposing special aggregation rules for self-insured group health plans, which is described in more detail in section III.C.11. of this preamble.

b. Other Improvements for File Users

The Departments have determined that, overall, provider network-level files would simplify data aggregation and analysis for researchers and other groups interested in analyzing specific provider networks, which is important to facilitate consumer's plan selection decisions. For example, the Departments understand that organizing In-network Rate Files by network would make it easier for employers and plan sponsors to analyze the negotiated rates of different networks to make informed decisions about which plans to offer their employees, potentially favoring networks with more competitive pricing, in addition to opening the door for employers to bring health care purchasing decisions in house through direct contracting with provider groups.⁶⁹ This proposal may be of particular benefit to smaller employers, who have historically had less leverage to negotiate directly with providers due to lower patient volume, by empowering them with access to network-level pricing data for negotiations.

Similarly, organizing in-network rate information by provider network would help service providers advise clients on network selection and cost management strategies. Likewise, researchers, academics, and policymakers would be better positioned to analyze pricing variations across different providers, specialties, and geographic areas within the same provider network and between

Recommendations for Improving Access to and Usability of Health Plan Price Data (Jan. 9, 2023), <https://georgetown.app.box.com/s/1ezsggz1c7smaexkr8rgh15sokgusl>.

⁶⁵ See Lester Adler, Michael Fiedler, & Benjamin Ippolito, *Assessing Recent Health Care Proposals from the House Committee on Energy and Commerce* (May 25, 2023), <https://www.brookings.edu/articles/assessing-recent-health-care-proposals-from-the-house-committee-on-energy-and-commerce>.

⁶⁶ *Id.*

⁶⁷ See Jianhui Zhu, Yuting Zhang, & Daniel Polsky, *Networks in ACA Marketplaces Are Narrower for Mental Health Care Than for Primary Care*, 36 *Health Affairs* 9 (Sept. 2017). (Researchers found that, using 2016 *HealthCare.gov* data, 531 unique provider networks were used by 281 different issuers, covering 5,022 qualified health plans in the Federally-facilitated Marketplaces).

⁶⁸ "Plain language" means "written and presented in a manner calculated to be understood by the average participant, beneficiary, or enrollee" under current 26 CFR 54.9815–2715A1(a)(2)(xx), 29 CFR 2590.715–2715A1(a)(2)(xix), and 45 CFR 147.210(a)(2)(xx) (redesignated as 26 CFR 54.9815–2715A1(a)(2)(xxi), 29 CFR 2590.715–2715A1(a)(2)(xx), and 45 CFR 147.210(a)(2)(xxi) under these proposed rules).

⁶⁹ See Samuel Haitoff, Jay Puthumana, Abhishek Dama, Yang Wang, et al., *Employer-Provider Direct Contracting: Practice and Policy*, *Health Affairs Forefront* (Apr. 1, 2025), <https://www.healthaffairs.org/content/forefront/employer-provider-direct-contracting-practice-and-policy>; See also Cynthia A. Fisher & Arthur B. Laffer, *Healthcare Price Transparency and Competition: How Real Price Transparency Can Reduce American Healthcare Costs More Than \$1 Trillion Annually and Extend Life Expectancy* (Oct. 2023), https://static1.squarespace.com/static/60065b8fc8cd61012ab89a7/t/652f0429f8ca6d62668bb43d/1697580073561/PRA_Fisher-Laffer+Healthcare+Price+Transparency+Paper_FINAL.pdf; See also Christopher Whaley, Geetika Sachdev, Michael Bartlett, & Ge Bai, *It's Time for Employers to Bring Health Care Decisions In-House*, *Health Affairs Forefront* (Sept. 22, 2022), <https://www.healthaffairs.org/content/forefront/s-time-employers-bring-health-care-decisions-in-house>.

different networks that may inform policy interventions aimed at cost containment and market regulations.

The Departments understand that State insurance regulators may also be able to use network-level data to inform and improve rate review processes, optimize public option plans, and potentially guide antitrust enforcement.⁷⁰ Currently, State regulators may review unit cost and utilization trends submitted by issuers as part of their rate review process. Access to more consumable provider rates by network and product type in the In-network Rate Files may make it easier for regulators to validate unit cost trends, and to use those trends to assess the reasonableness of premium increases. Also, the reduction of duplicative data in the In-network Rate Files may make it easier for States to monitor rates to identify collusive behaviors, as well as help establish benchmarks for negotiations with providers as part of State oversight activities related to coverage programs.

c. Better Alignment With Hospital Price Transparency Reporting

Organizing in-network rates by provider network would also promote standardization and streamlined comparison of pricing information across hospitals and health plans, consistent with Executive Order 14221.⁷¹ As discussed in section I.A. of this preamble, many interested parties have called for better alignment among Federal price transparency requirements to avoid consumer confusion and duplication of effort.⁷²

Currently, the Hospital Price Transparency machine-readable files required under 45 CFR part 180 generally disclose rates at the provider network level.⁷³ By contrast, rates

disclosed pursuant to the 2020 final rules are currently disclosed at the more granular plan or policy level, which presents complications for data matching. For example, a single set of Hospital Price Transparency rates negotiated between a plan and a hospital system could appear multiple times, under several different plan names, in an issuer's current In-network Rate Files, without any reference to the provider network name in the Hospital Price Transparency file. Standardization of price disclosures for providers, plans, issuers, and procedures at the same level would allow for more accurate comparisons between the different types of transparency files.

The Departments seek comment on all aspects of these proposals.

2. HIOS Identifier and Product Type

The Departments propose to amend the identifying coverage information that plans and issuers must disclose in the In-network Rate Files at redesignated 26 CFR 54.9815–2715A3(b)(1)(i)(B), 29 CFR 2590.715–2715A3(b)(1)(i)(B), and 45 CFR 147.212(b)(1)(i)(B), and in the Allowed Amount Files at 26 CFR 54.9815–2715A3(b)(1)(ii)(A), 29 CFR 2590.715–2715A3(b)(1)(ii)(A), and 45 CFR 147.212(b)(1)(ii)(A). Specifically, the Departments propose to remove the requirement for plans and issuers to report the 14-digit Health Insurance Oversight System (HIOS) identifier (ID) or, if the 14-digit HIOS ID is not available, the 5-digit HIOS ID, and instead require them to report the HIOS identifier associated with each coverage option for which data is being reported in a form and manner as specified in guidance issued by the Departments. The Departments also propose to add a requirement for plans and issuers to report the product type (for example, Health Maintenance Organization (HMO) or Preferred Provider Organization (PPO)) associated with the coverage option for which data is being reported.

The 2020 final rules require plans and issuers to include their 14-digit HIOS ID in the In-network Rate File and Allowed Amount File unless the plan or issuer does not have a 14-digit HIOS ID available, in which case the plan or issuer must include the HIOS ID at the 5-digit issuer level.⁷⁴ If a plan or issuer

does not have a HIOS ID, it must use its Employer Identification Number (EIN). The Departments received significant comments on GitHub about requiring the 14-digit HIOS ID,⁷⁵ stating that this requirement would result in an enormous amount of redundant data because provider rates are not established based on distinct plan designs, but rather they are applied across multiple plan offerings. The Departments have determined that the number of HIOS digits that plans and issuers must report is a technical implementation detail that should be removed from regulation and set forth in technical implementation guidance to better maintain the Departments' flexibility to determine appropriate technical reporting requirements and to make refinements in response to changes in technology or health care industry business practice. This is in line with the Departments' general approach as described in the preamble to the 2020 final rules, to provide specific technical direction in separate technical implementation guidance, rather than in rulemaking, in order to keep pace with and respond to technological developments.⁷⁶ The Departments propose to amend the reporting requirements to specify that for each applicable coverage option offered by a group health plan or health insurance issuer, the plan or issuer must report the name and the HIOS identifier, or, if no HIOS identifier is available, the EIN.

In addition to the HIOS digit amendment, the Departments propose to amend redesignated paragraph (b)(1)(i)(B) and amend paragraph (b)(1)(ii)(A) to newly require plans and issuers to report the product type for each applicable coverage option offered by a plan or issuer in the In-network Rate File and Allowed Amount File, respectively. The Departments have received feedback that requiring plans and issuers to disclose health plan product types (for example, HMO, PPO) would promote more meaningful transparency around the health care pricing information disclosed in the In-

⁷⁰ Colorado's State law mandates insurers provide in-network allowed amounts data tailored for State-specific analyses. See Colorado Rev. Statutes § 10–16–168(4); Medical Group Management Association, *Unlocking the Potential of Healthcare Price Transparency Data* (Dec. 5, 2024), <https://www.mgma.com/articles/unlocking-the-potential-of-healthcare-price-transparency-data> (noting that Colorado uses price transparency data “to inform rate reviews, optimize [its] public option plans, and potentially guide antitrust enforcement,” according to Colorado Insurance Commissioner Michael Conway); See also Sabrina Corlette, *The Health Plan Price Transparency Files Are a Mess: States Can Help Make Them Better*, Health Affairs Forefront (May 5, 2023), <https://chirblog.org/the-health-plan-price-transparency-data-files-are-a-mess-states-can-help-make-them-better>.

⁷¹ Exec. Order No. 14221, 90 FR 11005 (February 28, 2025).

⁷² See American Hospital Association, *Fact Sheet: Hospital Price Transparency* (Feb. 24, 2023), <https://www.aha.org/fact-sheets/2023-02-24-fact-sheet-hospital-price-transparency>.

⁷³ 45 CFR 180.50.

⁷⁴ The 14-digit HIOS ID is comprised of the following: (1) issuer's ID number (first 5 digits, for example, 12345), (2) issuer's State abbreviation (next 2 digits, for example, WA); (3) issuer's three-digit Product ID (next 3 digits, for example, 001); and (4) a four-digit sequence number that is the “Component ID” (last 4 digits, for example, 0001). Thus, HIOS ID at the 14-digit level would be

12345WA0010001, 10 digits would be 12345WA001, 7 digits would be 12345WA, and 5 digits would be 12345.

⁷⁵ See GitHub Users, *GitHub Discussion: Updating to allow for reporting at the 10-digit HIOS level vs the 14-digit level #447*, GitHub, <https://github.com/CMSgov/price-transparency-guide/pull/447#issuecomment-1102946004> (last updated Apr. 19, 2022); See also GitHub Users, *GitHub Discussion: In-Network-Rates File: Schema and Definition of Plan Name and HIOS/EIN #44*, GitHub, <https://github.com/CMSgov/price-transparency-guide/discussions/44#discussioncomment-645647> (last updated Mar. 28, 2022).

⁷⁶ 85 FR 72158, 72221 (November 12, 2020).

network Rate and Allowed Amount Files. The Departments agree with this feedback, as product types dictate the fundamental relationship between the payer and the provider regarding patient access and volume, which are key leverage points in contract negotiations over rates. For example, in instances where HMOs may have narrow networks, providers contracting with such HMOs are likely to see increased patient volume, which may encourage such providers to contract at a lower rate with the HMO than they might with a PPO that is less likely to result in higher patient volume. Product types also dictate the fundamental relationship between payer and patient, with differences, for example, related to patient choice, cost-sharing responsibilities, and accessibility.

Additionally, the Departments have heard from interested parties that although negotiated rates under a provider network are typically consistent across plans and policies with respect to a specific item or service and a specific provider, these rates may differ based on product type. As such, interested parties have stated that requiring plans and issuers to include the product type for each applicable coverage option offered by the plan or issuer in the In-network Rate File would allow users to account for those differences.

In addition to providing context on how prospective rates differ, the Departments have determined that adding a product type to the Allowed Amount Files would allow file users to compare how historical provider reimbursements differ based on product type. Disclosing product type data in the Allowed Amount Files would enable more accurate and actionable comparisons for employers, researchers, and regulators so they can understand true market pricing for specific product types. In addition, not only could users of these data make comparisons of allowed amounts across different product types for a specific service for a single payer, they could also make comparisons for the same service based on product type across different payers. For example, an employer or plan sponsor offering a PPO plan could benchmark their out-of-network costs specifically against other PPO plans in the market, rather than a generalized average that includes potentially lower-cost HMOs, and they could use this information to make future plan coverage determinations. Furthermore, with allowed amounts tied to product type, employers and plan sponsors would better understand the actual tradeoffs in plan design—that is, not just

premiums and network access, but also how much the plan will pay when employees go out-of-network. One study on out-of-network behavioral health care in employer-sponsored coverage observed that balance billing was higher for HMO enrollees versus non-HMO enrollees.⁷⁷ With the inclusion of data on plan type, employers could use historical allowed amounts segmented by plan type to evaluate the level of financial protection offered for out-of-network services.

The Departments acknowledge that product type is often used in the fully insured market, typically to comply with laws that apply to insured products. The Departments also acknowledge that the definitions of these product types may differ from State to State and seek comment on whether that would present difficulties for plans and issuers in determining which product type to indicate. The Departments also seek comment on whether possible inconsistency between State definitions of certain product types would cause confusion among file users. Under ERISA, self-insured plans are not currently required to be identified by product type and these traditional classifications may not necessarily apply or otherwise accurately describe a self-insured benefit arrangement. As such, the Departments seek comment on whether self-insured plans generally identify benefit package options by product type, whether there is any existing nomenclature that self-insured plans could use to accurately identify the type of benefit arrangement being offered, and whether it is practical to extend this requirement to self-insured plans.

3. Percentage-of-Billed-Charges Arrangements

The Departments propose to amend redesignated 26 CFR 54.9815–2715A3(b)(1)(i)(D)(1), 29 CFR 2590.715–2715A3(b)(1)(i)(D)(1), and 45 CFR 147.212(b)(1)(i)(D)(1) (redesignated from paragraph (b)(1)(i)(C)(1) as discussed in section III.C.1. of this preamble) of the In-network Rate Files provision to require that in-network rates must be reflected as a dollar amount except for contractual arrangements under which a plan or issuer agrees to pay an in-network provider a percentage of billed charges and is not able to assign a dollar amount to an item or service prior to a bill being generated. In such circumstances, plans and issuers must

report a percentage number, in lieu of a dollar amount, in the form and manner as specified in guidance issued by the Departments.

Paragraph (b)(1)(i)(C) of the current In-network Rate File provision requires plans and issuers to publish all applicable rates, which may include one or more of the following: negotiated rates, underlying fee schedule rates, or derived amounts for all covered items and services in the In-network Rate File. The Departments specified in the preamble to the 2020 final rules that the In-network Rate File requirement applies to plans and issuers regardless of the type of payment model or models under which they provide reimbursement.⁷⁸

Under the 2020 final rules, paragraph (b)(1)(i)(C)(1) of the In-network Rate File provision requires that rates must be reflected in the In-network Rate File as dollar amounts and if the rate is subject to change based upon participant, beneficiary, or enrollee-specific characteristics, that these dollar amounts should be reflected as the base negotiated rate applicable to the item or service prior to adjustments for participant, beneficiary, or enrollee-specific characteristics. While there are alternative reimbursement arrangements that do not have a dollar amount associated with particular items and services before the item or service is furnished, a dollar amount can still be determined in some instances under these arrangements. Accordingly, in the preamble to the 2020 final rules, the Departments provided a list of alternative reimbursement arrangements and summarized general reporting expectations for these arrangements, while acknowledging that the list was not exhaustive, as there may be other alternative reimbursement or contracting arrangements in use.⁷⁹ Specifically, the Departments summarized the general reporting expectations, including for bundled payment arrangements and capitation arrangements (including sole capitation arrangements and partial capitation arrangements), reference-based pricing without a defined network, reference-based pricing with a defined network, and value-based purchasing. For example, the preamble to the 2020 final rules clarified that for payment arrangements under which adjustments are made after care is provided, the plan or issuer should disclose the base negotiated rate before adjustments are applied.⁸⁰

⁷⁷ See Sarah A. Friedman, Hao Xu, Fernando Azocar & Susan L. Ettner, *Quantifying Balance Billing for Out-of-Network Behavioral Health Care in Employer-Sponsored Insurance*, 73 *Psychiatric Services* 1019 (2022).

⁷⁸ 85 FR 72158, 72226 (November 12, 2020).

⁷⁹ *Id.*

⁸⁰ 85 FR 72158, 72228 (November 12, 2020).

After the 2020 final rules were issued, interested parties used GitHub⁸¹ and other forums to raise to the Departments' attention alternative payment arrangements under which reporting a current and accurate dollar amount for items and services in the In-network Rate File before the item or service is furnished may not be possible and requested guidance from the Departments on how to meet the disclosure requirements for such arrangements. Specifically, interested parties questioned the Departments on how to report dollar amounts for negotiated rates that result from certain "percentage-of-billed-charges" contract arrangements, under which a dollar amount can be determined only retrospectively because the agreement between the plan or issuer and the in-network provider states that the plan or issuer will pay a fixed percentage of the billed charges. It is the Departments' understanding that these types of arrangements are not uncommon for certain types of items or services (such as low-volume procedures or high-cost, outlier inpatient care).

On April 19, 2022, the Departments issued FAQs Part 53⁸² to provide an enforcement safe harbor for satisfying the reporting requirements for plans and issuers that use an alternative payment arrangement that does not permit them to derive with accuracy specific dollar amounts contracted for covered items and services in advance of the provision of that item or service, or that otherwise cannot disclose specific dollar amounts according to the file formatting requirements as provided in the Departments' technical implementation guidance through GitHub. This guidance further advised that for contractual arrangements under which a plan or issuer agrees to pay an in-network provider a percentage of billed charges and is not able to assign a dollar amount to an item or service prior to a bill being generated, plans and issuers

may report a percentage number, in lieu of a dollar amount.

On September 27, 2023, the Departments clarified in FAQs Part 61⁸³ that whether a plan or issuer is able to comply with the requirement to disclose certain rates as dollar amounts is a fact-specific determination and that the Departments would exercise enforcement discretion with respect to this requirement on a case-by-case basis, without any categorical "safe harbor." The Departments instructed plans and issuers that are unable to determine dollar amounts for the applicable rate element to continue to follow the existing technical implementation guidance on GitHub.

Since issuing the guidance in 2023, the Departments have continued to receive feedback from interested parties that arrangements where a dollar amount is unable to be determined in advance are not uncommon and should be reflected in the data. Therefore, the Departments propose to amend redesignated 26 CFR 54.9815–2715A3(b)(1)(i)(D)(1), 29 CFR 2590.715–2715A3(b)(1)(i)(D)(1), and 45 CFR 147.212(b)(1)(i)(D)(1) to state that applicable rates must be reflected as dollar amounts, with respect to each covered item or service that is furnished by an in-network provider, except for contractual arrangements under which a group health plan or health insurance issuer agrees to pay an in-network provider a percentage of billed charges and is not able to assign a dollar amount to an item or service prior to a bill being generated. In these instances, plans and issuers must report a percentage number, in lieu of a dollar amount, in a form and manner as specified in guidance issued by the Departments.

While the Departments recognize the importance of allowing plans and issuers to disclose non-dollar amount rates when a dollar amount is unknown in advance, the Departments reiterate that plans and issuers must disclose rates as a dollar amount whenever a dollar amount can be calculated in advance, including when a negotiated base rate can be calculated prior to adjustments. Further, the Departments emphasize that this proposed change, if finalized, would permit plans and issuers to disclose an applicable rate in a non-dollar amount only in instances where the applicable rate is a percentage

of billed charges and expect that plans and issuers report all other applicable rates as dollar amounts consistent with the form and manner specified in guidance issued by the Departments.

The Departments seek comment on this proposal.

4. Enrollment Totals

The Departments propose to add new 26 CFR 54.9815–2715A3(b)(1)(i)(E), 29 CFR 2590.715–2715A3(b)(1)(i)(E), and 45 CFR 147.212(b)(1)(i)(E) requiring plans and issuers to include in each In-network Rate File, current numerical enrollment totals, as of the date the file is posted, for each coverage option offered by a plan or issuer represented in the In-network Rate File. Such numerical enrollment totals must include the number of participants, beneficiaries, and enrollees (including all dependents) in the coverage option offered by a plan or issuer.

Affordable Care Act sections 1311(e)(3)(A)(iii) and (iv) require health plans seeking certification as a qualified health plan to submit to the Exchange, the Secretary, the State insurance commissioner, and make available to the public, accurate and timely disclosure of data on enrollment and disenrollment. PHS Act section 2715A, incorporated into ERISA section 715 and Code section 9815, gives the Departments the statutory authority to require a plan or coverage that is not offered through an Exchange to submit the information required under Affordable Care Act section 1311(e)(3) to the Secretary and the relevant State's insurance commissioner, and to make that information available to the public. However, the 2020 final rules do not require the disclosure of enrollment data.

Since the publication of the 2020 final rules, the Departments have received feedback from interested parties on the importance of additional data elements that would allow users to weigh different plans and coverage options to understand their relative influence on the overall landscape of pricing in health insurance, such as plan enrollment numbers, in line with the goals stated in the 2020 final rules.⁸⁴ The Departments understand that requiring the reporting of plan enrollment counts would enable file users to develop analytical models that prioritize negotiated rates for health care

⁸¹ GitHub Users, *GitHub Discussion: If negotiated rate is based on percentage of charge—then how would this be reported in the in-network file?* #23, GitHub, <https://github.com/CMSgov/price-transparency-guide/discussions/23> (last updated Apr. 15, 2022); GitHub Users, *GitHub Discussion: Percentage of Billed Charges* #315, GitHub, <https://github.com/CMSgov/price-transparency-guide/discussions/315> (last visited Dec. 8, 2025); GitHub Users, *GitHub Discussion: Using Claims History for In-Network File when unable to extract rates (that is percent of billed charges)* #197, GitHub, <https://github.com/CMSgov/price-transparency-guide/discussions/197> (last updated Sep. 30, 2022).

⁸² U.S. Department of Labor, U.S. Department of Health & Human Services & U.S. Department of the Treasury, *FAQs about Affordable Care Act Implementation Part 53* (April 19, 2022), <https://www.cms.gov/files/document/faqs-part-53.pdf> and <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-53>.

⁸³ U.S. Department of Labor, U.S. Department of Health & Human Services & U.S. Department of the Treasury, *FAQs about Affordable Care Act Implementation Part 61* (September 27, 2023), <https://www.cms.gov/files/document/faqs-about-affordable-care-act-implementation-part-61.pdf> and <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-61>.

⁸⁴ 85 FR 72158, 72161 (November 12, 2020); See Gary Claxton, Lynne Cotter, & Shameek Rakshit, *Challenges with Effective Price Transparency Analyses*, Peterson-KFF Health System Tracker (Feb. 25, 2025), <https://www.healthsystemtracker.org/brief/challenges-with-effective-price-transparency-analyses/>.

items and services based on the number of individuals covered by the corresponding plan or coverage, thereby focusing analysis on prices with the broadest impact on the insured population. Plans with higher enrollments may have a larger impact on negotiated rates, due to relative market power, approximate size of the overall market, and other factors. Additionally, this contextual information would expand opportunities to conduct analysis and compare rates across “like” plans. The Departments understand, based on feedback from interested parties, that enrollment data would be particularly useful in analyzing the small group and individual markets, where small differences may have pronounced impacts on trends and patterns. The Departments are specifying that the numerical enrollment totals must include the number of participants, beneficiaries, and enrollees (including all dependents) to distinguish from other reporting requirements plans and issuers are required to comply with.

Therefore, the Departments have determined that requiring disclosure of this additional data in the In-network Rate File would provide important context to the health care pricing information and propose to require in new paragraph (b)(1)(i)(E) that plans and issuers are required to disclose enrollment totals for each coverage option they offer represented in the In-network Rate File. These proposed rules would require that plans and issuers include enrollment totals as of the date the In-network Rate File is posted. The Departments seek comment on the feasibility of including the enrollment total as of the date the file is posted and whether an enrollment total on a different specified date would be more feasible for file producers and more useful to the data users. The Departments also solicit comment on this proposal in general.

5. Excluded Provider Information

The Departments propose to add new 26 CFR 54.9815–2715A3(b)(1)(i)(F), 29 CFR 2590.715–2715A3(b)(1)(i)(F), and 45 CFR 147.212(b)(1)(i)(F) to the In-network Rate Files provision that would require plans and issuers to exclude from each In-network Rate File a provider and their negotiated rate (provider-rate combination) for an item or service, if the plan or issuer determines it is unlikely that such provider would be reimbursed for the item or service based on the scope of the provider’s license or area of specialty. The Departments further propose that plans and issuers must make such a

determination using their internal provider taxonomy that is typically used during the claims adjudication process. The Departments have determined that excluding provider-rate combinations that are not likely to result in a reimbursement is necessary to limit unnecessary information that inflates file size and limits the accessibility of the data in the In-network Rate File.

These proposed rules at paragraph (b)(1)(i)(F) would require plans and issuers to use their internal provider taxonomy that is typically used during the claims adjudication process to determine which provider-rate combinations to exclude from the In-network Rate File. The internal provider taxonomy is part of the claims adjudication workflow, in which the plan or issuer assesses whether the billed item or service (represented by a billing code) aligns with the specialty of the rendering provider (represented by a provider taxonomy code). If the specialty does not meet the plan or issuer’s requirements for that item or service, the claim may be denied. For example, the Departments expect that a plan or issuer’s internal provider taxonomy would be unlikely to reimburse a claim submitted for a heart surgery submitted from a podiatrist because the billing code associated with a heart surgery would not match with a taxonomy code for a podiatrist.

The Departments understand that it is standard business practice for the internal provider taxonomy maintained by a plan or issuer to identify provider specialties using a standardized code set established by the National Uniform Claim Committee (NUCC).⁸⁵ The NUCC maintains standard provider taxonomy codes, which are used to define a provider’s area of specialty.⁸⁶ Provider taxonomy codes are ten characters in length structured into three distinct “levels” including provider grouping, classification, and area of specialization.⁸⁷ The Departments understand that when a provider submits a claim for reimbursement to a

plan or issuer, the provider must include their NUCC code and the billing code for the item or service along with certain other information. The Departments understand that plans and issuers then compare the NUCC provider taxonomy code and billing code included from the claim against their internal provider taxonomy mappings to determine if the claim can proceed through the next step of the payment adjudication process.

The Departments have observed that several third-party data aggregation vendors successfully demonstrated various methods to efficiently filter existing machine-readable file content by utilizing NUCC provider taxonomy codes, demonstrating these codes can help determine whether a provider is likely going to be eligible for reimbursement for a specific service or procedure.⁸⁸ Therefore, the Departments have determined this may be a viable approach to excluding certain provider-rate combinations.

The 2020 final rules at 26 CFR 54.9815–2715A3(b)(1)(i)(C)(1), 29 CFR 2590.715–2715A3(b)(1)(i)(C)(1), and 45 CFR 147.212(b)(1)(i)(C)(1) require plans and issuers to disclose all applicable rates for in-network providers, including negotiated rates, underlying fee schedule rates, or derived amounts, to the extent they may be used for purposes of determining provider reimbursement or cost-sharing for in-network providers. The 2020 final rules do not specify any exclusions to this requirement. As a result, the Departments have observed and have received feedback that In-network Rate Files often include negotiated rates for providers for items and services that those providers would not likely be reimbursed for because the items and services are outside their specialty (for example, a mental health provider billing for knee replacement).⁸⁹ The Departments understand that plans and issuers frequently negotiate applicable rates at the provider organization level (such as large multi-specialty physician groups or integrated health systems) for every provider who is a member of that organization, regardless of whether that

⁸⁵ The NUCC establishes and maintains standard provider taxonomy codes, which are used to define a provider’s area of specialty. Provider taxonomy codes are ten characters in length structured into three distinct “levels” including provider grouping, classification, and area of specialization. See National Uniform Claim Committee, *Health Care Provider Taxonomy*, <https://www.nucc.org/index.php/code-sets-mainmenu-41/provider-taxonomy-mainmenu-40> (last visited Dec. 8, 2025).

⁸⁶ See National Uniform Claim Committee, *Health Care Provider Taxonomy*, <https://www.nucc.org/index.php/code-sets-mainmenu-41/provider-taxonomy-mainmenu-40> (last visited Dec. 8, 2025).

⁸⁷ See National Uniform Claim Committee, *Health Care Provider Taxonomy*, <https://www.nucc.org/index.php/code-sets-mainmenu-41/provider-taxonomy-mainmenu-40> (last visited Dec. 8, 2025).

⁸⁸ See Sameer Mukhi, *Zombie Hunting: Filtering Approaches for Price Transparency Data*, Serf Health Blog (Sept. 20, 2024), <https://www.serfhealth.com/blog/zombie-hunting-filtering-approaches-for-price-transparency-data/>; Matt Najarian, *Clinically Implausible Rates Are Getting the Boot*, Turquoise Health Blog (Aug. 30, 2023), <https://blog.turquoise.health/clinically-implausible-rates-are-getting-the-boot/>.

⁸⁹ See Sameer Mukhi, *Zombie Hunting: Filtering Approaches for Price Transparency Data*, Serf Health Blog (Sept. 20, 2024), <https://www.serfhealth.com/blog/zombie-hunting-filtering-approaches-for-price-transparency-data/>.

provider would be likely to be reimbursed for that item or service.

Under the 2020 final rules, these rates are required to be disclosed. As a result, the Departments and interested parties have observed that there are many provider-rate combinations that are not meaningful for transparency purposes and impose unnecessary burden on both producers and users of the In-network Rate File. This overinclusion leads to significant file sizes, where In-network Rate Files are consistently enlarged by the inclusion of these unlikely provider-rate combinations. One early examination found that plans and issuers were posting approximately a petabyte (PB)⁹⁰ of information each month, in part due to the inclusion of what it refers to as “clinically implausible rates.”⁹¹ In September 2024, the Departments analyzed a subset of In-network Rate Files and discovered that 73 percent of hematologists’ negotiated rates were for 500 billing codes for services for which they would be unlikely to be reimbursed for. Another researcher reported that 96.5 percent of rates reported in the In-network Rate Files were for services with respect to providers who would be unlikely to be reimbursed for those services based on their specialty.⁹² The Departments understand from feedback from interested parties that excessive file size creates network bandwidth and data storage problems for file producers and users alike, including significant costs associated with hosting, downloading, or analyzing significant amounts of data.

In addition, the Departments understand that excess data of limited use poses an unnecessary barrier to analyzing these files for users seeking to understand health care price variation, and to carrying out research on pricing data.⁹³ For example, one researcher

identified a negotiated rate for a Caesarean section (C-section) for a neurological institute that was almost ten times the median rate for a C-section in that geographic region.⁹⁴ The researcher identified that the neurological institute must share the same rate for a C-section with all the providers in their parent organization per their contract even though neurologists would be unlikely to be reimbursed for a C-section.⁹⁵ These rates may distort patterns, averages, and medians when conducting market-wide analyses, leading to an inaccurate understanding of health care prices.⁹⁶

The Departments recognize that the 2020 final rules specifying that plans and issuers disclose all negotiated rates for all covered items and services for all in-network providers have led to the disclosure of rates beyond what was intended by the Departments. The Departments have determined that excluding provider-rate combinations for services that providers are unlikely to perform or be reimbursed for—because they fall outside their specialty—would significantly reduce the size of the In-network Rate Files. This significant decrease in file size would also reduce the storage space and computer processing resources needed to generate, store, and analyze In-network Rate Files, reducing burden for file producers and users alike.

Therefore, the Departments propose to revise the content requirements for the In-network Rate File to require plans and issuers to exclude provider-rate combinations for an item or service if the provider would be unlikely to be reimbursed for the item or service given the provider’s area of specialty, according to the plan’s or issuer’s internal provider taxonomy that is typically used during the claims adjudication process.

In order for users of the In-network Rate Files to understand how plans and issuers constructed the files according to this new proposed requirement, the Departments also propose to add new 26 CFR 54.9815–2715A3(b)(2)(iii), 29 CFR 2590.715–2715A3(b)(2)(iii), and 45 CFR 147.212(b)(2)(iii), to require plans and issuers to publish a taxonomy machine-readable file. As discussed in more

detail in section III.C.7. of this preamble, this new machine-readable file would disclose the mapping of billing codes to internal provider taxonomy codes, providing transparency into how plans and issuers determined which provider-rate combinations for covered items and services have been excluded from the In-network Rate Files based on the plan’s or issuer’s taxonomy rules.

The Departments seek comment on all aspects of this proposal. The Departments are particularly interested in feedback from interested parties on whether there are plans or issuers that do not map provider specialties to billing codes within their claims adjudication process or use different code sets, and whether there could be a way to standardize the provider specialty mapping to billing code process. The Departments are also interested in whether there are alternative approaches to excluding any provider that has a rate for an item or service that interested parties consider to not be a meaningful rate. While the Departments have included a discussion of some potential alternatives in section VI.D.2. of this preamble, the Departments are interested in feedback from interested parties on the relative burdens and benefits of alternative approaches to both producers and file users. The Departments are also interested in any concerns that parties may have with a proposal to require plans and issuers to make such exclusions at all. For instance, do file users have concerns about plans and issuers intentionally or inadvertently over-excluding provider-rate combinations from the In-network Rate File? Additionally, do file users recommend alternative approaches to best achieve the goals of transparency as set out in the 2020 final rules? For example, are there alternative approaches that will help meet the Departments’ goals of limiting unnecessary information that inflates file size, without limiting the accessibility of the data, and promoting meaningful transparency of in-network rate pricing information?

6. Out-of-Network Allowed Amount Machine-Readable File

The Departments propose to make several amendments to the Allowed Amount File provision at 26 CFR 54.9815–2715A3(b)(1)(ii), 29 CFR 2590.715–2715A3(b)(1)(ii), and 45 CFR 147.212(b)(1)(ii) to increase the amount of historical out-of-network claims data disclosed in the files, including a proposal to lower the threshold for including claims from 20 to 11 different

⁹⁰ One petabyte (PB) is a unit of digital information equal to 1,000 terabytes (TB) in the decimal system (or 1,000,000 gigabytes (GB)). In binary terms, which is sometimes used in computing, 1 PB equals 1,024 terabytes.

⁹¹ Adam Geitgey, *A Petabyte of Health Insurance Prices Per Month*, *Turquoise Health Blog* (July 11, 2023), <https://blog.turquoise.health/a-petabyte-of-health-insurance-rates-a-month/>.

⁹² See David Muhlestein, *Improving Price Transparency Data: Recommendations From Practice*, *Health Affairs Forefront* (Mar. 19, 2025), <https://www.healthaffairs.org/content/forefront/improving-price-transparency-data-recommendations-practice>.

⁹³ See Gary Claxton, Lynne Cotter, & Shameek Rakshit, *Challenges with Effective Price Transparency Analyses*, *Peterson-KFF Health System Tracker* (Feb. 25, 2025), <https://www.healthsystemtracker.org/brief/challenges-with-effective-price-transparency-analyses/>; See also David Muhlestein, *Improving Price Transparency Data: Recommendations From Practice*, *Health Affairs Forefront* (Mar. 19, 2025), <https://www.health>

[affairs.org/content/forefront/improving-price-transparency-data-recommendations-practice](https://www.healthaffairs.org/content/forefront/improving-price-transparency-data-recommendations-practice).

⁹⁴ See Adam Stein, *Beyond the Trillion Prices: Pricing C-Sections in America*, *D01thUb Blog* (Oct. 13, 2022), <https://www.dolthub.com/blog/2022-10-03-c-sections/>.

⁹⁵ *Id.*

⁹⁶ See James Hines, *Zombie Rates: A Data-Driven Approach to Healthcare Price Transparency*, *Gigasheet Blog* (Jan. 27, 2025), <https://www.gigasheet.com/post/price-transparency-zombie-rates>.

claims per item or service, a proposal to increase the reporting period from 90 days to 6 months, a proposal to increase the lookback period from 180 days to 9 months, and a proposal to require reporting at the health insurance market level, rather than the plan or policy level. Lastly, the Departments propose to remove the phrase “and provider” from paragraph (b)(1)(ii)(C) to clarify that the claims threshold pertains to the number of claims for an item or service overall for the file, not the number of claims for an item or service from a particular provider.

The 2020 final rules at paragraph (b)(1)(ii)(C) require plans and issuers to disclose on a public website a machine-readable file that includes, among other things, each unique out-of-network allowed amount with respect to covered items or services furnished by a particular out-of-network provider during the 90-day time period that begins 180 days prior to the publication date of the Allowed Amount File. In addition, plans and issuers must omit such data in relation to a particular item or service and provider when including it would require the plan or issuer to report payment of out-of-network allowed amounts in connection with fewer than 20 different claims for payments for an item or service under a single plan or coverage.⁹⁷ Current rules at paragraph (b)(4)(iii) also permit, but do not require, plans and issuers to satisfy the public disclosure requirements of paragraph (b)(1)(ii) by making available out-of-network allowed amount data that has been aggregated to include information from more than one plan or policy, under certain circumstances.

a. Reducing the Claims Threshold

Initially, the Departments established the 20-claims threshold to limit the possibility that individual participants, beneficiaries, and enrollees may be identified through the public disclosure of historical allowed amount data. In the 2019 proposed rules, the Departments proposed to require plans and issuers to omit out-of-network allowed amounts from the Allowed Amount File in relation to a particular item or service and provider when including this data would require the plan or issuer to report payment of out-of-network allowed amounts in connection with fewer than 10 different claims for payments.⁹⁸ The Departments requested comment on whether a higher minimum

claims threshold, such as a threshold of 20 claims, would better mitigate privacy concerns and minimize complexity in complying with Federal or State privacy laws without compromising the integrity of the compiled information.⁹⁹ As discussed in the 2020 final rules, some commenters expressed concerns about maintaining Health Insurance Portability and Accountability Act (HIPAA) protections on the Allowed Amount File due to the small number of claims associated with specific items and services for out-of-network providers.¹⁰⁰ Several commenters stated that the threshold of 10 different claims to require public disclosure of unique historical allowed amounts would be too low to protect consumers’ protected health information. Based on commenters’ concerns, the Departments determined that increasing the claims threshold from 10 to 20 claims in the 2020 final rules would better balance the policy goal of transparency with the need to protect participants, beneficiaries, and enrollees from the possibility of being re-identified through the data included in the Allowed Amount File.¹⁰¹

The Departments clarified in technical implementation guidance that while a plan or issuer with fewer than 20 claims for a particular item or service must omit information on payment of out-of-network allowed amounts for that item or service, the Allowed Amount File must still be produced pursuant to paragraph (b)(1)(ii)(C); however, information in the file would be minimal due to the lack of information to report.¹⁰² The Departments reasoned that the file must be created so that file users know that the plan or issuer does not have any claims that meet the 20-claims threshold, and that maintenance of such files would be minimal.¹⁰³

Since the publication of the 2020 final rules, however, the Departments have received feedback and observed that many plans and issuers produce Allowed Amount Files with limited to

no out-of-network claims data, which the Departments have determined is due in part to the 20-claims threshold. Given the limited data available, file users are unable to perform meaningful analyses using out-of-network data.¹⁰⁴ This is because there are too many “gaps” in out-of-network data in the file, which occur whenever there are fewer than 20 claims for a specific out-of-network item or service for a given plan.

Out-of-network price transparency data is vital for employers, researchers, and regulators to analyze health care spending, benchmark costs, and inform future policy decisions. This data offers new insight into actual health care expenditures, including a window into the price of an item or service in the context of an arms-length transaction between a provider and a plan or issuer who have not negotiated the rate, and where there is therefore no discount associated with the advantage to a provider of being “in network.”¹⁰⁵ Employers and plan sponsors can use this data to benchmark costs, refine benefit designs, and negotiate more effectively with administrators. Health care providers and service providers can use it to estimate what they might be reimbursed and what their patients or their participants, beneficiaries, or enrollees, respectively, might be charged for out-of-network care.¹⁰⁶

Therefore, to increase the volume of allowed amount data available, the Departments propose to amend paragraph (b)(1)(ii)(C) to lower the minimum claims threshold for a particular item or service under a single plan or coverage to 11 different claims for a particular item or service in a single health insurance market. The proposed 11-claims threshold would align with the CMS cell suppression policy, which sets minimum thresholds for the display of CMS data by researchers or other custodians of CMS data sets, such as Limited Data Set (LDS) files.¹⁰⁷ The policy stipulates that

¹⁰⁴ Matthew Robben, *Learnings from MRF Land*, Serif Health Blog (Mar. 31, 2023), <https://www.serifhealth.com/blog/learnings-from-mrf-land>.

¹⁰⁵ Zack Cooper, Hao Nguyen, Nathan Shekita & Fiona Scott Morton, *Out-of-Network Billing and Negotiated Payments for Hospital-Based Physicians*, 39 Health Affairs 24 (2020) (published Dec. 16, 2019), <https://www.healthaffairs.org/doi/10.1377/hlthaff.2019.00507>.

¹⁰⁶ Rebecca Hodes, *Demystifying “Allowed Amounts” in Out-of-Network Billing*, Mentaya Blog (Apr. 1, 2025), <https://www.mentaya.com/blog/demystifying-allowed-amounts-in-out-of-network-billing>.

¹⁰⁷ Centers for Medicare & Medicaid Services, *Limited Data Set (LDS) Files*, <https://www.cms.gov/data-research/files-for-order/data-disclosures-and-data-use-agreements-duas/limited-data-set-lds> (last modified July 7, 2025); Research Data Assistance Center (ResDAC), *CMS Cell Size Suppression Policy*

⁹⁷ 26 CFR 54.9815–2715A3(b)(1)(ii)(C), 29 CFR 2590.715–2715A3(b)(1)(ii)(C), and 45 CFR 147.212(b)(1)(ii)(C).

⁹⁸ 84 FR 65464, 65481 (November 27, 2019).

⁹⁹ *Id.*

¹⁰⁰ 85 FR 72158, 72233 (November 12, 2020).

¹⁰¹ *Id.*

¹⁰² Centers for Medicare & Medicaid Services, *Technical Clarifications Question 23: After we compile all our allowed amounts and billed charges for the Allowed Amount file, how do we adjust the file to make sure we have taken into account the 20-claim threshold?*, <https://www.cms.gov/priorities/healthplan-price-transparency/overview/resources/technical-clarification> (last visited Dec. 8, 2025).

¹⁰³ Centers for Medicare & Medicaid Services, *Technical Clarifications Question 15: If a plan does not meet the 20-claim threshold for any of its allowed amounts, must a file be produced?*, <https://www.cms.gov/priorities/healthplan-price-transparency/overview/resources/technical-clarification> (last visited Dec. 8, 2025).

no cell (such as admittances, discharges, patients, services, etc.) containing a value of 1 to 10 can be reported directly.¹⁰⁸ This policy is a safeguard designed to prevent the identification of individual Medicare or Medicaid beneficiaries when CMS data is shared publicly¹⁰⁹ and helps ensure compliance with Federal privacy laws, such as HIPAA, by reducing the risk of re-identification of individuals from aggregated data.

The Departments have determined that the proposed 11-claims threshold, combined with the proposal to require reporting by health insurance market type discussed later in this section of the preamble, would provide sufficient protection against the disclosure of sensitive patient information. Under the proposal to require reporting by health insurance market type, data disclosed in the Allowed Amount Files would not be directly associated with a single plan or policy when two or more plans or policies are aggregated into one file (as discussed in more detail later in this section of the preamble). Instead, the data would be aggregated to a broader health insurance market type (such as “individual market” or “large group market”). For example, a unique allowed amount and billed charge for a given item or service furnished by a given provider might be associated with “Large Group Market offered by Insurer A,” rather than “Insurer A’s Employer X Gold PPO Plan.” This high-level aggregation would provide a strong shield for patient privacy.

Additionally, the Departments also note that, as specified in current paragraph (b)(1)(ii)(C), disclosure of such information would not be required if doing so would violate applicable health information privacy laws. This is consistent with paragraph (c)(3), which specifies that, among other things, nothing in 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, or 45 CFR 147.212 alters or otherwise affects a plan’s or issuer’s duty to comply with requirements under other applicable State or Federal laws, including those governing the privacy or security of information required to be disclosed under this section.

As such, the Departments have determined that lowering the claims threshold in this way would strike a better balance between protecting sensitive health information and allowing for a more comprehensive and

useful dataset to support the end goals of price transparency.

Lastly, the Departments propose to delete “and provider” from the parenthetical language in (b)(1)(ii)(C) to more clearly specify that the claims threshold pertains to the number of claims for an item or service overall for the file, not the number of claims for an item or service from a particular provider. This change would reflect the Departments’ current policy (other than the proposed changes to this paragraph discussed elsewhere in this section of the preamble), and is proposed as a technical clarification.¹¹⁰ The parenthetical in paragraph (b)(1)(ii)(C) would be revised to specify that a plan or issuer must omit out-of-network allowed amount and billed charge data in relation to a particular item or service if including it would require the plan or issuer to report payment of out-of-network allowed amounts in connection with fewer than 11 different claims for payment of that item or service in a single health insurance market. The Departments seek comment on this proposal.

b. Increasing the Reporting Period

The Departments also propose to amend paragraph (b)(1)(ii)(C) to specify that plans and issuers would be required to include in the Allowed Amount File allowed amounts and billed charges with respect to covered items or services furnished by out-of-network providers during the 6-month time period that begins 9 months prior to the publication date of the file. This amendment would increase the reporting period from 90 days to 6 months and increase the lookback period from 180 days to 9 months. In the preamble to the 2020 final rules, the Departments noted that they would monitor the implementation of the lookback period for the Allowed Amount Files and may revisit it if the 90-day reporting period and 180-day lookback period failed to yield sufficient out-of-network data on allowed amounts.¹¹¹ By approximately doubling the reporting period from 90 days to 6 months and shifting the lookback period from 180 days to 9 months, the Departments expect that more out-of-network claims for items and services would meet the required threshold for

reporting requirements, meaning there would be more data to populate the Allowed Amount Files.

The Departments welcome comment on all aspects of this proposal. The Departments are also particularly interested in feedback on the impact of the proposed amendment to the required reporting cadence (proposed to be quarterly as discussed in section III.C.10. of this preamble) on the proposed changes to the lookback period. For example, since the proposed quarterly reporting period would require reporting 6 months’ worth of data every 3 months, the Departments seek comment on whether a potential duplication of out-of-network allowed amounts across multiple files would present any difficulties for the analysis of the data, such as calculating averages or annual amounts.

c. Aggregating Data by Requiring Reporting by Market Type

Lastly, the Departments propose to amend the introductory language in paragraph (b)(1)(ii) to require plans and issuers to aggregate their allowed amount reporting at the health insurance market level (as defined in proposed new 26 CFR 54.9815–2715A1(a)(2)(xi), 29 CFR 2590.715–2715A1(a)(2)(x), and 45 CFR 147.210(a)(2)(xi) and discussed in section III.A. of this preamble). Specifically, under paragraph (b)(1)(ii), plans and issuers would be required to make available an Allowed Amount File for each health insurance market in which a plan or coverage is offered. The Departments also propose to make conforming amendments in paragraphs (b)(1)(ii)(A) through (C) to indicate that each Allowed Amount File for a given health insurance market must include information aggregated across the coverage options offered by the plan or issuer in that market, rather than all coverage options offered by the plan or issuer.

The Departments have received feedback from interested parties indicating that aggregating health insurance out-of-network claims by health insurance market type—specifically (1) individual market, (2) large group market, (3) small group market, and (4) self-insured group health plans maintained by the same plan sponsor—provides a structured approach to organizing and analyzing claims data. Interested parties suggested that this categorization would be useful because pricing dynamics and reimbursement rates tend to vary by

(Jan. 26, 2024), <https://resdac.org/articles/cms-cell-size-suppression-policy>.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ Centers for Medicare & Medicaid Services. *Technical Clarifications Question 23: After we compile all our allowed amounts and billed charges for the Allowed Amount file, how do we adjust the file to make sure we have taken into account the 20-claim threshold?*, <https://www.cms.gov/priorities/healthplan-price-transparency/overview/resources/technical-clarification> (last visited Dec. 8, 2025).

¹¹¹ 85 FR 72158, 72230 (November 12, 2020).

market segments.¹¹² Therefore, the Departments expect that organizing out-of-network allowed amounts in this way would facilitate a more comprehensive assessment of the volume and characteristics of out-of-network claims and enhance the data's utility for users by aligning it with the distinct pricing structures and regulatory environments of each market type. It would also make comparing allowed amounts for plans and policies within the same market easier for file users.

If this proposed amendment is finalized, the Departments also anticipate a significant reduction in the overall number of Allowed Amount Files (since these would be reported at the market level, rather than at the plan level), even as those data files become more populated. Additionally, this approach would further protect patient privacy, as discussed earlier in this section of the preamble, because data aggregated across two or more plans or policies would not be directly associated with a single plan or policy.

On the other hand, the Departments acknowledge that requiring market-level aggregation may limit or eliminate the ability of file users to map specific allowed amounts and billed charges to an individual plan or policy. However, plans and issuers would still be required under paragraph (b)(1)(ii)(A) to disclose information about the plans or policies whose allowed amounts are included in each file. Therefore, file users would be able to determine which plans or policies have allowed amounts included in the Allowed Amount File, even if they would be unable to match a specific out-of-network allowed amount to a particular plan or policy. The Departments have determined that the advantages of having more populated Allowed Amount Files at the market level would outweigh the drawbacks of missing plan-level data. The Departments seek comment on what additional information might be limited or lost by aggregating allowed amount and billed charges data by health insurance market type, and the potential importance of that information to price transparency. The Departments

also invite comments more broadly on the proposal to require reporting of out-of-network allowed amount data by health insurance market type.

Lastly, the Departments are also proposing special aggregation rules for self-insured group health plans, which are described in more detail in section III.C.11. of this preamble. The Departments request comment on all aspects of these proposals. For a discussion of the Departments' proposal to amend paragraph (b)(1)(ii)(A) related to disclosing HIOS IDs and product types in Allowed Amount Files, see section III.C.2. of this preamble.

7. Contextual Files: Change-log, Utilization, Taxonomy, and Text

The Departments propose to require plans and issuers to publicly disclose, through machine-readable files, additional contextual information that would help file users better understand the public disclosures required under paragraph (b)(1)(i). These files, which include a Change-log File, Utilization File, and Taxonomy File would contain information about the data within the In-network Rate and Allowed Amount Files. The Departments also propose to require a contextual machine-readable file to help users find the In-Network Rate, Allowed Amount, and prescription drug machine-readable files required under paragraph (b)(1) and new paragraph (b)(2) of this section, which the Departments are proposing to identify as a Text File.¹¹³ In particular, the Departments propose to amend 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212 to redesignate paragraphs (b)(2) through (4) as paragraphs (b)(3) through (5), respectively, and to add new paragraph (b)(2) to require contextual files. Specifically, the Departments propose to add new paragraphs (b)(2)(i) through (iv) requiring: a Change-log File at paragraph (b)(2)(i), a Utilization File at paragraph (b)(2)(ii), a Taxonomy File at paragraph (b)(2)(iii), and a Text File at paragraph (b)(2)(iv).

The 2020 final rules at 26 CFR 54.9815–2715A3(b), 29 CFR 2590.715–2715A3(b), and 45 CFR 147.212(b)

require plans and issuers to make available on a public internet website the disclosure of health care pricing information in machine-readable files, in accordance with specific manner and format requirements. In particular, the Departments require plans and issuers to disclose in-network provider rates, out-of-network allowed amounts and the associated billed charges and negotiated rates and historic net prices for prescription drugs. In the 2020 final rules, the Departments recognized the necessity of public disclosure of health care pricing information due to the variation in health care prices across the health care industry and the complexity of health insurance and health plan coverage.¹¹⁴

While price disclosures required in the 2020 final rules contributed to a broader understanding of the data that drives plan and issuer payments for health care items and services, the intervening years demonstrated that additional context is necessary to promote a fuller understanding of health care industry pricing dynamics. These proposed additional files would help make the data disclosures of the machine-readable files required under paragraph (b)(1) more meaningful and accessible, which would promote greater transparency in health care pricing information. Under this proposal, plans and issuers would be required to prepare a Change-log File, a Utilization File, and a Taxonomy File for each In-network Rate File prepared pursuant to these proposed rules, and a single Text File to facilitate locating the other machine-readable files required under these proposed rules. Each Change-log File would reflect changes in data from one In-network Rate File (under these proposed rules, prepared for a specific provider network) to the publishing of the next In-network Rate File; each Utilization File would reflect utilized covered items and services under the plans and policies represented in one In-network Rate File; and each Taxonomy File would represent the mapping of billing codes to internal provider taxonomy codes used as part of the claims adjudication

¹¹² There is evidence of consistent alignment within market types and significant divergence between market types when comparing allowed amounts relative to a common benchmark (Medicare). This pattern holds even for in-network prices. Out-of-network allowed amounts often derive from similar underlying cost structures. Caroline Hanson, Ian McCarthy, Eamon Molloy & Karen Stockley, *Providers Paid Substantially Less by Marketplace Nongroup Insurers Than by Employer Small-Group Plans*, 2021, 43 Health Affairs 1672 (Dec. 20, 2024), <https://www.healthaffairs.org/doi/10.1377/hlthaff.2024.00913>.

¹¹³ As previously mentioned, several proposed amendments would amend requirements related to the prescription drug machine-readable files, specifically: the requirement that plans and issuers must include a plain text file in a .txt format in the root folder of a plan's or issuer's website as describe in proposed paragraphs (b)(2)(iv) of 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212 (section III.C.7.d of this preamble) and the requirements related to the method and format for disclosing information to the public as described in proposed paragraph (b)(3) of 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212 (section III.C.9 of this preamble).

¹¹⁴ The 2020 final rules stated that “many consumers do not fully comprehend the basics of health coverage, much less the more complex facets of the health care system that can affect an individual's out-of-pocket cost for items and services, including: Its specialized billing codes and payment processes; the various specialized terms used in plan and coverage contracts and related documents (such as copayment and coinsurance); and the various billing and payment structures plans and issuers use to compensate providers and assign cost-sharing liability to individuals (for example, bundled payment arrangements).” 85 FR 72158, 72210 (November 12, 2020).

process for the plans and policies represented in the In-network Rate File. Each Text File would direct users to the location of the machine-readable files required under paragraphs (b)(1) and (2) and provide contact information for an individual who can address inquiries and issues related to the required machine-readable files. To ensure this data can be imported and read by a computer system directly, without reliance on proprietary software, and to promote standardization, these contextual files would also need to be machine-readable, in the form and manner as specified in guidance pursuant to proposed re-designated paragraph (b)(3)(i).

a. Change-log File

The Departments propose to require, in new 26 CFR 54.9815–2715A3(b)(2)(i), 29 CFR 2590.715–2715A3(b)(2)(i), and 45 CFR 147.212(b)(2)(i), that plans and issuers must make available, in a machine-readable format, a Change-log File for each In-network Rate File, that identifies any changes made to the required information in the In-network Rate File since the immediately preceding published In-network Rate File. The proposed Change-log File would be required to be publicly posted in the form as specified in guidance issued by the Departments, consistent with redesignated and amended paragraph (b)(3) and discussed in section III.C.9. of this preamble. It would be required to be posted in accordance with the timing requirements proposed at redesignated paragraph (b)(4)(iii) and discussed in section III.C.10. of this preamble. Specifically, it would be required to be posted on the first day of the calendar-year quarter following the date on which the first In-network Rate File would be required to be posted under proposed paragraph (b)(4)(i).¹¹⁵ The purpose of the proposed Change-log File would be to assist all file users in identifying changes to the required information in the In-network Rate File from one reporting period to the next. Pursuant to the proposed requirement to publish the In-network Rate File described at (b)(1)(i) quarterly, the updated Change-log File would also be required to be published quarterly, indicating whether or not there were changes.

The total amount of information contained in every plan's and issuer's set of machine-readable files is extremely large,¹¹⁶ creating challenges

for file users of all backgrounds in ingesting and analyzing the information. Therefore, rather than downloading and analyzing each set of newly posted files to determine if there have been any changes to the required information in a plan's or issuer's In-network Rate File, file users would only need to look at the Change-log File to determine which new files they need to examine. These proposed rules would create efficiencies for file users by reducing the amount of required data storage for file users and save time by eliminating the need to review data that has not changed. This would also allow researchers and other interested parties to more easily track changes over time.

The Departments seek comment on how the Change-log File can be most effective, including what machine-readable file format it should be required to be published. The Departments also seek comment on if any specific information should be required to be included, and if so, what information should be required to be included in the Change-log File. For example, the Departments are interested in feedback from interested parties on whether the Change-log File should only identify the information in the file that has changed between one reporting to the next or if it should also identify how the specific information has changed since the last reporting. The Departments also seek comment on whether there are particular data elements that, when changed, should not be captured in the Change-log File so as to maximize the usefulness of the reporting. The Departments expect that plans and issuers would likely incur a burden from having to create this new file and develop a system for identifying changes, therefore the Departments are interested in the minimal level of change information necessary to create the desired efficiencies. For instance, the Departments assume that identifying changes to rate information from one In-network Rate File to the next is critical to the usefulness of the Change-log File but are less certain of the relative benefits and drawbacks of requiring plans and issuers to identify less material changes, such as minor changes to the plain language description for each billing code. The Departments also seek comment on the specific burdens to plans and issuers for the different possibilities for a Change-log File.

b. Utilization File

The Departments propose to require at new paragraphs 26 CFR 54.9815–2715A3(b)(2)(ii), 29 CFR 2590.715–2715A3(b)(2)(ii), and 45 CFR 147.212(b)(2)(ii), that plans and issuers must make available in a machine-readable format an annual Utilization File for each In-network Rate File specified under paragraph (b)(1)(i), that includes, for the 12-month period that ends 6 months prior to the publication of each Utilization File: items and services covered under the plans or policies included in the files prepared as specified in proposed amended paragraph (b)(1)(i) for which a claim has been submitted and reimbursed, in whole or in part, and each in-network provider identified by the National Provider Identifier (NPI), Tax Identification Number (TIN), and Place of Service Code who was reimbursed, in whole or in part, for a claim for each covered item or service included as specified in paragraph (b)(2)(ii)(A) of this section. The Utilization File would be required to be published in the form and manner specified in proposed redesignated paragraph (b)(3) and discussed in section III.C.9. of this preamble and in accordance with the timing requirements proposed at redesignated paragraph (b)(4)(iv) and discussed in section III.C.10. of this preamble. Specifically, it would be required to be updated and posted annually beginning on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1). Plans and issuers would be required to update and post the Utilization File in accordance with the timing requirements proposed at redesignated paragraph (b)(4)(iv) and discussed in section III.C.10. of this preamble.

The Departments have determined that the Utilization File would provide important insights, both as a stand-alone dataset, as well as in combination with the In-network Rate File. On its own, the Utilization File would reveal which providers are actively serving enrollees and delivering covered items and services within a plan's or issuer's network. If a provider appears in a plan's or issuer's In-network Rate File but does not appear in the plan's or issuer's Utilization File, then users may reasonably conclude that that provider, despite having a negotiated rate, has had no recent interactions with that plan's or issuer's participants, beneficiaries, or enrollees. This type of analytical approach to the Utilization File would provide empirical evidence regarding which providers are actively providing

¹¹⁵ See Table 2 for an example.

¹¹⁶ Gary Claxton, Lynne Cotter, & Shameek Rakshit, *Challenges with Effective Price*

Transparency Analyses, Peterson-KFF Health System Tracker (Feb. 25, 2025), <https://www.healthsystemtracker.org/brief/challenges-with-effective-price-transparency-analyses/>.

covered items and services to participants, beneficiaries, or enrollees and billing for items or services within a plan's network, as opposed to relying on static provider directories, which can be over-inclusive when describing providers' availability. In turn, the Utilization File could aid consumers in understanding whether certain providers are actually available (whether they are actively seeking new patients or have the capacity to accept new patients) to provide covered items and services to participants, beneficiaries, and enrollees under certain plans.

Extending this type of analysis to all providers for a plan or issuer's network could provide important insights into network adequacy. For example, a plan's In-network Rate File might include many providers who, in theory, deliver a wide range of services in a particular geographic area. However, if the Utilization File reveals that those providers are not actually delivering those services, then this could indicate whether health plans are offering a sufficient and accessible network of providers for the services their members use.

The Utilization File could also provide insights into the types of services performed by specific providers, by indicating whether those providers perform more routine procedures within their field of expertise or instead concentrate on rarer or more complex procedures. This type of analysis performed with the Utilization File could reveal whether networks in specific geographic areas have larger pools of providers performing certain procedures, thereby offering valuable insights into regional provider availability and specialization. Such insights into provider specialization would not be evident from the In-network Rate File alone, since that file lists negotiated rates for all services, regardless of whether a specific provider actually performs them.

The Departments have determined that taken together, these examples of analyses that could be performed with the Utilization File suggest that this file would become a valuable transparency resource for researchers, regulators, consumer-facing decision-tool makers, and other interested parties, who could help consumers benefit from a more accurate picture of provider service patterns, along with the information published in the In-network Rate Files. Some organizations that currently use the In-network Rate Files already combine the data in those files with utilization data from other sources to

conduct these types of analyses.¹¹⁷ But by requiring plans and issuers to generate and publish Utilization Files, this pairing of in-network rates to actual utilization would become more widely and consistently available to users of the Transparency in Coverage pricing data. Finally, the Utilization Files would act as an important qualifier to the data disclosed in the In-network Rate Files, by providing a strong indication of the degree to which negotiated rates are used by providers to deliver actual services to health plan enrollees.

Under this proposed requirement, plans and issuers would not be required to disclose the number of times that any given provider submitted a claim for any particular item or service, but rather only that a given provider submitted and was reimbursed, partially or in whole, for at least one claim for a covered item or service during the reporting period. The Departments have determined this appropriately balances the need for additional transparency around which in-network providers are actively providing a covered item or service with the burden on plans and issuers associated with extracting data from a claims data repository. The Departments recognize that because plans and issuers would not be required to disclose the number of items and services performed by specific providers, the Utilization File would be limited in its ability to address some research questions that might be of interest to some interested parties. As such, the Departments request comment on whether the inclusion of the volume of items and services performed by an in-network provider would be a valuable addition to the Utilization File. The Departments also request comment on whether additional data elements, such as metrics analyzing a plan or overall percentage of providers with zero utilization for the lookback period should be included in order to make it easier for file users to examine provider network adequacy. The Departments also request comment on the burden to plans and issuers to produce a Utilization File with claims volume and any additional metrics included in the files, as well as comments on how to mitigate these concerns.

The Departments are also proposing at 26 CFR 54.9815–2715A3(b)(2)(ii), 29 CFR 2590.715–2715A3(b)(2)(ii), and 45 CFR 147.212(b)(2)(ii), to require the Utilization File to include data for the 12-month period that ends 6 months

prior to the publication date of each Utilization File, to allow for enough time for plans and issuers to complete the claims processing lifecycle including pre-claim submission, pre-claim payment, and payment determination and collection.¹¹⁸ This figure is obtained from research suggesting that claims that take the longest to resolve can take up to 75 days to reach payment determination.¹¹⁹ While 75 days is considerably shorter than 6 months, due to the lack of available metrics on the time it takes payers to complete payment to providers, the Departments propose a longer lookback period to ensure the Utilization File captures all applicable payments.

The Departments request comment on this lookback period.

c. Taxonomy File

The Departments propose at new 26 CFR 54.9815–2715A3(b)(2)(iii), 29 CFR 2590.715–2715A3(b)(2)(iii), and 45 CFR 147.212(b)(2)(iii), to require plans and issuers to make available, in a machine-readable format, a Taxonomy File that includes the plan or issuer's internal provider taxonomy, which maps items and services (represented by a billing code) to provider specialties (represented by specialty code as established by the NUCC) to determine if the plan or issuer should deny reimbursement for an item or service because it was not furnished by a provider in an appropriate specialty. Under these proposed rules and as discussed in section III.C.5. of this preamble, plans and issuers would be required to use their internal provider taxonomy to determine whether to exclude certain provider-rate combinations from the In-Network Rate file because they are unlikely to result in reimbursement, and therefore do not provide useful information to users of the In-network Rate File. The Taxonomy File would be required to include the plan or issuer's internal provider taxonomy mappings and would be required to be published in the form and manner specified in proposed redesignated paragraph (b)(3) and discussed in section III.C.9. of this preamble. Additionally, and as discussed in section III.C.10. of this preamble, the Departments propose to

¹¹⁸ FinThrive, *Understanding the Claims Lifecycle: A Step-by-Step Guide* (Nov. 26, 2024), <https://finthrive.com/blog/understanding-the-claims-lifecycle-a-step-by-step-guide>.

¹¹⁷ Sameer Mukhi, *Zombie Hunting: Filtering Approaches for Price Transparency Data*, Serf Health Blog (Sept. 20, 2024), <https://www.serfhealth.com/blog/zombie-hunting-filtering-approaches-for-price-transparency-data/>.

¹¹⁹ Rajiv Chandawarkar, Prakash Nadkarni, Elizabeth Barmash, Stephany Thomas, et al., *Revenue Cycle Management: The Art and the Science*, 12 Plastic and Reconstructive Surgery Global Open 7 (July 2, 2024).

add paragraph (b)(4)(v) to require plans and issuers to post an updated Taxonomy File quarterly beginning on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1). If there are no changes to the taxonomy that affect the information required in the machine-readable file required under (b)(1)(i) in a subsequent quarter, the posted Taxonomy File would not be required to be updated for that quarter.

The Taxonomy File would provide transparency into how plans and issuers determine whether to exclude certain provider-rate combinations from an In-network Rate File. As explained in section III.C.5. of this preamble, the Departments are proposing to require plans and issuers to exclude from each In-network Rate File a provider-rate combination for an item or service, if the provider would be unlikely to be reimbursed for the item or service given that provider's area of specialty, according to the plan's or issuer's internal provider taxonomy. This is because rates for such items and services generally do not provide useful information to users of the In-network Rate File, and excluding them would improve the reliability of the data reported and significantly reduce the file size.

The Departments have determined that it is necessary to give plans and issuers specific guidance for how to exclude provider-rate combinations for items and services for which the provider would not likely be reimbursed given their practice area of specialty, rather than leaving it to each plan and issuer to determine how to exclude such information. Accordingly, the Departments have determined that plans and issuers should be required to post their internal provider taxonomy mappings in the Taxonomy File.

Requiring plans and issuers to create a separate provider Taxonomy File that discloses their internal provider taxonomy would provide valuable data for file users about the data included in the In-network Rate File. The Taxonomy File would disclose the mapping rules already used by plans and issuers for their claims adjudication process, ensuring that the mapping rules could be available to file users to understand how plans and issuers determined which provider-rate combinations to include in the In-network Rate Files and which to exclude.

In addition to providing critical contextual information to understand the data in the In-network Rate File, the proposed requirement for plans and issuers to provide a Taxonomy File would also offer researchers and other

file users potentially valuable insights into the degree of standardization in mapping used by plans and issuers, and how this varies across different market types. Furthermore, the Taxonomy File would offer new information to potentially guide future rate negotiations between plans and issuers and providers, particularly concerning the scope of reimbursable services by provider type to include in contract discussions.

The Departments solicit comment on the Taxonomy File proposal, including whether there are other provider taxonomy code sets commonly used by plans and issuers other than the ones established by the NUCC or if there are other commonly used processes for plans and issuers to determine which providers should be reimbursed for which types of items and services, based on specialty, and which providers should not. The Departments also seek comment on how frequently plans and issuers update their internal taxonomy used during the claims adjudication process.

d. Text File

The Departments also propose to add paragraphs 26 CFR 54.9815–2715A3(b)(2)(iv), 29 CFR 2590.715–2715A3(b)(2)(iv), and 45 CFR 147.212(b)(2)(iv), requiring plans and issuers to post a plain text file in .txt format (Text File) in the root folder (the top-level directory on an electronic file system) of a plan's or issuer's website that includes: (1) the source page URL for the internet website that hosts machine-readable files required under paragraphs (b)(1) and (2); (2) a direct link to the URL for the machine-readable files required under paragraphs (b)(1) and (2); and (3) point-of-contact information including an up-to-date name, title, and email address for an individual who can address inquiries and issues related to the machine-readable files required under paragraphs (b)(1) and (2).¹²⁰ This contact information must be prominently displayed on the same website where the machine-readable files are made available and be kept updated per the requirements in paragraph (b)(4)(vi) of this section. This information would allow users to more easily locate the plan's or issuer's machine-readable files,

¹²⁰ As previously mentioned, proposed paragraph (b)(2)(iv) (relating to the proposed requirement to include a plain text file in a .txt format in the root folder of a plan's or issuer's website) and (b)(3) (relating to the method and format for disclosing information to the public) of 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212 applies to the prescription drug machine-readable files.

increasing both automated and non-automated access to the machine-readable files. Additionally, and as discussed in section III.C.10. of this preamble, the Departments propose to add paragraph (b)(4)(vi) to require plans and issuers to post a Text File beginning on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1) and subsequently update the Text File as soon as practicable but not later than 7 calendar days following a change in any of the information required under paragraph (b)(2)(iv) of this section.

The Departments have observed and received feedback from interested parties that locating the files on a plan's or issuer's website can be difficult. To assist the public, CMS provided guidance on how to locate machine-readable files on the Transparency in Coverage website.¹²¹ However, in considering how to improve both automated and non-automated access to the machine-readable files, the Departments have determined it is appropriate to require a standardized Text File at a consistent location (specifically, the root folder of the plan's or issuer's website), which would provide a direct link to the machine-readable files as opposed to the current approach of having to locate the correct web page within the website. If a plan or issuer does not have a website, they can satisfy this requirement by entering into a written agreement under which another party (such as a TPA) posts the Text File in the root folder on its public website on behalf of the plan or issuer pursuant to proposed paragraph (b)(3)(iv).

Further, the Departments also received feedback regarding the difficulty of contacting plans and issuers to alert them to problems with their machine-readable files or to ask for additional information or clarifying context. Contact information for someone at the plan or issuer who is familiar with the details of the machine-readable files would allow the public to reach out for assistance with accessing or utilizing the machine-readable files.

Therefore, the Departments propose to require the Text File to include plan or issuer point-of-contact information, who could help in verifying the contents of the machine-readable files and respond to requests for assistance related to accessing and utilizing the machine-

¹²¹ Centers for Medicare & Medicaid Services, *Use of Pricing Information Published Under the Transparency in Coverage Final Rule*, <https://www.cms.gov/priorities/healthplan-price-transparency/overview/use-pricing-information-published-under-transparency-coverage-final-rule> (last modified Aug. 14, 2025).

readable files. The Departments also propose to require that the point-of-contact information be posted prominently on the same web page where the machine-readable files are located to further reduce the difficulty file users have faced in reaching out to plans and issuers for assistance. Under this proposal, and consistent with the flexibility described in redesignated 26 CFR 54.9815–2715A3(b)(3)(iv), 29 CFR 2590.715–2715A3(b)(3)(iv), and 45 CFR 147.212(b)(3)(iv), nothing would prevent a group health plan or health insurance issuer who contracts with a service provider to provide the machine-readable files on their behalf from listing the service provider as a point-of-contact.

The Departments considered whether frequent changes to the host website could negate the benefit to automated access as well as impose burden in creating and maintaining this Text File. The Departments have determined that the benefits outweigh the drawbacks for having a plan or issuer ensure that the public website on which it chooses to host the machine-readable file includes a Text File in the root folder that includes a direct link to the machine-readable files to establish and maintain automated access.

The Departments also propose these new requirements in accordance with Executive Order 14221 Section 3(b), which directs the Departments to “issue updated guidance or proposed regulatory action ensuring pricing information is standardized and easily comparable across hospitals and health plans.”¹²² CMS added new requirements to the 2019 Hospital Price Transparency rule¹²³ in the 2023 Hospital Price Transparency rule.¹²⁴ The 2023 Hospital Price Transparency rule,¹²⁵ which went into effect on January 1, 2024, requires certain hospitals to include a Text File in the root folder of the hospital’s public website that includes a direct link to the hospital’s machine-readable file containing standard charge information and a link in the footer on its website that links directly to the publicly available web page that hosts the link to the machine-readable file. In proposing to adopt a similar requirement, the Departments would align this

requirement with the 2023 Hospital Price Transparency rule¹²⁶ requirement to improve machine-readable file accessibility for the public. Based on feedback on this similar provision for the 2023 Hospital Price Transparency rule,¹²⁷ the Departments have determined this would be a relatively simple, low burden change, and that the increased benefits to the public outweigh the costs.

The Departments request comment on all aspects of this proposal, and in particular on whether the Departments should issue guidance regarding whether any standards are required to ensure that the identified point-of-contact for plans and issuers is responsive to inquiries submitted by file users (such as a timeline to respond to inquiries or designated hours of availability for phone contact, and, if so, the recommended timeline and designated hours) or whether additional forms of contact (such as a physical address) are necessary.

8. File Format

The 2020 final rules at 26 CFR 54.9815–2715A3(b)(2), 29 CFR 2590.715–2715A3(b)(2), and 45 CFR 147.212(b)(2) (which the Departments are proposing to redesignate as paragraph (b)(3) per section III.C.9. of this preamble) state that the machine-readable files described in paragraph (b) must be available in the form and manner as specified in guidance issued by the Departments and must be publicly available and accessible free of charge and without conditions.

In the 2020 final rules, the Departments clarified that this meant all machine-readable files must conform to a non-proprietary, open-standards format that is platform-independent and made available to the public without restrictions that would impede the re-use of the information.¹²⁸

The Departments are not including in these proposed rules any changes to the required format for disclosing information under paragraph (b). The Departments are, however, considering whether to indicate in either rulemaking or technical implementation guidance that the machine-readable files required under paragraph (b) must be published in a single, non-proprietary, open-standards format, and, if so, naming either JavaScript Object Notation (JSON) or Comma Separate Value(s) (CSV) as that single format in technical implementation guidance. As such, the Departments seek input from interested

parties on such potential future rulemaking or technical implementation guidance.

In the 2019 proposed rules, the Departments requested comment on whether the final rules should require a single, specific non-proprietary format for the machine-readable files, specifically JSON files.¹²⁹ The Departments noted that this format generally is easily downloadable, and it could simplify the ability of file users to access the data. The Departments received a comment in support of requiring JSON as the standardized file format for the required machine-readable files. However, in the 2020 final rules, the Departments acknowledged that their internal technical experts agreed that the speed of technology developments weighs heavily in favor of maintaining flexibility to adopt a suitable file format as a non-substantive, operational requirement that will be identified in the relevant implementation guidance for the required machine-readable files.¹³⁰ In addition to maintaining the Departments’ flexibility, the Departments indicated in the 2020 final rules that being overly prescriptive regarding the file type would impose an unnecessary cost on issuers and service providers despite the advantages of JSON.¹³¹ Therefore, the Departments did not require in the 2020 final rules one, specific non-proprietary open format. The Departments did, however, indicate that they would provide additional guidance regarding the file format in future technical implementation guidance.¹³²

When first developing machine-readable file guidance, the Departments considered various file formats that could satisfy the goals of the final rules, including hierarchical, tabular, and columnar formats. The technical implementation guidance hosted on GitHub includes a repository set of schemas describing the data formats (encoded as JSON, Extensible Markup Language (XML), and CSV). The technical implementation guidance was also published as part of the Paperwork Reduction Act (PRA) package developed for the Information Collection Requests (ICRs) included in the 2020 final rules.¹³³ To help plans and issuers understand the machine-readable file requirements, the Departments built a

¹²² Centers for Medicare & Medicaid Services, *Use of Pricing Information Published Under the Transparency in Coverage Final Rule*, <https://www.cms.gov/priorities/healthplan-price-transparency/overview/use-pricing-information-published-under-transparency-coverage-final-rule> (last modified Aug. 14, 2025).

¹²³ 84 FR 65524 (November 17, 2019).

¹²⁴ 88 FR 81540 (November 22, 2023).

¹²⁵ *Id.*

¹²⁶ 88 FR 81540, 82112 (November 22, 2023).

¹²⁷ 88 FR 81540 (November 22, 2023).

¹²⁸ 85 FR 72158, 72242 (November 12, 2020).

¹²⁹ 84 FR 65464, 65481 (November 27, 2019).

¹³⁰ 85 FR 72158, 72242 (November 12, 2020).

¹³¹ 85 FR 72158, 72272 (November 12, 2020).

¹³² *Id.*

¹³³ Transparency in Pricing Information (CMS–10715), OMB control number 0938–1429 (October 14, 2021), https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202410-0938-006.

JSON schema on the Transparency in Coverage GitHub site and provided samples in JSON and XML formats.

After more than 3 years since the publication of the 2020 final rules' machine-readable file requirements, the Departments have had time to analyze the landscape of plan and issuer file format use in published machine-readable files and have considered feedback from interested parties on the viability, benefits, and drawbacks of various file formats. Given that, based on internal analysis, over 90 percent of plans and issuers have chosen one format (that is, JSON), that initial flexibility regarding file type may no longer be needed, and to advance the goals in section 3(b) of Executive Order 13877¹³⁴ to ensure pricing information is standardized and easily comparable across health plans, the Departments are now considering indicating in either rulemaking or technical implementation guidance that the machine-readable files required under paragraph (b)(1) must be published in a standard non-proprietary open format, as well as specifying the particular file format through technical implementation guidance.

The Departments have received feedback in support of specifying either JSON or CSV formats. Both JSON and CSV formats have benefits and drawbacks, and each serves different audiences. JSON is a widely adopted industry standard that allows the machine-readable file data to be accessible to various users and adaptable to various use-cases. In the 2020 final rules, the Departments noted that the machine-readable files' primary benefit to health care consumers will be the availability of web-based tools and mobile applications developed for consumer use by third-party developers, aggregation, and analysis conducted by researchers, and oversight efforts by regulators. The required machine-readable files will be optimal for ingestion, data aggregation, and data analysis, all of which are functions performed by third-party internet-based developers, researchers, and regulators who use large data sets in a manner that will lead to benefits for consumers."¹³⁵ In the 3 years since the publication of the machine-readable file requirements, the Departments have observed the creation of a number of web-based tools developed for consumer use by third-party developers. These developers provided feedback on the benefits and drawbacks of various file formats but largely indicated a preference for using

JSON due to its flexibility and adaptability.

It is the Departments' understanding that JSON's suitability for the broad, high-volume disclosures required pursuant to the Transparency in Coverage rules stems in part from its ability to effectively handle different stages of the process by which raw data is transformed into more user-friendly outputs. This data process, known as Extract, Transform, and Load (ETL), begins with raw data gathered ("extracted") from a range of sources; then cleaned and standardized ("transformed") into a selected format; and then loaded into a repository or database for subsequent uses (and ultimately, for downstream analysis). Different file formats are best suited for different stages of the ETL process. An optimal file format for the machine-readable files would accurately represent the data's underlying relationships through the file format's organizational structure, ensure efficient storage and processing of the data, and make the data accessible to a variety of users with diverse use cases. As applied to the machine-readable files, JSON's strength is its capacity to handle all stages of the ETL process. It is also lightweight and effective for the extraction step from raw data, and it is highly flexible for both the initial transformation step and subsequent transformation of machine-readable file data by downstream users. The widespread use of JSON for the machine-readable files is expected given the advantages of JSON in the data extraction stage, and in efficiently representing the underlying complex relationships in machine-readable file data. Additionally, JSON is widely adopted by industry and government as a common means of data exchanges, and enjoys native support for most programming languages, meaning that these languages and tools already "speak" JSON, limiting the time and effort required to work with JSON-formatted files.

The Departments have also received feedback that many file users, especially researchers, prefer to work with the machine-readable file data in CSV format due to its relative simplicity and accessibility, and that they migrate the data from JSON to CSV in order to conduct analyses. For example, CSV files can include a header row specifying the titles of each subsequent column in the file for visual simplicity. CSV files are highly portable and can be loaded into commonly used tools that do not require engineering capability such as Microsoft Excel and may be a

more familiar format to a wider audience than JSON.

The Departments recognize that both of these file formats have limitations. A JSON format requires users to have some data engineering sophistication to interact with the machine-readable files directly—capabilities and resources that many individuals and organizations may not have. Additionally, working with JSON may require more computing resources than some other formats to process. Other file formats may have attributes that suit the needs of certain users of the machine-readable files better than JSON does. However, the drawback with using CSV or any row-based tabular flat file structure for machine-readable file publishing and consumption of the amount of data that is being generated pursuant to the Transparency in Coverage requirements is that it makes it challenging for a file user with a standard personal computer to load and work with it effectively. For example, those opening large CSV machine-readable files in Microsoft Excel will encounter the software's limitations in how many rows of data can be opened and will often crash the program.¹³⁶ Most significantly, the flat structure of CSV files would force publishers to create numerous columns where the same data values would be repeated up to millions of times per file, which is both inefficient and impractical given current file size concerns by interested parties.

As explained, the Departments are now strongly considering specifying a single, non-proprietary open format in technical implementation guidance. Specifying the file format in technical implementation guidance would reduce flexibility for plans and issuers in selecting alternate file formats but would further standardize reporting of critical health care pricing information. The Departments are of the view that specifying a single format presents an important part of fully realizing the goals of price transparency and Executive Orders 13877 and 14221.¹³⁷ The Departments seek comment on specifying a single, non-proprietary open-source format for the machine-readable files and on the relevant benefits and burdens associated with the CSV and JSON formats. The Departments also seek comment on the

¹³⁴ See Exec. Order No. 13877, 84 FR 30849 (June 27, 2019).

¹³⁵ 85 FR 72158, 72240 (November 12, 2020).

¹³⁶ The average file size from the files sampled during the Departments' two environmental scans was 5 GB. Excel's limit is 1,048,576 rows by 16,384 columns. See <https://support.microsoft.com/en-us/office/excel-specifications-and-limits-1672b34d-7043-467e-8e27-269d656771c3>.

¹³⁷ See Exec. Order No. 13877, 84 FR 30849 (June 27, 2019); See also Exec. Order No. 14221, 90 FR 11005 (February 28, 2025).

Departments' position that specifying a single format in technical implementation guidance, as opposed to regulation, is advisable to maintain maximum flexibility to change formats more quickly to keep pace with technological changes.

Additionally, in recognition of the developments of electronic data transfer systems since the publication of the 2020 final rules and in anticipation of future developments of new technologies, the Departments are revisiting the request for comment made in the 2019 proposed rules regarding a requirement that plans and issuers provide rate information through a publicly accessible API that would comply with standards defined by the Departments.¹³⁸ In light of the publication of the CMS Interoperability and Prior Authorization Final Rule,¹³⁹ the Departments seek comment on whether the required information in paragraphs (b)(1) and (2) should be required to be disclosed through an electronic data transfer technology, such as a publicly accessible API, as well as what standards should apply. The Departments also seek comment on whether the use of a standards-based API would benefit consumers, developers of consumer-facing applications, and other entities seeking to access this data.

9. Required Method and Format for Disclosing Information to the Public

As discussed in section III.C.7. of this preamble, the Departments propose to redesignate paragraphs (b)(2) through (3) of 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212 as paragraphs (b)(3) and (4), respectively. The Departments propose to add paragraph (iii) to redesignated paragraph (b)(3) to require that the source page URL for the internet website that hosts the machine-readable files required by paragraph (b)(1) and new paragraph (b)(2) must be included as a link in the footer on the home page of the group health plan's or health insurance issuer's website, as well as any page of the website that features a footer, that is labeled "Price Transparency" or "Transparency in Coverage" and links directly to the publicly available web page that hosts the link to the machine-readable files.¹⁴⁰ Additionally, in redesignating

paragraph (b)(2) as paragraph (b)(3), the Departments propose to make three changes: first, the Departments propose to divide the existing language in paragraph (b)(2) into two paragraphs at redesignated paragraphs (b)(3)(i) and (ii); second, the Departments propose to indicate that the machine-readable files in paragraphs (b)(1) and (2) (instead of paragraph (b) generally as currently written) must be available in a form and manner as specified in guidance issued by the Departments; and third, the Departments propose to amend redesignated paragraph (b)(3)(ii) to ensure that the machine-readable files remain publicly accessible to automated scripts and web crawlers as well as human users and that blocking server configurations or firewalls cannot be used to impede access. The Departments also propose to add paragraph (iv) at redesignated 26 CFR 54.9815–2715A3(b)(3), 29 CFR 2590.715–2715A3(b)(3), and 45 CFR 147.212(b)(3), allowing a group health plan or health insurance issuer to satisfy the disclosure requirements of paragraph (b)(3)(iii) by entering into a written agreement under which another party posts the machine-readable files on its public website on behalf of the plan or issuer. However, if the files are posted on a service provider's website and the plan or issuer maintains a public website but chooses not to host the files separately on its own public website, it must provide a link on its own public website to the location where the files are made publicly available. This requirement applies to a public website maintained by the plan or issuer and does not apply to a public website maintained by an employer or plan sponsor.

The 2020 final rules at 26 CFR 54.9815–2715A3(b)(2), 29 CFR 2590.715–2715A3(b)(2), and 45 CFR 147.212(b)(2) require plans and issuers to make the machine-readable files described in paragraph (b) of that section available and accessible to any person on a public website in a form and manner as specified in guidance issued by the Departments. In the 2020 final rules, the Departments finalized the proposal to allow plans and issuers flexibility to publish the files in the locations of their choosing based upon their knowledge of their website traffic and the places on their website where the machine-readable files would be readily accessible by the intended users.¹⁴¹ As discussed in section III.C.7. of this preamble, the Departments have observed and received feedback from interested parties that locating the files on a plan's or issuer's website can be

difficult and that there are occasional obstacles to automated and human access.

Therefore, the Departments have determined that they should require the addition of standardized hyperlinks in the footer of a plan's or issuer's website home page, as well as any other page on their website that features a footer, in order to aid file users in the automated and non-automated retrieval of machine-readable files by creating a predictable navigation path to internal web pages that host the machine-readable files posted pursuant to the Transparency in Coverage requirements. Additionally, the Departments propose to amend the existing requirement that the machine-readable files described in paragraphs (b)(1) and (2) must be publicly available and accessible to any person free of charge and without conditions, to specify that they must be publicly available and accessible to any person, automated scripts, or web crawlers free of charge and without conditions such as establishment of a user account, password, submission of personally identifiable information or other credentials, or blocking server configurations or firewalls to access the file. Requiring the machine-readable files to be available to both human and automated users more directly aligns with the purpose of the files being machine-readable. Examples of conditions include a "captcha,"¹⁴² a 403 error,¹⁴³ or limits on the number of downloads allowed by a user or at a time.

Once a human user or automated web crawler arrives at the website of the plan or issuer, they would be able to identify the specific location of the files. The Departments have determined that making this information more easily accessible to automated searches and data aggregation would help third parties to develop tools that further assist the public in understanding this information and capturing it in a meaningful way for making informed health care decisions. Moreover, the Departments have determined that this requirement would be simple for plans and issuers to implement, because plans

¹⁴² See IBM, *What is a CAPTCHA?*, <https://www.ibm.com/think/topics/captcha> (last visited Dec. 8, 2025). ("CAPTCHA stands for 'completely automated public Turing test to tell computers and humans apart.' It refers to various authentication methods that validate users as humans, not bots, by presenting a challenge that is simple for humans but difficult for machines.")

¹⁴³ See Mozilla, *403 Error*, <https://developer.mozilla.org/en-US/docs/Web/HTTP/Reference/Status/403> (last updated July 4, 2025). ("The HTTP 403 Forbidden client error response status code indicates that the server understood the request but refused to process it.")

¹³⁸ See 84 FR 65464, 65483 (November 27, 2019).

¹³⁹ See 89 FR 8758 (February 24, 2024).

¹⁴⁰ As previously mentioned, proposed paragraph (b)(3) (relating to the method and format for disclosing information to the public) of 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212 applies to the prescription drug machine-readable files.

¹⁴¹ 85 FR 72158, 72242 (November 12, 2020).

and issuers commonly link to other information in their website footer. In addition, using a standardized label for the link in the footer would make the location of the machine-readable files easier to identify by individual consumers manually searching for such files.

Both this proposed requirement and the proposed contextual machine-readable Text File as discussed in section III.C.7.d. of this preamble, are intended to improve both automated and manual location of the machine-readable files on a plan's or issuer's website. While the Text File will enhance automated searching more so than manual searching, the footer links would assist manual searching more so than automated searching as individuals are likely to first examine a footer for web page navigation. Thus, these proposed requirements would complement each other and improve overall accessibility.

Additionally, for a plan or issuer that does not have a public website, the Departments have determined that it would be overly burdensome to require such plan or issuer to create and maintain a website to satisfy this requirement. Therefore, the Departments also propose to add paragraph (iv) at redesignated 26 CFR 54.9815–2715A3(b)(3), 29 CFR 2590.715–2715A3(b)(3), and 45 CFR 147.212(b)(3), in line with guidance issued on April 19, 2022 in FAQs Part 55,¹⁴⁴ but extended to apply to issuers, such that any plan or issuer may satisfy the disclosure requirements of paragraph (b)(3)(iii) by entering into a

written agreement under which another party posts the machine-readable files on its public website on behalf of the plan or issuer. Additionally, if the files are hosted on a service provider's website, and the plan or issuer does maintain a public website and chooses not to also post the files separately on its own public website, it must provide a link on its own public website to the location where the files are made publicly available. This requirement applies to a public website maintained by the plan or issuer and does not apply to a public website maintained by an employer or plan sponsor. This proposed new paragraph also moves part of current 26 CFR 54.9815–2715A3(b)(4)(iii), 29 CFR 2590.715–2715A3(b)(4)(iii), and 45 CFR 147.212(b)(4)(iii) addressing plans or issuers who do not have a website to new paragraph (b)(3)(iv) for clarity and alignment with other proposed changes.

The Departments recognize that many employer-sponsored ERISA plans do not currently maintain a separate dedicated internet page for their group health plans or have an internet website at all. This proposed new paragraph would codify FAQs Part 55¹⁴⁵ and extend it to apply to issuers, and recognize the hardship for impacted group health plans, especially for smaller employers. The Departments are proposing this extension to issuers because they were not covered under the guidance in FAQs Part 55 and this would make the requirements consistent across all entities subject to the requirements of paragraph (b)(3)(iii).

The Departments also propose to amend paragraph (b)(3)(i) at redesignated 26 CFR 54.9815–2715A3(b)(3), 29 CFR 2590.715–2715A3(b)(3), and 45 CFR 147.212(b)(3) to require that the proposed method and format requirements for disclosing information to the public would apply to both the machine-readable files under paragraph (b)(1) and the contextual machine-readable files under new paragraph (b)(2).

Finally, as with the public disclosure requirements in the 2020 final rules, the Departments intend to continue to issue form and manner requirements for the machine-readable files specified in technical guidance in the form of sample file schemas and data attributes on GitHub.¹⁴⁶ The technical guidance for the machine-readable files, in the form of schemas,¹⁴⁷ will be updated when appropriate as the Departments receive feedback from the community and interested parties. Additionally, guidance on applicability timelines for new schema requirements and implementation of policy requirements will continue to be posted in the form of Frequently Asked Questions.¹⁴⁸ Table 2 summarizes the technical guidance documents that the Departments expect to publish pursuant to the finalization of these proposed rules. The Departments encourage interested parties to submit all questions and issues on GitHub, as it enables a centralized response and helps to efficiently identify and address common concerns across interested parties.

TABLE 2: Potential Guidance Documents Following Finalization of Proposed Rules

Guidance Document	Potential Issuance Date	Purpose
Schema 3.0 FAQ	Approximately three months post-finalization	Announcing the timeline for developing and finalizing technical implementation requirements for Schema 3.0 following the finalization of the new Transparency in Coverage final rules.
Draft schema examples	Approximately three months post-finalization	Draft parameters for the data attributes and the reporting structure to meet the new Schema 3.0 requirements.

¹⁴⁴ See U.S. Department of Labor, U.S. Department of Health & Human Services & U.S. Department of the Treasury, *FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 55* (Aug. 19, 2022), <https://www.cms.gov/files/document/faqs-part-55.pdf> and <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-55>.

¹⁴⁵ U.S. Department of Labor, U.S. Department of Health & Human Services & U.S. Department of the Treasury, *FAQs about Affordable Care Act and*

Consolidated Appropriations Act, 2021 Implementation Part 55 (Aug 19, 2022), <https://www.cms.gov/files/document/faqs-part-55.pdf> and <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-55>.

¹⁴⁶ Centers for Medicare & Medicaid Services, *Price Transparency Guide*, <https://github.com/CMSgov/price-transparency-guide> (last updated Oct. 1, 2025).

¹⁴⁷ Centers for Medicare & Medicaid Services, *Schema Examples*, <https://github.com/CMSgov/>

price-transparency-guide/tree/master/examples (last updated Oct. 1, 2025).

¹⁴⁸ Centers for Medicare & Medicaid Services, *Affordable Care Act Frequently Asked Questions*, https://www.cms.gov/marketplace/resources/fact-sheets-faqs#Affordable_Care_Act (last updated July 30, 2025); U.S. Department of Labor, *Affordable Care Act Implementation Frequently Asked Questions*, <https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/aca-implementation-faqs> (last updated July 30, 2025).

The Departments seek comment on these proposals.

10. Timing

Under 26 CFR 54.9815–2715A3(b)(4), 29 CFR 2590.715–2715A3(b)(4), and 45 CFR 147.212(b)(4) (proposed to be redesignated from paragraph (b)(3), as discussed in section III.C.7. of this preamble), the Departments propose to add new paragraphs to specify timing requirements for each machine-readable file that would be required under these proposed rules. With respect to the In-network Rate Files and Allowed Amount Files under paragraph (b)(1)(i) and (ii), the Departments propose to amend the publication frequency under new paragraph (b)(4)(i), from a requirement to post monthly to quarterly.

The Departments also propose to add disclosure timing requirements for the new contextual machine-readable files that would be required under proposed new paragraph (b)(2) at new paragraphs (b)(4)(iii) through (vi) under redesignated paragraph (b)(4). The Departments note that the first machine-readable files prepared based upon these proposed rules would be required to be disclosed according to the applicability date as proposed at paragraph (c)(1) and discussed in section III.C.12. of this preamble, which is 12 months after the publication of the final rules. These proposed rules also specify the timing for each machine-readable file to be updated thereafter and example dates are shown in Table 3.

In particular, the Departments propose to amend redesignated paragraph (b)(4)(i) to require plans and issuers to update and post the In-network Rate and Allowed Amount Files required under paragraphs (b)(1)(i) and (ii), respectively, quarterly rather than monthly and beginning on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1). The Departments have received feedback from both producers and users of the machine-readable files recommending reducing the reporting frequency to quarterly, to help lower data storage and hosting costs, decrease bandwidth needs, and reduce ongoing maintenance expenses. The Departments have received feedback that a reduced reporting cadence may also provide more time to analyze the data,¹⁴⁹ as some file users have

informed the Departments that they have difficulty keeping up with the pace of downloading and ingesting the file data monthly.

With respect to In-network Rate File data, interested parties have indicated that negotiated rates between issuers and health care organizations (for example, hospital systems)—in contrast to individual providers—tend to change slowly over time because contracts generally last a year or more, with some multi-year contracts lasting 2 to 5 years. As such, the Departments have determined negotiated rates between health care organizations and issuers should not significantly change from month to month, so the proposed quarterly reporting cadence would not meaningfully affect the accuracy of reported rates in the In-network Rate File for these entities.

The Departments acknowledge that the accuracy of rates at the individual provider level are more likely to be affected by the proposed quarterly reporting cadence, though not significantly. The Departments understand that individual providers can regularly move in and out of relationships with the institutions that employ them (for example, hospital systems, group medical practices);¹⁵⁰ thus, reported rates at the individual provider level may be less accurate with a change from monthly to quarterly reporting. More specifically, the turnover of individual providers within the roster of a large provider organization (like specialist physicians associated with a hospital system) means that the reporting of negotiated rates that “flow down” to the individual providers might become increasingly out of date, given a longer cadence for the reporting requirement. One recent study that quantified physician turnover rates due to retirements and shifts in practice affiliations suggested an annual turnover rate of 7.6 percent in 2018.¹⁵¹ Given that this relatively low annual percentage would translate to an even smaller quarterly turnover rate, the Departments have determined that under the proposed change in reporting cadence, negotiated rates for individual providers would likely become only

somewhat less accurate because there would be more providers who terminate employment with their parent organizations during the extended reporting interval.

Notwithstanding the potential for some of the data in the files to be less accurate, particularly with respect to individual providers, the Departments expect the benefits of quarterly reporting to outweigh these potential limitations, given that for the majority of use cases for the In-network Rate Files, the proposed change in reporting cadence would have only minimal impact on the ability to use the data for reasonable analytic purposes and would significantly reduce burdens both on producers and file users. For example, for a file user that analyzes aggregated rates between plans or issuers and health care organizations and compares reimbursement for orthopedic services in the same geographic market between two issuers, the impact of individual providers (who all share the same rates) moving in and out of health care systems would be immaterial.

The Departments request comment on the benefits, drawbacks, and potential impact of the proposed change in reporting cadence for the In-network Rate Files.

The Departments have also determined there would be no loss in data value by changing the reporting cadence from monthly to quarterly for the Allowed Amount File under paragraph (b)(1)(ii) since the data represents a historical snapshot that would continue to be captured in its entirety. The Departments seek comment on the potential impact of the proposed change in reporting cadence for the Allowed Amount File.

The Departments are not proposing to change the monthly reporting cadence for the prescription drug machine-readable file under paragraph (b)(1)(iii) in proposed paragraph (b)(4)(ii).

With respect to the proposals to require new contextual files under new paragraph (b)(2), the Departments intend for them to be updated at a frequency at which they will be maximally useful and provide the most context to the In-network Rate File and Allowed Amount File. The Departments have determined that since the Change-log File serves as a reference to an In-network Rate File, it should be posted at the same time as the In-network Rate File to show what has changed from an In-network Rate File since it was last updated. Therefore, the Departments propose to require at proposed paragraph (b)(4)(iii) that plans and issuers update the Change-log File under proposed paragraph (b)(2)(i) on

georgetown.app.box.com/s/1ezsggz1c7smaexkr8ght15sokgusl.

¹⁵⁰ Cf. Code section 9820(a)(2), ERISA section 720(a)(2), and PHS Act section 2799A–5(a)(2) (requiring plans and issuers to verify and update their provider directory database not less frequently than once every 90 days, and to remove providers and facilities which have the plan or issuer has been unable to verify).

¹⁵¹ Amelia M. Bond, Lawrence P. Casalino, Ming Tai-Seale, Matthew A. Unruh, et al., *Physician Turnover in the United States*, 175 *Annals of Internal Medicine* 896, 903 (2023).

¹⁴⁹ See Michael Chernen, Sabrina Corlette, Kevin Davenport, François de Brantes, et al., *Transparency in Coverage: Recommendations for Improving Access to and Usability of Health Plan Price Data* (2022), Georgetown University, <https://>

the same day as each In-network Rate File described in (b)(1)(i) is required to be updated, except for the first In-network Rate File for which there would be no changes to report. This would mean the plan or issuer would be required to post their first Change-log File beginning on the first day of the calendar-year quarter following the date on which the first In-network Rate File would be required to be posted under paragraph (b)(4)(i).¹⁵² The Departments propose to require that if there are no changes to an In-network Rate File since it was updated last, a Change-log File would still be required to be posted at that time indicating there are no changes for that quarter.

The Departments also propose to require at proposed paragraph (b)(4)(iv) that the Utilization File described in proposed new paragraph (b)(2)(ii) be updated and posted every 12 months after the initial posting. The Utilization File would be required to be initially posted on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1) and annually on the same date thereafter.

The Departments have determined that an annual cadence for this file is sufficient to illustrate provider reimbursement for corresponding items and services and appropriately balances the benefit of having recent historical data with the burden on plans and issuers to extract data from their claims systems annually.

The Departments also propose to require at proposed paragraph (b)(4)(v) that plans and issuers update the Taxonomy File prepared pursuant to proposed paragraph (b)(2)(iii) and post such file beginning on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1). This would help to ensure file users have all necessary information to assess the data disclosed through the In-network Rate Files as described under paragraph (b)(1)(i) and to provide clarity around what data was excluded from the In-network Rate Files pursuant to the new proposed requirement to exclude certain information under new paragraph (b)(1)(i)(F). If there are no changes to the taxonomy that impact the information required to be included in

the In-network Rate File from one quarter to the next, the posted Taxonomy File would not be required to be updated.

The Departments also propose in new paragraph (b)(4)(vi) to require that the Text File required under proposed paragraph (b)(2)(iv) of this section be initially posted on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1) and updated and posted as soon as practicable but no later than 7 calendar days following a change in any of the information required under paragraph (b)(2)(iv). The Departments request comment on all aspects of these proposed timing requirements. In particular, the Departments request comment on whether the proposed requirement that plans and issuers update the Text File as soon as practicable but not later than 7 calendar days following a change in any of the information required under paragraph (b)(2)(iv) of this section provides sufficient time for plans and issuers to make the required update.

TABLE 3: Example Initial and Subsequent File Disclosure Timing Requirements

	Example Final Rule Publication Date	Example Applicability Date	Example Initial Disclosure Date	Example Subsequent Disclosures Dates
In-network Rate File (quarterly)	October 15, 2026	October 15, 2027	January 1, 2028	April 1, 2028; July 1, 2028; October 1, 2028, etc.
Allowed Amount File (quarterly)	October 15, 2026	October 15, 2027	January 1, 2028	April 1, 2028; July 1, 2028; October 1, 2028, etc.
Change-log File (quarterly)	October 15, 2026	October 15, 2027	April 1, 2028	July 1, 2028; October 1, 2028; January 1, 2029, etc.
Utilization File (annually)	October 15, 2026	October 15, 2027	January 1, 2028	January 1, 2029, January 1, 2030, etc.
Taxonomy File	October 15, 2026	October 15, 2027	January 1, 2028	Quarters when there are updates
Text File	October 15, 2026	October 15, 2027	January 1, 2028	Within 7 days of any updates

The Departments seek comment on these proposed timing requirements.

11. Special Rules To Prevent Unnecessary Duplication

The Departments propose in 26 CFR 54.9815–2715A3, 29 CFR 2590.715–

2715A3, and 45 CFR 147.212 to redesignate paragraph (b)(4)(i) as paragraph (b)(5)(i) and redesignate paragraph (b)(4)(ii) as paragraph

¹⁵² See Table 3 for an example.

(b)(5)(ii)—each without any substantive changes to the existing policy in the 2020 final rules. The Departments also propose to redesignate and amend paragraph (b)(4)(iii), which permits aggregation of out-of-network allowed amounts in certain circumstances, as paragraph (b)(5)(iv) and to add new paragraph (b)(5)(iii) to include similar permissions with respect to in-network rates.

In new paragraph (b)(5)(iii), the Departments propose, under certain conditions, to allow self-insured group health plans to permit another party (pursuant to a contract) to make available in a single In-network Rate File, the information required under paragraph (b)(1)(i) for multiple plans, insurance policies, and contracts, including those offered by different plan sponsors with which the other party contracts and across markets that share the same provider network.¹⁵³ Similarly, in redesignated paragraph (b)(5)(iv), the Departments propose amendments that would allow, under certain conditions, self-insured group health plans to permit another party (pursuant to a contract) to make available in a single Allowed Amount File the information required under paragraph (b)(1)(ii) for more than one self-insured group health plan, including those offered by different plan sponsors with which the other party contracts. The Departments also propose two amendments to redesignated paragraph (b)(5)(iv) to account for proposed amendments to the Allowed Amount File requirements in paragraph (b)(1)(ii): (1) to require that the minimum claims threshold apply across multiple self-insured group health plans whose information is included in a single Allowed Amount File, as described in proposed paragraph (b)(5)(iv), rather than for each such individual self-insured group health plan, and (2) to revise the minimum claims threshold to 11-claims in accordance with proposed paragraph (b)(1)(ii)(C). Lastly, the Departments propose amendments to better organize and streamline requirements in redesignated paragraph (b)(5)(iv) which do not affect any substantive rights or obligations.

a. Special Rule for Self-Insured Group Health Plans With Respect to the Disclosure of In-Network Rate Files

In new paragraph (b)(5)(iii), the Departments propose to permit In-

network Rate Files, which for self-insured group health plans under the proposed amendments to paragraph (b)(1)(i) would have been required to be made available at the plan sponsor level, to instead be made available at the service provider level for each provider network used by the self-insured group health plan. This In-network Rate File could include such information for more than one self-insured group health plan with which the other party has an agreement, as well as other policies and contracts offered by the other party acting as a health insurance issuer, that uses the same provider network. This In-network Rate File may also include the relevant information from plans or coverage in different health insurance markets, as described below.

As discussed in section III.C.1 of this preamble, the Departments propose to amend paragraph (b)(1)(i) to require plans and issuers to make an In-network Rate File available for each provider network maintained or contracted by the plan or issuer. This organization by provider network would reduce file size and the overall number of files and make more meaningful information available to file users. Under this proposal, each self-insured group health plan would be required to make available an In-network Rate File for each provider network it maintains. For self-insured group health plans that are administered by the same service provider and use the same provider network, this approach would require duplicate In-network Rate Files that include the same negotiated rates under the same provider network for each self-insured group health plan using that network. Therefore, to further the goals of reducing duplicative rates and simplifying analysis for file users, the Departments propose in paragraph (b)(5)(iii) to permit and encourage self-insured group health plans to allow another party with which they contract, such as a service provider, to make available an In-network Rate File for each provider network used by more than one self-insured plan.

Further, the Departments propose that these In-network Rate Files may include information about plans, insurance policies, and contracts across health insurance markets, since a service provider may use the same provider network for multiple self-insured group health plans it administers and also for multiple fully-insured group health plans or individual health insurance coverage it offers as a health insurance issuer. Such a service provider, when acting as a health insurance issuer, would already be required under the Departments' proposed amendments to

paragraph (b)(1)(i) to disclose an In-network Rate File for that provider network that includes negotiated rate information for the fully-insured group health plans it offers across the small group and large group markets, as well as any individual policies it offers in the individual market, to the extent those plans or policies use that same provider network. Under new paragraph (b)(5)(iii), a self-insured group health plan could permit its service provider to include plans and coverage offered in different health insurance markets in the same In-network Rate File, to the extent they use the same provider network. If this In-network Rate File includes the required rates for individual and group health insurance coverage offered by the issuer, the issuer would also be considered to comply with the Departments' proposed amendments to paragraph (b)(1)(i).

The Departments also propose to add new paragraphs (b)(5)(iii)(A) and (B) to include two conditions on the applicability of the special rule for self-insured group health plans with respect to the disclosure of the In-network Rate File. In new paragraph (b)(5)(iii)(A), the Departments propose that a self-insured group health plan may only avail itself of the special rule described in (b)(5)(iii) if each In-network Rate File made available for a provider network includes information for all covered items and services under each plan, insurance policy, or contract that uses the same provider network for which the In-network Rate File is made available, consistent with the requirements for disclosing rate information under proposed (b)(1)(i).

In new paragraph (b)(5)(iii)(B), the Departments propose that a self-insured group health plan may only use the special rule described in (b)(5)(iii) if each proposed Change-log, Utilization, and Taxonomy File (all of which must be made available for each In-network Rate File, as discussed in section III.C.7. of this preamble, under proposed new paragraphs (b)(2)(i), (ii) and (iii), respectively), include data from the same plans, insurance policies, or contracts (including those offered by different plan sponsors and across different health insurance markets, if applicable) that are represented in the corresponding In-network Rate File. This is because, as discussed in section III.C.7. of this preamble, for the Change-log, Utilization, and Taxonomy Files to be meaningful, they must directly correspond to the disclosures in the In-network Rate Files for which they are made available. Under this proposal, a self-insured group health plan that contracts with another party that takes

¹⁵³ For the purposes of this section III.C.11, the term "health insurance market" refers to the definition in proposed 25 CFR 54.9815–2715A1, 29 CFR 2590.715.2715A1, and 45 CFR 147.210 as described in section III.A of these proposed rules.

advantage of the special rule would not be permitted to publish (either itself or by contracting with another party) the corresponding Change-log, Utilization, and Taxonomy Files only with respect to its own plans.

b. Special Rule for Self-Insured Group Health Plans With Respect to the Disclosure of Out-of-Network Allowed Amount Files

As described above, the Departments propose in 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212 to redesignate paragraph (b)(4)(iii) as paragraph (b)(5)(iv), and to amend redesignated paragraph (b)(5)(iv) to state that a self-insured group health plan may permit another party with which it contracts, such as a service provider, to include the required allowed amount and billed charge information in a single Allowed Amount File for more than one self-insured group health plan, including those offered by different plan sponsors with which the other party contracts, provided certain conditions are met.

For improved readability, the Departments propose to move the condition currently described in paragraph (b)(4)(iii) (related to application of the claims threshold to the Allowed Amount File) into new paragraph (b)(5)(iv) and to amend it to align with the Departments' proposed revisions to the claims threshold in paragraph (b)(1)(ii).

Under paragraph (b)(4)(iii) of the 2020 final rules, group health plans and health insurance issuers are currently permitted to satisfy the Allowed Amount File disclosure requirements in paragraph (b)(1)(ii) by contracting with an issuer, service provider, or other party to make available out-of-network allowed amount data that has been aggregated to include information from more than one plan, policy, or contract (provided that the claims threshold described in paragraph (b)(1)(ii)(C) is met independently for each item or service and for each plan or coverage included in an aggregated Allowed Amount File). These plans, policies, or contracts may be across multiple health insurance markets.

As discussed in section III.C.6 of this preamble, the Departments now propose to amend paragraph (b)(1)(ii) to require all plans and issuers to aggregate out-of-network allowed amount data across the plans or coverage they offer in each health insurance market. For example, an issuer offering six plans in the small group market and four in the individual market would be required to make available two Allowed Amount Files: one that aggregates allowed amounts

across the issuer's six small group market plans and another that aggregates allowed amounts across its four individual market plans.

Therefore, if proposed (b)(1)(ii) were finalized and current paragraph (b)(4)(iii) were retained, plans and issuers would be required to aggregate out-of-network allowed amount data across the plans or coverage they offer in each health insurance market, and, if a plan or issuer contracts with an issuer, service provider or other party to satisfy the disclosure requirement of (b)(1)(ii), such party would additionally be permitted to aggregate allowed amount data across the plans or coverage in different health insurance markets. Permitting plans and issuers to aggregate data within a health insurance market and then again across multiple different health insurance markets would undermine the Departments' goal of improving data useability of the Allowed Amount Files as discussed in section III.C.6 of this preamble.

As discussed in section III.A. of this preamble, the Departments propose to add new paragraphs 26 CFR 54.9815–2715A1(a)(2)(xi), 29 CFR 2590.715–2715A1(a)(2)(x), and 45 CFR 147.210(a)(2)(xi) to define health insurance markets for purposes of the proposed amendments to the Allowed Amount File at proposed paragraph (b)(1)(ii). If finalized as proposed, for purposes of self-insured group health plans (other than account-based plans, as defined in 26 CFR 54.9815–2711(d)(6)(i), 29 CFR 2590.715–2711(d)(6)(i), and 45 CFR 147.126(d)(6)(i) of this subchapter, and plans that consist solely of excepted benefits), health insurance market would be defined as all self-insured group health plans maintained by the plan sponsor. Therefore, proposed paragraph (b)(1)(ii) would require self-insured group health plans to aggregate out-of-network allowed amount data across the plans offered by the same plan sponsor (that is, in the same health insurance market), but would not permit aggregation across more than one plan sponsor. The Departments have determined that allowing aggregation of allowed amount data only across self-insured group health plans offered by different plan sponsors maintains the market division grouping necessary to make the data more actionable for research and analysis as discussed in section III.C.6 of this preamble. As such, proposed paragraph (b)(5)(iv) states that a self-insured group health plan that enters into an agreement with another party described in paragraph (b)(5)(ii) may permit such other party to make available the information required

under paragraph (b)(1)(ii) in a single out-of-network allowed amount file for more than one self-insured group health plan, including those offered by different plan sponsors with which the other party contracts. This would mean that a self-insured group health plan may permit their service provider or other party with which they contract to include their required allowed amount and billed charges information in a single Allowed Amount File along with allowed amount and billed charges information from more than one self-insured group health plan, including those offered by different plan sponsors (that is, in different health insurance markets). Therefore, the Departments propose to limit the application of redesignated paragraph (b)(5)(iv) to self-insured group health plans; allowed amounts and billed charges from fully-insured group health plans or individual market coverage must not be included.

In addition, in new paragraph (b)(5)(iv), the Departments propose that a self-insured group health plan may not take advantage of the special rule under paragraph (b)(5)(iv) unless the proposed 11-claim threshold applies across all plans included in the Allowed Amount File. Under current paragraph (b)(1)(ii)(C), plans and issuers must apply the minimum claims threshold by evaluating the number of different claims for payments under a single plan or coverage. Under current paragraph (b)(4)(iii), when allowed amount data is aggregated at the service provider level, rather than reported by plan, policy, or contract, the minimum claims threshold is applied the same way: it must be met independently for each item or service and for each plan, insurance policy, or coverage included in an aggregated Allowed Amount File.¹⁵⁴

The Departments finalized this requirement in the 2020 final rules because if the threshold were applied to the aggregated claims data at the service provider level, rather than for each plan or coverage as is required under current paragraph (b)(1)(ii)(C), the Departments determined that the goal of the minimum claims threshold could be undermined.¹⁵⁵ The Departments gave the following example in the 2020 rules: “Plan A has 20 claims for Service X, while Plan B only has six claims for Service X. In aggregate, the plans meet the 20-claim threshold with 26 total claims for Service X. However, individually, only Plan A has met the

¹⁵⁴ 26 CFR 54.9815–2715A1(b)(4)(iii), 29 CFR 2590.715–2715A1(b)(4)(iii), and 45 CFR 147.212(b)(4)(iii).

¹⁵⁵ 85 FR 72158, 72246 (November 12, 2020).

minimum claim threshold.”¹⁵⁶ If the claims threshold were applied to the aggregated data set, data for Service X would be required to be included from both Plan A and Plan B. The Departments determined that “allowing Plan B data to be included in the file for Service X would undermine the minimum claim threshold, increasing risk that individual patients’ claims histories could be identified.”¹⁵⁷

As discussed in section III.C.6. of this preamble, the Departments now propose in paragraph (b)(1)(ii)(C) to lower the claims threshold from 20 to 11 and apply it at the health insurance market level, rather than the individual plan or policy level. That is, plans and issuers would be required to exclude claims data for an item or service if there are fewer than 11 claims for that item or service in an Allowed Amount File, regardless of how many plans, insurance policies, or contracts are represented in the file.

For consistency in the application of the claims threshold, the Departments propose in new paragraph (b)(5)(iv) that in order for a self-insured group health plan to take advantage of the special rule under paragraph (b)(5)(iv), the proposed 11-claim threshold must be applied to the aggregated data set. Applying the threshold to aggregated data, especially when aggregated across multiple self-insured group health plans offered by different plan sponsors, would likely increase the amount of allowed amount data available because more services would likely exceed the 11-claim threshold. Notwithstanding, and as discussed in more detail in section III.C.6. of this preamble, the Departments expect this approach would result in maintaining appropriate patient privacy protections.

Finally, the Departments propose to revise the paragraph heading for redesignated paragraph (b)(5)(iv) to better describe the proposed requirements in this paragraph.

c. Better Organizing Existing Requirements

Current paragraph (b)(4)(iii), redesignated as paragraph (b)(5)(iv), also

provides that nothing in 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212 prevents the Allowed Amount File from being hosted on a third-party website or prevents a plan administrator or issuer from contracting with a service provider to post the file, but that if a plan or issuer chooses not to also host the file separately on its own website, it must provide a link on its own public website to the location where the file is made publicly available. The Departments have determined that this provision more logically belongs in redesignated paragraph (b)(3) concerning the method and format for disclosing information to the public. As such, the Departments propose to move it to new paragraph (b)(3)(iv) with proposed amendments that are discussed in section III.C.9. of this preamble.

The Departments seek comment on these proposals.

12. Applicability

The Departments propose to require under paragraph (c)(1) that the proposed amendments to the provisions of paragraph (b) of 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212 apply 12 months following the date of publication of the final regulations in the **Federal Register**. The Departments are proposing this applicability date to ensure that all plans and issuers begin following the updated set of technical requirements at the same time. Until such time, the current provisions of paragraph (b) continue to apply.

Based on initial implementation experience, the Departments have determined that the proposed applicability date appropriately balances the need for achieving increased usability of the machine-readable file data in a timely manner with the time necessary for both file developers and other users to collaborate with the Departments on GitHub and for plans and issuers to make the operational and systems changes to implement these proposals.

The Departments seek comment on this proposed applicability date, including whether 12 months following publication of final regulations provides enough time for plans and issuers to

comply with the amended provisions of paragraph (b) and whether there are particular challenges in complying with such applicability date compared to an applicability date based on plan or policy year.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), the Departments are required to provide notice in the **Federal Register** and solicit comment before a collection of information request (ICR) is submitted to OMB for review and approval. These proposed rules contain ICRs that are subject to review by OMB. A description of these provisions is given in sections IV.C. and D. of this preamble with an estimate of the annual burden, summarized in Tables 35 and 36.

To evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that the Departments solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of an agency, including whether the information shall have practical utility.
- The accuracy of the Departments’ estimate of the information collection burden, including the validity of the methodology and assumptions used.
- 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.

A. Allocation of Total Burden Hours to the Departments of Health and Human Services, Labor, and the Treasury

Based on their respective jurisdiction over issuers and third-party administrators (TPAs), HHS is estimated to account for 50 percent of the total burden, while the Departments of Labor and the Treasury would each account for 25 percent. Tables 4 and 5 present each Department’s share of the total ongoing and one-time estimated burden hours needed to implement the proposed requirements.

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

TABLE 4: Estimated Annual Burden Hours of HHS, Labor, and the Treasury to Implement Requirements for Disclosures to Participants, Beneficiaries, or Enrollees and Public Disclosure of In-Network Rates and Allowed Amount Data for Covered Items and Services from In- and Out-of-Network Providers

Agency	Burden Share Percentage	Number of Respondents	Number of Responses*	Burden Hours per Response	Total Burden Hours
HHS	50%	790	3,901,580	0.2	703,720
Labor	25%	395	1,950,790	0.2	351,860
Treasury	25%	395	1,950,790	0.2	351,860

* High-end estimated values are represented in the table and used to calculate the overall estimated figures.

TABLE 5: Estimated One-time Burden Hours of HHS, Labor, and the Treasury to Implement Requirements for Disclosures to Participants, Beneficiaries, or Enrollees and Public Disclosure of In-Network Rates and Allowed Amount Data for Covered Items and Services from In- and Out-of-Network Providers

Agency	Year	Burden Share Percentage	Number of Respondents	Number of Responses*	Burden Hours per Response	Total Burden Hours
HHS	2027	50%	790	8,690	385	3,349,732
Labor	2027	25%	395	4,345	385	1,674,866
Treasury	2027	25%	395	4,345	385	1,674,866

* High-end estimated values are represented in the table and used to calculate the overall estimated figures.

B. Wage Estimates

To estimate wages, the Departments used data from the Contract Awarded Labor Category (CALC) database tool¹⁵⁸ to calculate average labor costs associated with the burden and equivalent costs of the information collection requirements (ICRs). The CALC tool was developed to assist acquisition professionals with market

research and price analysis of labor categories under multiple U.S. General Services Administration (GSA) and Veterans Administration (VA) contracts. While the Departments recognize that various methods exist for estimating fringe benefits and overhead costs, the CALC database was selected because, unlike Bureau of Labor Statistics (BLS) data, which is valuable for identifying broad labor market trends, the CALC tool is specifically designed to support market research for government procurement. It provides cost estimates for specific labor categories based on

actual contract rates. More importantly, CALC data reflects fully burdened hourly rates, including both base pay and benefits, whereas BLS data reflects only base wages. The Departments determined that CALC's occupation-specific data better aligns with the skill sets and job functions necessary for implementing the requirements in these proposed rules and therefore provides a more suitable basis for estimating labor costs. Table 6 presents the fully burdened mean hourly wage and occupations used in the Departments' estimates.

¹⁵⁸ U.S. General Services Administration, *Pricing Intelligence Suite, CALC information and wage rates*, <https://buy.gsa.gov/pricing/> (last visited Dec. 8, 2025).

TABLE 6: Hourly Wages Used in Burden Estimates

CALC Occupation Title	Mean Hourly Wage (\$/hour)
Project Manager/Team Lead	\$153.00
Scrum Master	\$105.00
Technical Architect	\$149.00
Senior Application Developer	\$143.00
Business Analyst	\$120.00
DevOps Engineer III	\$181.00
Customer Service Representative	\$40.00
Training Specialist	\$104.00
Supervisor	\$91.00
Attorney III	\$143.00

C. ICRs Regarding Requirements for Disclosures to Participants, Beneficiaries, or Enrollees Under 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211

As discussed previously in this preamble, the Departments propose several amendments to the 2020 final rules to improve price transparency and strengthen consumer protections for participants, beneficiaries, and enrollees. First, the Departments propose revising the disclaimer required under paragraph (b)(1)(vii)(A) to clarify that the cost-sharing information does not account for potential additional amounts in situations where applicable State and Federal law allow out-of-network providers to balance bill participants, beneficiaries, and enrollees. These revisions reflect the Federal balance billing protections introduced by the No Surprises Act, which were not in effect when the original provision was finalized. These proposed revisions aim to ensure that participants, beneficiaries, and enrollees understand that cost-sharing estimates disclosed through their plan's or issuer's self-service tool may not account for additional amounts owed to out-of-network providers.

In addition, the Departments propose adding a new paragraph (b)(2)(iii) requiring plans and issuers to make cost-sharing information available by telephone, consistent with requirements under the No Surprises Act. The Departments propose to require a telephone number for consumer assistance that Code section 9816(e), ERISA section 716(e), and PHS Act section 2799A–1(e), as added by section 107 of the No Surprises Act, requires be indicated on any physical or electronic plan or insurance identification card

issued to a participant, beneficiary, or enrollee. The proposal further states that, to reduce unnecessary administrative burden and prevent consumer confusion, providing the information as specified in paragraph (b)(1) and in the method and format as specified in paragraph (b)(2), as amended by these proposed rules, would satisfy the price comparison tool requirements under section 114 of the No Surprises Act. The requirements in these proposed rules apply to non-grandfathered group health plans and health insurance issuers offering non-grandfathered coverage in the group and individual markets.

As discussed in section VI.C.3. of this preamble, the Departments assume that self-insured group health plans would depend on TPAs, including issuers providing administrative services only and non-issuer TPAs, to implement these proposed updates, including the new phone disclosure requirement. This assumption is based on the Departments' understanding that most self-insured group health plans already rely on TPAs to perform core administrative functions, such as enrollment and claims processing.¹⁵⁹ For those self-insured plans that choose to develop their own internet-based self-service tools (and which are included in the total count of issuers and TPAs used to estimate burden), the Departments assume that they would incur costs and burdens similar to those estimated for issuers and TPAs. Accordingly, the Departments use issuers and TPAs as the unit of analysis for estimating the

cost of proposed changes. The Departments also assume that issuers and TPAs have already developed internet-based self-service tools, originally required for plan or policy years beginning on or after January 1, 2023, and would only need to modify these existing systems to comply with the proposed provisions. The Departments acknowledge that some interactive voice response (IVR) programming work may be necessary, but the Departments expect the associated cost would be minimal. The Departments welcome comment on these assumptions.

As also noted in section VI.C.3. of this preamble, the Departments estimate that approximately 1,375 issuers¹⁶⁰ and 205 TPAs¹⁶¹ (a total of 1,580 entities) would implement the proposed requirements. The Departments acknowledge that actual costs may vary depending on factors such as the volume of providers and items or services for which cost-sharing information must be disclosed, and whether plans (or TPAs on behalf of plans) and issuers already have tools that fully or partially meet the proposed requirements or can be readily adapted. The Departments welcome comment on the assumptions and inputs used to develop these burden and cost estimates.

The Departments also assume that plans (or TPAs on behalf of plans) have

¹⁶⁰ The Departments' estimate of the number of health insurance companies and the number of issuers (issuer/State combinations) is based on medical loss ratio reports submitted by issuers for the 2023 reporting year. Centers for Medicare & Medicaid Services, *Medical Loss Ratio Data and System Resources* (December 23, 2024), <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr>.

¹⁶¹ Non-issuer TPAs based on data derived from the 2016 Benefit Year reinsurance program contributions.

¹⁵⁹ Louise Norris, *What is Self-Insured Health Insurance? Most Very Large Employers Self-Insure*, Verywell Health (November 9, 2024), <https://www.verywellhealth.com/what-is-self-insured-health-insurance-and-how-is-it-regulated-4688567>.

already built self-service tools and would only be required to revise the disclaimer stating that out-of-network providers may engage in balance billing, subject to applicable State and Federal laws. Although these updates build on existing infrastructure, they would require a one-time cost for minor

technical modifications including editing disclosure text, testing for quality assurance, and implementing the update. The Departments estimate that, on average, each issuer or TPA would require 10 minutes (approximately 0.17 hours) of a Senior Application Developer's time (at \$143

per hour) to update the disclosure. As shown in Table 7, across all 1,580 issuers and TPAs, the total one-time burden is estimated at 263 hours, with an associated cost of approximately \$37,657.

TABLE 7: One-Time Estimated Cost and Hour Burden for All Issuers and TPAs to Update Cost-Sharing Disclosure Reflecting Federal Balance Billing Protections

Number of Respondents	Number of Responses	Burden Hours per Respondent	Total Burden Hours	Total Cost
1,580	1,580	0.17	263	\$37,657

a. High Impact for Providing Cost-Sharing Information Via Phone

Under a scenario with increased call volume and duration (that is, high impact), the Departments anticipate that requiring cost-sharing information to also be accessible by phone, could increase call volume and call duration to the plan's or issuer's customer support line. This anticipated increase is driven by participants, beneficiaries,

and enrollees who may prefer verbal assistance, have limited digital access or literacy, or need help interpreting complex pricing information.

Accordingly, the Departments estimate that for each issuer or TPA, it would require 10 minutes¹⁶² for a customer service representative (at \$40 per hour) to speak with each consumer and provide the requested information and complete post-call documentation. Assuming, as a high impact scenario

estimate, there would be 7.8 million calls annually,¹⁶³ each issuer or TPA would receive approximately 4,937 calls per year, resulting in an estimated annual burden of 823 hours,¹⁶⁴ with an estimated associated cost of \$32,911. As shown in Table 8, the Departments estimate that for all 1,580 issuers and TPAs, the estimated total ongoing annual burden would be approximately 1,300,000 hours, with an estimated associated cost of \$52 million annually.

TABLE 8: Estimated High Impact Annual Cost and Hour Burden to Provide Cost-Sharing Information via Phone

Number of Respondents	Number of Responses	Burden Hours per Respondent	Total Burden Hours	Total Cost
1,580	7,800,000	823	1,300,000	\$52,000,000

b. Lower Impact Estimate for Providing Cost-Sharing Information Via Phone

¹⁶² According to a 2012 report by the Healthcare Financial Management Association, the average handle time for call centers generally ranges from 7 to 8 minutes. For purposes of this analysis, the Departments assume an additional 2 minutes would be needed for call documentation, resulting in an average handle time of 9 to 10 minutes. Accordingly, the Departments use 9 minutes as the lower bound and 10 minutes as the upper bound to estimate the potential impact of increased call times under the proposed disclosure requirements. Healthcare Financial Management Association, *Ask the Expert: Setting Industry Standards for Call Center Activities* (Oct. 25, 2012), <https://www.hfma.org/revenue-cycle/kpis/7256/>.

¹⁶³ According to data from the Congressional Research Service, the total insured population in private/commercial insurance, including employer-sponsored and individual market coverage, is projected to be approximately 156 million in 2023 (of the estimated 304 million insured individuals in

2023, approximately 148 million are covered by public programs, including Medicare, Medicaid, VA Care, and TRICARE. The remaining 156 million are covered under private/commercial insurance, including both employer-sponsored and individual market plans). The Departments estimate 5 percent of total calls would be shopping-related calls per year under the high-call time scenario. This estimate is informed by a KFF study (<https://www.kff.org/affordable-care-act/kff-survey-of-consumer-experiences-with-health-insurance/>) in which 57 percent of adults contacted their insurance in 2023, with under 31 percent asking about out-of-pocket expenses—a subset of which could reasonably be considered shopping related calls. Considering that consumers contact plans via phone, online, in-person, or in writing, it was estimated that 25 percent of these contacts were by phone. Of these phone contacts, 10–20 percent of the 31 percent asking about out-of-pocket expenses were assumed to be shopping calls, resulting in an

estimated range of 2.5 percent to 5 percent of total calls being shopping-related. Using the upper bound of 5 percent for the high-call time scenario, this results in approximately 7.8 million shopping-related calls per year. Congressional Research Service, U.S. Health Care Coverage and Spending (Feb. 19, 2025), <https://www.congress.gov/crs-product/IF10830>.

¹⁶⁴ This calculation distributes the total workload across all 1,580 issuers and TPAs. At the industry level, there are 7,800,000 high-call time calls per year, with an average handle time of 10 minutes per call, resulting in 78,000,000 total minutes (1,300,000 hours). To compute the per-entity workload, the total calls are divided by the number of issuers and TPAs: $7,800,000/1,580 \approx 4,937$ calls per entity per year. Multiplying the per-entity calls by the 10-minute average handle time gives 49,370 minutes annually per entity, which converts to approximately 823 hours (49,370/60).

Under a scenario with less call volume and duration (that is, lower-impact scenario), the Departments assume that a smaller subset of participants, beneficiaries, and enrollees would opt to request pricing information by phone. In this scenario, the Departments estimate that for each issuer or TPA it would take 9 minutes

for a customer service representative (at \$40 per hour) to speak with consumers and provide the requested information and complete post-call documentation. Assuming 3.9 million calls annually,¹⁶⁵ each issuer or TPA would receive approximately 2,468 calls per year, resulting in an estimated annual burden of 370 hours¹⁶⁶ with an estimated

associated cost of \$14,810 per issuer or TPA. As shown in Table 9, across all 1,580 issuers and TPAs, the estimated total ongoing burden would be approximately 585,000 hours, with a total annual cost of approximately \$23.4 million.

TABLE 9: Estimated Lower Impact Annual Cost and Hour Burden to Provide Cost-Sharing Information via Phone

Number of Respondents	Number of Responses	Burden Hours per Respondent	Total Burden Hrs	Total Cost
1,580	3,900,000	370	585,000	\$23,400,000

Plans (or TPAs on behalf of plans) and issuers would also incur a one-time burden and cost to train customer service representatives and their supervisors on the proposed phone requirement. The Departments assume this requirement would not necessitate hiring additional full-time staff. Instead, the Departments expect issuers and TPAs to rely on existing customer

service representatives and supervisors for this task. For each issuer or TPA, the Departments estimate that one training specialist would spend 8 hours (at \$104 per hour) to train 20 customer service representatives (totaling 160 hours at \$40 per hour) and two supervisors (totaling 16 hours at \$91 per hour) on how to respond to participants, beneficiaries, and enrollees seeking

pricing information by phone. This results in a one-time burden of 184 hours per issuer or TPA, with an estimated associated cost of \$8,688. As shown in Table 10, for all 1,580 issuers and TPAs, the total estimated one-time training hour burden would be 290,720 hours, with a corresponding cost of approximately \$13,727,040.

TABLE 10: One-Time Estimated Cost and Hour Burden for All Issuers and TPAs to Train Customer Service Representatives and Supervisors to Provide Cost-Sharing Information via Phone

Number of Respondents	Number of Responses	Burden Hours per Respondent	Total Burden Hours	Total Cost
1,580	1,580	184	290,720	\$13,727,040

The Departments anticipate that, in the future, ongoing training costs associated with the proposed phone requirements would be incorporated into existing onboarding programs for new employees and included in the regular annual training provided to current staff.

The Departments request comment on the estimated cost and burden hours

presented in this analysis, including any additional costs or challenges that commenters may identify.

D. ICRs Regarding Requirements for Public Disclosure Under 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212

The Departments are proposing updates to the 2020 final rules to

improve the accessibility, clarity, and usefulness of the public disclosures through machine-readable files. The proposed changes aim to help users better locate machine-readable files, revise the content and format of disclosures, and modify the publication frequency for certain files. For In-network Rate Files, the proposal would

¹⁶⁵ According to data from the Congressional Research Service, the total insured population in private/commercial insurance, including employer-sponsored and individual market coverage, is projected to be approximately 156 million in 2023 (of the estimated 304 million insured individuals in 2023, approximately 148 million are covered by public programs, including Medicare, Medicaid, VA Care, and TRICARE. The remaining 156 million are covered under private/commercial insurance, including both employer-sponsored and individual market plans). The Departments estimate that 2.5 percent of total calls would be shopping-related calls per year under the low-call time scenario. This estimate is informed by a KFF study (<https://www.kff.org/affordable-care-act/kff-survey-of-consumer-experiences-with-health-insurance/>) in which 57 percent of adults contacted their insurance in 2023, with under 31 percent asking about out-of-pocket expenses—a subset of which could reasonably be considered shopping related calls. Considering that consumers contact plans via phone, online, in-person, or in writing, it was estimated that 25 percent of these contacts were by phone. Of these phone contacts, 10–20 percent of the 31percent asking about out-of-pocket expenses were assumed to be shopping calls, resulting in an estimated range of 2.5 percent to 5 percent of total calls being shopping-related. Using the lower bound of 2.5 percent for the low-call time scenario, this results in approximately 3.9 million shopping-related calls per year. Congressional Research

Service, U.S. Health Care Coverage and Spending (Feb. 19, 2025), <https://www.congress.gov/crs-product/IF10830>.

¹⁶⁶ This calculation distributes the total workload across all 1,580 issuers and TPAs. At the industry level, there are 3,900,000 high-volume calls per year, with an average handle time of 9 minutes per call, resulting in 35,100,000 total minutes (585,000 hours). To compute the per-entity workload, the total calls are divided by the number of issuers and TPAs: 3,900,000/1,580 = 2,468 calls per entity per year. Multiplying the per-entity calls by the 9 minute average handle time gives 22,212 minutes annually per entity, which converts to approximately 370 hours (22,212/60).

require plans and issuers to create a separate file for each provider network, allow rates to be expressed as a percentage of billed charges when appropriate, associate enrollment totals for each plan or coverage option, disclose provider network product types, and exclude providers unlikely to be reimbursed based on their scope of practice. For Allowed Amount Files, the proposals include requiring data reporting at the market level instead of the individual plan level, lowering the claims threshold from 20 to 11, extending the reporting period from 90 days to 6 months, and increasing the lookback period from 180 days to 9 months to enhance the robustness of historical data. In addition, these proposed rules would require plans and issuers to post several contextual machine-readable files: a Change-log File, a Utilization File, a Taxonomy File, and a Text File, each with specific update and posting requirements. These changes are intended to strengthen transparency and improve the usefulness of publicly available pricing information.

As discussed in section VI.C.3. of this preamble, the Departments assume that self-insured group health plans would depend on TPAs, including issuers providing administrative services only and non-issuer TPAs, to implement these proposed updates, noting that some self-insured plans may choose to comply individually, likely incurring a similar hour burden.

The Departments recognize that some proposed requirements may be integrated into existing operational processes, potentially reducing implementation burdens, though the Departments acknowledge that the extent of integration varies significantly across different requirements. Marginal modifications may include adjusting reporting thresholds from 20 to 11 claims, extending lookback and reporting periods, and adding website footer links, while higher-burden implementations likely include network-level file reorganization, new file creation such as Taxonomy, Change-log, and Utilization Files, and provider-rate combination exclusion logic. Although some activities may align with routine system updates and maintenance cycles, the Departments provide detailed burden estimates for requirements involving substantial system modifications or new operational processes. The Departments seek public comment on additional costs or implementation challenges that may not be fully captured in this assessment.

1. ICRs Regarding Requirements To Organize Files by Provider Network, Allow Service Providers or Other Parties To Organize by Provider Network Across Multiple Self-Insured Group Health Plans (26 CFR 54.9815–2715A3(b)(1)(i) and (b)(5)(iii), 29 CFR 2590.715–2715A3(b)(1)(i) and (b)(5)(iii), and 45 CFR 147.212(b)(1)(i) and (b)(5)(iii))

The Departments propose to amend 26 CFR 54.9815–2715A3(b)(1)(i), 29 CFR 2590.715–2715A3(b)(1)(i), and 45 CFR 147.212(b)(1)(i) to require plans and issuers to make an In-network Rate File available for each provider network they maintain or contract with associated with the plan or policy being reported. The Departments also propose to add new 26 CFR 54.9815–2715A3(b)(5)(iii), 29 CFR 2590.715–2715A3(b)(5)(iii), and 45 CFR 147.212(b)(5)(iii) to permit In-network Rate Files to be made available by provider network for multiple plans administered by service providers or other parties, including those offered by different plan sponsors and including across different health insurance markets.

Under the current technical reporting requirements, plans and issuers publish an In-network Rate File for each plan or coverage they offer. As a result, the scope of the existing disclosure is at the individual plan or policy level, rather than at the broader provider network level. Current technical implementation guidance gives plans and issuers flexibility in how they structure their In-network Rate File to associate providers with negotiated rates. As a result, some plans or issuers may already be using network-based aggregation to both optimize the size of their output files as well as allow for greater file reuse across multiple plans. As discussed in section III.C.1. of this preamble, the Departments understand that many plans and issuers already leverage a Table of Contents to organize their files, an approach that would allow them to combine common negotiated rates across multiple In-network Rate Files, rather than publishing negotiated rates individually for each plan ID. However, the Departments assume that few have fully implemented that second step to organize files by provider networks with common negotiated rates across multiple In-network Rate Files, and many have not adopted it at all.

For burden estimation, the Departments make the assumption that no plans or issuers have adapted their In-network Rate File processes to align with this proposed provision. While this may overstate the implementation

burden for some, it provides a reasonable upper bound, ensuring the estimates cover the substantial and complex changes that most plans or issuers may need to make to comply with this proposal.

To implement this proposed provision, plans (or TPAs on behalf of plans) and issuers would need to modify their In-network Rate File processes to produce files aggregated at the provider network level rather than the plan level, and to generate a crosswalk table that associates each coverage option to the corresponding provider network the plan or issuer maintains or contracts with. The implementation will involve a meaningful, one-time recoding effort to revise existing In-network Rate File processes. However, because the underlying data used to build the In-network Rate Files will not change, these revisions will be incremental and build on the current process.

The proposed provision would also require, under newly proposed paragraph (b)(1)(i)(A), that each In-network Rate File be associated with its common provider network name. In practice, this means plans (or TPAs on behalf of plans) and issuers would need to add a new data element and identify the source of the common provider network names within their systems of record so these can be incorporated into the automated process for generating the required information for the In-network Rate Files. However, the Departments assume that plans (or TPAs on behalf of plans) and issuers would already have identified and captured these common provider network names as part of the related proposal to organize the In-network Rate Files by provider network. As a result, the Departments expect that any burden associated with disclosing this new data element is accounted for in the burden estimate for organizing these files by provider network, with no additional burden anticipated. The Departments seek comment on this assumption.

The Departments estimate that issuers and TPAs would incur a one-time cost and burden to modify a plan's or issuer's current process for generating In-network Rate Files to disclose discrete provider networks and crosswalk those networks to relevant plans or policies. As shown in Table 11, the Departments estimate that, on average, each issuer or TPA would require 16 hours from a Project Manager or Team Lead (at \$153 per hour), 80 hours from a Technical Architect/Sr. Developer (at \$149 per hour), 80 hours from a Senior Application Developer (at \$143 per hour), and 16 hours from a

Business Analyst (at \$120 per hour) to modify the plan’s or issuer’s current process, resulting in a one-time burden for each issuer or TPA of 192 hours with

an estimated associated cost of \$27,728. For all 1,580 issuers and TPAs, as shown in Table 12, the Departments estimate a total one-time burden of

303,360 hours with an estimated associated cost of \$43,810,240.

TABLE 11: One-Time Estimated Cost and Hour Burden per Health Insurance Issuer or TPA to Organize Files by Provider Network, Allow Service Providers or Other Parties to Organize by Provider Network across Multiple Self-insured Group Health Plans

Occupation	Burden Hours per Respondent	Labor Cost per Hour	Total Cost per Respondent
Project Manager/Team Lead	16	\$153.00	\$2,448
Technical Architect/Sr. Developer	80	\$149.00	\$11,920
Senior Application Developer	80	\$143.00	\$11,440
Business Analyst	16	\$120.00	\$1,920
Total per Respondent	192		\$27,728

TABLE 12: One-Time Estimated Cost and Hour Burden for All Health Insurance Issuers or TPAs to Organize Files by Provider Network, Allow Service Providers or Other Parties to Organize by Provider Network across Multiple Self-insured Group Health Plans

Number of Respondents	Number of Responses	Burden Hours per Respondent	Total Burden Hours	Total Cost
1,580	1,580	192	303,360	\$43,810,240

The Departments request comment on the estimated cost and burden hours presented in this analysis, including any additional costs or challenges that commenters may identify.

2. ICRs Regarding Requirements To Include Product Type in Both In-Network Rate and Allowed Amount Files (26 CFR 54.9815–2715A3(b)(1)(i)(B) and (b)(1)(ii)(A), 29 CFR 2590.715–2715A3(b)(1)(i)(B), and (b)(1)(ii)(A), and 45 CFR 147.212(b)(1)(i)(B) and (b)(1)(ii)(A))

The Departments propose to amend redesignated paragraphs 26 CFR 54.9815–2715A3(b)(1)(i)(B) and (b)(1)(ii)(A), 29 CFR 2590.715–2715A3(b)(1)(i)(B), and (b)(1)(ii)(A), and 45 CFR 147.212(b)(1)(i)(B) and (b)(1)(ii)(A) to require plans and issuers to report the product type (for example, HMO or PPO) associated with each

coverage option in both the In-network Rate File and the Allowed Amount File. Currently, there is no requirement for plans and issuers to include a product type in their machine-readable files. The only identifier currently required is the HIOS ID or the EIN when a HIOS ID is not available.

The Departments have determined that product type data is readily available to most plans and issuers and that this proposed requirement would only involve a one-time system update to include the product type variable in the machine-readable files. The assumptions account for time and effort to access the data sources from which to populate the product type variable within the machine-readable files.

The Departments estimate a one-time cost and burden for plans (or TPAs on behalf of plans) and issuers to

implement the required system automation updates. Each issuer or TPA would, on average, require 8 hours from a Project Manager or Team Lead (at \$153 per hour), 8 hours from a Senior Application Developer (at \$143 per hour), 8 hours from a Technical Architect/Sr. Developer (at \$149 per hour), and 8 hours from a Business Analyst (at \$120 per hour) to make the system updates and implement the requirements proposed in these rules. As shown in Table 13, this results in a total estimated burden of 32 hours, with an associated estimated cost of \$4,520 per issuer or TPA. As shown in Table 14, for all 1,580 issuers TPAs, the Departments estimate a total one-time burden of 50,560 hours with an associated total cost of approximately \$7,141,600.

TABLE 13: One-Time Estimated Cost and Hour Burden per Health Insurance Issuer or TPA to Include Product Type in Both In-network Rate and Allowed Amount Files

Occupation	Burden Hours per Respondent	Labor Cost per Hour	Total Cost per Respondent
Project Manager/Team Lead	8	\$153.00	\$1,224
Senior Application Developer	8	\$143.00	\$1,144
Technical Architect/Sr. Developer	8	\$149.00	\$1,192
Business Analyst	8	\$120.00	\$960
Total per Respondent	32		\$4,520

TABLE 14: One-Time Estimated Cost and Hour Burden for All Health Insurance Issuers or TPAs to Include Product Type in Both In-network Rate and Allowed Amount Files

Number of Respondents	Number of Responses	Burden Hours per Respondent	Total Burden Hours	Total Cost
1,580	1,580	32	50,560	\$7,141,600

The Departments request comment on the estimated cost and burden hours presented in this analysis, including any additional costs or challenges that commenters may identify.

3. ICRs Regarding Requirements To Report Dollar Amounts Except for Only “Percentage-of-Billed-Charges” Payments (26 CFR 54.9815–2715A3(b)(1)(i)(D)(1), 29 CFR 2590.715–2715A3(b)(1)(i)(D)(1), and 45 CFR 147.212(b)(1)(i)(D)(1))

The Departments propose to amend 26 CFR 54.9815–2715A3(b)(1)(i)(D)(1), 29 CFR 2590.715–2715A3(b)(1)(i)(D)(1), and 45 CFR 147.212(b)(1)(i)(D)(1) to clarify that plans and issuers are required to report in-network rates as a dollar amount, except when the contractual arrangement specifies payment as a percentage of billed charges and it is not possible to determine a dollar amount before the bill is generated. In those cases, the plan or issuer would instead be required to report the applicable percentage. This requirement is intended to improve data quality by ensuring plans and issuers consistently use a percentage when the contract bases payment on a percentage of billed charges and plans and issuers

cannot calculate a dollar amount in advance.

Since this proposal codifies an exception for situations in which the Departments have indicated they are unlikely to pursue enforcement action, the Departments have determined that many systems would already be compliant, as plans and issuers should already be reporting dollar amounts for rates except in certain “percentage-of-billed charges” arrangements. The Departments are also of the view that most plans and issuers have already incurred a one-time cost to make this adjustment and would incur no additional implementation costs or burden to update the In-network Rate Files. However, for those plans and issuers that may not have made this alteration to their In-network Rate Files, the Departments estimate a one-time burden and cost to meet the requirements of this proposed provision. For a low-end estimate, the Departments assume that 20 percent of plans (or TPAs on behalf of the plan) and issuers would need to make this one-time modification to their In-network Rate Files, while for a high-end estimate, it’s assumed that all plans (or TPAs on behalf of the plan) and issuers

would need to make this adjustment to their In-network Rate Files.

The Departments estimate, on average, each affected issuer or TPA would require 8 hours from a Project Manager or Team Lead (at \$153 per hour), 8 hours from a Technical Architect/Sr. Developer (at \$149 per hour), 8 hours of work from a Senior Application Developer (at \$143 per hour), and 8 hours from a Business Analyst (at \$120 per hour) to review their In-network Rate File generation code to determine if there are any instances where a non-dollar amount would appear in the file and then make the necessary coding adjustments and validate the changes, resulting in an estimated burden of 32 hours, with an estimated associated cost of \$4,520 per issuer or TPA, as shown in Table 15. The Departments estimate that, under the low-end scenario, affected issuers and TPAs would incur a total one-time burden of 10,112 hours with an associated total cost of approximately \$1,428,320. Under the high-end scenario, for all issuers and TPAs, the total one-time burden would be 50,560 hours with an associated total cost of approximately \$7,141,600, as shown in Table 16.

TABLE 15: One-Time Estimated Cost and Hour Burden per Health Insurance Issuer or TPA to Adjust In-network Rate Files to Report Dollar Amounts Except for “Percentage-of-Billed Charges” Payments

Occupation	Burden Hours per Respondent	Labor Cost per Hour	Total Cost per Respondent
Project Manager/Team Lead	8	\$153.00	\$1,224
Technical Architect/Sr. Developer	8	\$149.00	\$1,192
Senior Application Developer	8	\$143.00	\$1,144
Business Analyst	8	\$120.00	\$960
Total per Respondent	32		\$4,520

TABLE 16: One-Time Estimated Cost and Hour Burden for Health Insurance Issuers or TPAs to Adjust In-network Rate Files to Report Dollar Amounts Except for “Percentage-of-Billed-Charges” Payments Under High- and Low-End Scenarios

Estimate	Number of Respondents	Number of Responses	Burden Hours per Respondent	Total Burden Hours	Total Cost
Low-end estimate – 20 percent of issuers and TPAs need to update their In-network Rate Files	316	316	32	10,112	\$1,428,320
High-end estimate – 100 percent of issuers and TPAs need to update their In-network Rate Files	1,580	1,580	32	50,560	\$7,141,600

The Departments request comment on the estimated cost and burden hours presented in this analysis, including any additional costs or challenges that commenters may identify.

4. ICRs Regarding Requirements To Report Required Enrollment Data (26 CFR 54.9815–2715A3(b)(1)(i)(E), 29 CFR 2590.715–2715A3(b)(1)(i)(E), and 45 CFR 147.212(b)(1)(i)(E))

The Departments propose adding a new provision at 26 CFR 54.9815–2715A3(b)(1)(i)(E), 29 CFR 2590.715–2715A3(b)(1)(i)(E), and 45 CFR 147.212(b)(1)(i)(E) requiring plans and issuers to include the current enrollment totals (number of individuals) for each coverage option associated with the applicable In-network Rate File, as of the date the file is posted.

The Departments recognize that each plan or issuer would report a different number of coverage options, so the estimates reflect a presumed average. These estimates include the preparatory work needed for plans (or TPAs on behalf of plans) and issuers to understand the requirement, identify data sources (enrollment data may be stored across multiple systems), assess current systems, and agree on necessary system changes.

To implement this provision, plans (or TPAs on behalf of plans) and issuers would incur a one-time cost to update their systems to automate the retrieval and reporting of the required enrollment data. Furthermore, the Departments expect this work to be coordinated with efforts to comply with the proposed amendments under section IV.D.1. of this preamble, which requires listing each plan associated with a network.

Accordingly, the Departments estimate a one-time burden and cost for issuers and TPAs to update their systems to include a field for current enrollment totals and to automate ongoing data extraction. On average, each issuer or TPA would require 8 hours from a Project Manager or Team Lead (at \$153 per hour), 8 hours from a Technical Architect/Sr. Developer (at \$149 per hour), 8 hours from a Senior Application Developer (at \$143 per hour), and 8 hours from a Business Analyst (at \$120 per hour) to complete this work. As shown in Table 17, this results in a total estimated burden of 32 hours per issuer or TPA, with an associated cost of approximately \$4,520. For all 1,580 issuers and TPAs, as shown in Table 18, the Departments estimate a total one-time burden of 50,560 hours and a total cost of approximately \$7,141,600.

TABLE 17: One-Time Estimated Cost and Hour Burden per Health Insurance Issuer or TPA to Report Required Enrollment Data

Occupation	Burden Hours per Respondent	Labor Cost per Hour	Total Cost per Respondent
Project Manager/Team Lead	8	\$153.00	\$1,224
Technical Architect/Sr. Developer	8	\$149.00	\$1,192
Senior Application Developer	8	\$143.00	\$1,144
Business Analyst	8	\$120.00	\$960
Total per Respondent	32		\$4,520

TABLE 18: One-Time Estimated Cost and Hour Burden for All Health Insurance Issuers or TPAs to Report Required Enrollment Data

Number of Respondents	Number of Responses	Burden Hours per Respondent	Total Burden Hours	Total Cost
1,580	1,580	32	50,560	\$7,141,600

The Departments request comment on the estimated cost and burden hours presented in this analysis, including any additional costs or challenges that commenters may identify.

5. ICRs Regarding Requirements To Exclude Certain Providers From In-Network Rate Files (26 CFR 54.9815–2715A3(b)(1)(i)(F), 29 CFR 2590.715–2715A3(b)(1)(i)(F) and 45 CFR 147.212(b)(1)(i)(F))

The Departments propose to amend the paragraph on required information under 26 CFR 54.9815–2715A3(b)(1)(i), 29 CFR 2590.715–2715A3(b)(1)(i), and 45 CFR 147.212(b)(1)(i) to increase access to and improve the usability of the data reported in the In-network Rate File, by adding new paragraph (b)(1)(i)(F). This new paragraph would require plans and issuers to exclude from their In-network Rate Files a provider's negotiated rate (provider-rate combination) for an item or service if the plan or issuer determines it is unlikely that such provider would be reimbursed for such item or service given that provider's area of specialty according to the plan's or issuer's internal provider taxonomy used during the claims adjudication process.

In addition, the Departments propose at 26 CFR 54.9815–2715A3(b)(2)(iii), 29 CFR 2590.715–2715A3(b)(2)(iii), and 45 CFR 147.212(b)(2)(iii) to require plans and issuers to publish an additional machine-readable file, called a Taxonomy File, that includes the plan or issuer's internal provider taxonomy, which maps items and services

(represented by a billing code) to provider specialties (represented by specialty code) to determine if the plan or issuer should deny reimbursement for an item or service because it was not furnished by a provider in an appropriate specialty. This new file would increase transparency by showing how decisions to exclude certain provider-rate combinations from the In-network Rate File were determined.

This proposed provision would require plans and issuers to perform two specific updates: (1) update their current programmatic code to exclude certain provider-rate combinations from the existing In-network Rate Files, and (2) create and publish a new Taxonomy File.

The Departments have determined that (1) plans (or TPAs on behalf of plans) and issuers already maintain a complete listing of their in-network providers along with the specialties of those providers; (2) plans and issuers possess the taxonomy needed to map provider specialties to the appropriate billing codes; and (3) plans and issuers have implemented similar logic within their claims adjudication systems to pend or deny claims that fall outside a provider's scope of practice, for example, if a claim for brain surgery is submitted by a provider whose specialty does not align with that procedure.

Given this, the additional burden and cost required to automate the exclusion of certain provider-rate combinations would include (1) extracting and adapting the claims adjudication logic

built off the internal provider taxonomy that determines whether a provider is authorized to bill for a particular service for use in generating the In-network Rate File; (2) implementing an automated process to extract the in-network provider list along with their specialties from the plan's or issuer's system of record; and (3) modifying the programmatic logic of the In-network Rate File generation software to exclude the provider-rate combinations for those that are not eligible to submit claims for specific services.

Additionally, posting a Taxonomy File would require plans (or TPAs on behalf of plans) and issuers to list each taxonomy code they use and specify the associated service codes (for example, CPT codes). These mappings are typically stored in a reference table used by issuer claims adjudication systems. The Taxonomy File must be produced separately, in addition to each In-network Rate File.

To update the programmatic code to exclude certain provider-rate combinations from the existing In-network Rate File and to create and publish a new Taxonomy File, the Departments estimate a one-time cost and burden for plans (or TPAs on behalf of plans) and issuers. On average, each issuer or TPA would require 48 hours from a Project Manager or Team Lead (at \$153 per hour), 48 hours from a Technical Architect/Sr. Developer (at \$149 per hour), 48 hours from a Senior Application Developer (at \$143 per hour), and 48 hours from a Business Analyst (at \$120 per hour). As shown in

Table 19, this results in a total estimated burden of 192 hours per issuer or TPA, with an associated cost of

approximately \$27,120. For all 1,580 issuers and TPAs, as shown in Table 20, the Departments estimate a total one-

time burden of 303,360 hours and a total cost of approximately \$42,849,600.

TABLE 19: One-Time Estimated Cost and Hour Burden per Health Insurance Issuer or TPA to Exclude Certain Providers from In-network Rate Files

Occupation	Burden Hours per Respondent	Labor Cost per Hour	Total Cost per Respondent
Project Manager/Team Lead	48	\$153.00	\$7,344
Technical Architect/Sr. Developer	48	\$149.00	\$7,152
Senior Application Developer	48	\$143.00	\$6,864
Business Analyst	48	\$120.00	\$5,760
Total per Respondent	192		\$27,120

TABLE 20: One-Time Estimated Cost and Hour Burden for All Health Insurance Issuers or TPAs to Exclude Certain Providers from In-network Rate Files

Number of Respondents	Number of Responses	Burden Hours per Respondent	Total Burden Hours	Total Cost
1,580	1,580	192	303,360	\$42,849,600

The Departments request comment on the estimated cost and burden hours presented in this analysis, including any additional costs or challenges that commenters may identify.

6. ICRs Regarding Requirements To Lower Claims Reporting Threshold in the Allowed Amount File From 20 to 11 Claims (26 CFR 54.9815–2715A3(b)(1)(ii)(C), 29 CFR 2590.715–2715A3(b)(1)(ii)(C), and 45 CFR 147.212(b)(1)(ii)(C))

The Departments propose to amend 26 CFR 54.9815–2715A3(b)(1)(ii)(C), 29 CFR 2590.715–2715A3(b)(1)(ii)(C), and 45 CFR 147.212(b)(1)(ii)(C) to require plans and issuers to include data in the Allowed Amount File for items and services provided under a single plan or coverage when there are 11 or more unique claims for that item or service, lowering the current threshold from 20 to 11 to expand the data available.

The Departments assume this requirement would not create additional burden for plans and issuers. Existing systems are currently designed to report out-of-network allowed amounts when there are more than 20 claims for a covered item or service within a relevant 90-day period. Lowering the threshold to 11 claims is expected to require only marginal system variable

adjustments, with any associated costs absorbed into the routine system maintenance activities that plans (or TPAs on behalf of plans) and issuers already perform in the normal course of business. The change constitutes a standard simple administrative update, rather than a system redesign, and therefore does not necessitate additional infrastructure, a dedicated project budget, or significant developer time. The adjustment can be implemented by existing IT personnel as part of their routine operational duties, with no disruption and minimal costs.

The Departments request comment on the estimated cost and burden hours presented in this analysis, including any additional costs or challenges that commenters may identify.

7. ICRs Regarding Expansion of Reporting and Lookback Periods for Allowed Amount Files From 90 Days to 6 Months and 180 Days to 9 Months (26 CFR 54.9815–2715A3(b)(1)(ii)(C), 29 CFR 2590.715–2715A3(b)(1)(ii)(C), and 45 CFR 147.212(b)(1)(ii)(C))

The Departments propose to amend 26 CFR 54.9815–2715A3(b)(1)(ii)(C), 29 CFR 2590.715–2715A3(b)(1)(ii)(C), and 45 CFR 147.212(b)(1)(ii)(C) to expand the data included in the Allowed Amount Files by requiring plans and

issuers to report on items and services furnished by out-of-network providers over a 6-month reporting period starting 9 months before the file’s publication date, replacing the current 90-day reporting period that begins 180 days prior to the file’s publication date.

The Departments assume extending the reporting period from 90 days to 6 months would not create additional burden for plans and issuers, who the Departments assume currently have automated systems in production to report out-of-network allowed amounts. This change is expected to require only marginal system variable adjustments, with any associated costs absorbed into the routine system maintenance activities that plans (or TPAs on behalf of plans) and issuers already perform in the normal course of business. The change constitutes a standard simple administrative update, rather than a system redesign, and therefore does not necessitate additional infrastructure, a dedicated project budget, or significant developer time.

The Departments request comment on the estimated cost and burden hours presented in this analysis, including any additional costs or challenges that commenters may identify.

8. ICRs Regarding Requirements To Aggregate Allowed Amount Files by Market Type and Allow Service Providers or Other Parties To Aggregate by Market Type Across Multiple Self-Insured Group Health Plans (26 CFR 54.9815–2715A3(b)(1)(ii), 29 CFR 2590.715–2715A3(b)(1)(ii), and 45 CFR 147.212(b)(1)(ii) and Permit Such Aggregation at the TPA Level (26 CFR 54.9815–2715A3(b)(5)(iv), 29 CFR 2590.715–2715A3(b)(5)(iv), and 45 CFR 147.212(b)(5)(iv))

The Departments propose to amend 26 CFR 54.9815–2715A3(b)(1)(ii), 29 CFR 2590.715–2715A3(b)(1)(ii), and 45 CFR 147.212(b)(1)(ii) to require plans and issuers to aggregate out-of-network data reporting by health insurance market, specifically by grouping plan-level data into one of four categories: (1) small group market, (2) individual market, (3) large group market, and (4) plans in self-insured group markets. Under current technical reporting requirements, plans and issuers may, but are not required to, aggregate data across multiple plans or policies to meet

public disclosure requirements for the Allowed Amount Files. The Departments also propose to amend redesignated 26 CFR 54.9815–2715A3(b)(5)(iv), 29 CFR 2590.715–2715A3(b)(5)(iv), and 45 CFR 147.212(b)(5)(iv) to permit Allowed Amount Files to be aggregated by market type at the service provider level, rather than the plan level, for more than one self-insured group health plan, including those offered by different plan sponsors.

The Departments are of the view that this proposal would not require plans (or TPAs on behalf of plans) and issuers to make substantial changes to how they currently generate Allowed Amount Files. Instead, it would require modifying the output so that, rather than producing a separate Allowed Amount File for each plan or policy, plans and issuers would aggregate data into a single file for each applicable market category. The four market categories, small group, large group, individual, and plans in self-insured group markets, are already well established under existing market-wide

regulations, and plans and issuers can use existing data elements in their systems to classify each plan appropriately.¹⁶⁷

The Departments estimate that plans (or TPAs on behalf of plans) and issuers would incur a one-time cost and burden to modify and update their existing Allowed Amount File processes to produce output files aggregated by market segment. On average, each issuer or TPA would require 16 hours from a Project Manager or Team Lead (at \$153 per hour), 16 hours from a Technical Architect/Sr. Developer (at \$149 per hour), 16 hours of work from a Senior Application Developer (at \$143 per hour), and 16 hours from a Business Analyst (at \$120 per hour) to complete this work. As shown in Table 21, this results in a total estimated burden of 64 hours per issuer or TPA, with an associated cost of approximately \$9,040. For all 1,580 issuers and TPAs, as shown in Table 22, the Departments estimate a total one-time burden of 101,120 hours and a total cost of approximately \$14,283,200.

TABLE 21: One-Time Estimated Cost and Hour Burden per Health Insurance Issuer or TPA to Aggregate Allowed Amount Files by Market Type and Allow Service Providers or Other Parties to Aggregate by Market Type across Multiple Self-insured Group Health Plans and Permit Such Aggregation at the TPA Level

Occupation	Burden Hours per Respondent	Labor Cost per Hour	Total Cost per Respondent
Project Manager/Team Lead	16	\$153.00	\$2,448
Technical Architect/Sr. Developer	16	\$149.00	\$2,384
Senior Application Developer	16	\$143.00	\$2,288
Business Analyst	16	\$120.00	\$1,920
Total per Respondent	64		\$9,040

TABLE 22: One-Time Estimated Cost and Hour Burden for All Health Insurance Issuers or TPAs to Aggregate Allowed Amount Files by Market Type and Allow Service Providers or Other Parties to Aggregate by Market Type across Multiple Self-insured Group Health Plans and Permit Such Aggregation at the TPA Level

Number of Respondents	Number of Responses	Burden Hours per Respondent	Total Burden Hours	Total Cost
1,580	1,580	64	101,120	\$14,283,200

The Departments request comment on the estimated cost and burden hours

presented in this analysis, including any

additional costs or challenges that commenters may identify.

¹⁶⁷ 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103, as applicable.

9. ICRs Regarding Requirements To Add a Change-Log File Related to the In-Network Rate File Disclosures (26 CFR 54.9815–2715A3(b)(2)(i), 29 CFR 2590.715–2715A3(b)(2)(i), and 45 CFR 147.212(b)(2)(i))

The Departments propose adding a new provision under 26 CFR 54.9815–2715A3(b)(2)(i), 29 CFR 2590.715–2715A3(b)(2)(i), and 45 CFR 147.212(b)(2)(i) that would require plans and issuers to publish a Change-log File on a quarterly basis, on the same day the In-network Rate File is published, identifying all changes made since the previous version.

Under this proposal, each plan or issuer would be required to publish a Change-log File each quarter, identifying any changes made to the In-network Rate File for each provider network maintained or contracted by that plan or issuer compared to the file in the preceding quarter. If there are no changes made to the machine-readable file since that previous file’s posting, a Change-log File must still be posted indicating there are no changes.

This proposed requirement does not currently specify the required level of detail for the Change-log File, such as whether it should include high-level summaries or detailed information about changes to specific data points. As noted in section III.C.7.a. of this preamble, the Departments are seeking comment on which data elements should be included and on the overall design of the Change-log File. Due to the nature of the proposed provision, the Departments have made certain assumptions based on current information available to estimate the burden hours and cost of this proposed provision.

The Departments assume that plans and issuers would develop an automated system to track changes in the required data fields and report specific detailed information, such as the exact dollar amount of an applicable rate change. The Departments estimate that each issuer and TPA would incur a one-time burden and cost to develop and implement the to the proposed provision including to identify data

sources for each field, write code to detect changes from the previous file, generate the Change-log File, and conduct testing and quality control before establishing a process to make the file available to the public. Once these systems are in place, creating the Change-log File is expected to be automated.

On average, each plan (or a TPA on behalf of the plan) or issuer would require 50 hours from a Project Manager or Team Lead (at \$153 per hour), 220 hours from a Technical Architect/Sr. Developer (at \$149 per hour), 220 hours from a Senior Application Developer (at \$143 per hour), 50 hours from a Business Analyst (at \$120 per hour), and 36 hours from a DevOps Engineer (at \$181 per hour) to complete this work. As shown in Table 23, this results in a total estimated burden of 576 hours per issuer or TPA, with an associated cost of approximately \$84,406. For all 1,580 issuers and TPAs, as shown in Table 24, the Departments estimate a total one-time burden of 910,080 hours and a total cost of approximately \$133,361,480.

TABLE 23: One-Time Estimated Cost and Hour Burden per Health Insurance Issuer or TPA to Add a Change-log File for Disclosures Related to the In-network Rate File

Occupation	Burden Hours per Respondent	Labor Cost per Hour	Total Cost per Respondent
Project Manager/Team Lead	50	\$153.00	\$7,650
Technical Architect/Sr. Developer	220	\$149.00	\$32,780
Senior Application Developer	220	\$143.00	\$31,460
Business Analyst	50	\$120.00	\$6,000
DevOps Engineer	36	\$181.00	\$6,516
Total per Respondent	576		\$84,406

TABLE 24: One-Time Estimated Cost and Hour Burden for All Health Insurance Issuers or TPAs to Add a Change-log File for Disclosures Related to the In-network Rate File

Number of Respondents	Number of Responses	Burden Hours per Respondent	Total Burden Hours	Total Cost
1,580	1,580	576	910,080	\$133,361,480

The Departments request comment on the estimated cost and burden hours presented in this analysis, including any additional costs or challenges that commenters may identify.

10. ICRs Regarding Requirements To Implement the Disclosures Required for the Utilization File (26 CFR 54.9815–2715A3(b)(2)(ii), 29 CFR 2590.715–2715A3(b)(2)(ii), and 45 CFR 147.212(b)(2)(ii)).

At 26 CFR 54.9815–2715A3(b)(2)(ii), 29 CFR 2590.715–2715A3(b)(2)(ii), and

45 CFR 147.212(b)(2)(ii), the Departments propose requiring a Utilization File, which would require plans and issuers to list all items and services for which a claim has been submitted and reimbursed, in whole or in part from in-network providers and identify each provider who submitted claims for each item or service. The

Departments propose that the Utilization File include information from the 12-month period that ends 6 months prior to the publication of the Utilization File and be updated every 12 months.

The Departments assume that data for the new Utilization File is readily accessible to all plans and issuers through their existing claims databases. Posting a Utilization File would require issuers to programmatically generate a list of each unique combination of provider NPI, TIN, and place of service from their claims database for in-network providers reimbursed for any covered item or service during a specified period. In addition to the one-time burden and cost associated with the initial coding effort to create the Utilization File, plans and issuers would incur annual ongoing operational

burden and cost to produce the annual Utilization File, validate the data, store the Utilization File, and post it to the designated public access location.

Because the process for generating the Utilization File is similar to the logic used for creating the Allowed Amount File, and existing programmatic logic could serve as a starting point for the creation of the Utilization File, the Departments assume the burden and cost would be lower than those originally estimated in the 2020 final rules for the development and implementation of the Allowed Amount File.

Given the differences in the two files and past experience with the Allowed Amount File, the Departments estimate a one-time cost and burden for plans (or TPAs on behalf of plans) and issuers to develop, implement, and operate the

Utilization File to meet the requirements of these proposed rules. On average, each issuer or TPA would require 364 hours from a Scrum Master (at \$105 per hour), 546 hours from a Technical Architect/Sr. Developer (at \$149 per hour), 1,456 hours of work from a Senior Application Developer (at \$143 per hour), 364 hours from a Business Analyst (at \$120 per hour), and 182 hours from a DevOps Engineer (at \$181 per hour). As shown in Table 25, this results in a total estimated burden of 2,912 hours per issuer or TPA, with an associated cost of approximately \$404,404. For all 1,580 issuers and TPAs, as shown in Table 26, the Departments estimate a total one-time burden of 4,600,960 hours and a total cost of approximately \$638,958,320.

TABLE 25: One-Time Estimated Cost and Hour Burden per Health Insurance Issuer or TPA to Implement the Required Utilization File Disclosures

Occupation	Burden Hours per Respondent	Labor Cost per Hour	Total Cost per Respondent
Scrum Master	364	\$105.00	\$38,220
Technical Architect/Sr. Developer	546	\$149.00	\$81,354
Senior Application Developer	1,456	\$143.00	\$208,208
Business Analyst	364	\$120.00	\$43,680
DevOps Engineer	182	\$181.00	\$32,942
Total per Respondent	2,912		\$404,404

TABLE 26: One-Time Estimated Cost and Hour Burden for All Health Insurance Issuers or TPAs to Implement the Required Utilization File Disclosures

Number of Respondents	Number of Responses	Burden Hours per Respondent	Total Burden hours	Total Cost
1,580	1,580	2,912	4,600,960	\$638,958,320

In addition to the one-time burden and cost estimated in Tables 25 and 26, plans (or TPAs on behalf of plans) and issuers would incur ongoing annual burden and cost to update the Utilization File. The Departments estimate that, on average, each issuer or TPA would annually require 6 hours from a Scrum Master (at \$105 per hour),

16 hours of work from a Senior Application Developer (at \$143 per hour), and 16 hours from DevOps Engineer (at \$181 per hour) to make the required updates. As shown in Table 27, this results in a total estimated annual burden of 38 hours per issuer or TPA, with an associated cost of approximately \$5,814. For all 1,580

issuers and TPAs, as shown in Table 28, the Departments estimate a total ongoing annual burden of 60,040 hours and a total cost of approximately \$9,186,120. The 3-year average costs and burden for this proposal are presented in Table 29.

TABLE 27: Estimated Annual Cost and Hour Burden per Health Insurance Issuer or TPA to Update the Utilization File

Occupation	Burden Hours per Respondent	Labor Cost per Hour	Total Cost per Respondent
Scrum Master	6	\$105.00	\$630
Senior Application Developer	16	\$143.00	\$2,288
DevOps Engineer	16	\$181.00	\$2,896
Total per Respondent	38		\$5,814

TABLE 28: Estimated Annual Cost and Hour Burden for All Health Insurance Issuers or TPAs to Update the Utilization File

Number of Respondents	Number of Responses	Burden Hours per Respondent	Total Burden Hours	Total Cost
1,580	1,580	38	60,040	\$9,186,120

TABLE 29: Estimated 3-Year Average Annual Hour Burden and Costs for All Issuers and TPAs to Develop, Implement, and Annually Update the Utilization File

Year	Number of Respondents	Number of Responses	Burden Hours per Respondent	Total Burden Hours	Total Cost
2027	1,580	1,580	2,950	4,661,000	\$648,144,440
2028	1,580	1,580	38	60,040	\$9,186,120
2029	1,580	1,580	38	60,040	\$9,186,120
3-year average	1,580	1,580	1,009	1,593,693	\$222,172,227

The Departments request comment on the estimated cost and burden hours presented in this analysis, including any additional costs or challenges that commenters may identify.

11. ICRs Regarding Requirements To Add a Text File, Identify Point-of-Contact for Inquiries To Improve Discoverability and Accessibility of Machine-Readable Files, and Respond to Machine-Readable File Inquiries (26 CFR 54.9815–2715A3(b)(2)(iv), 29 CFR 2590.715–2715A3(b)(2)(iv), and 45 CFR 147.212(b)(2)(iv))

The Departments propose to add new 26 CFR 54.9815–2715A3(b)(2)(iv), 29 CFR 2590.715–2715A3(b)(2)(iv), and 45 CFR 147.212(b)(2)(iv), which would establish a new requirement for plans and issuers to improve the accessibility of their machine-readable files. Under this proposal, plans (or TPAs on behalf

of plans) and issuers would be required to generate a Text File that includes the URL of the page hosting the machine-readable files, a direct link to the machine-readable files themselves, and contact information for the individual at the plan, issuer, or TPA that is responsible for the machine-readable files. This Text File would be required to be placed in the root folder of the public website domain selected to host the machine-readable files, without regard to the website's page structure. This proposed new requirement would align with similar provisions under the 2023 Hospital Price Transparency rule¹⁶⁸ at 45 CFR 180.50(d)(6) and is intended to enhance the discoverability, usability, and consistency of pricing information for participants,

¹⁶⁸ 88 FR 81540 (November 22, 2023).

beneficiaries, and enrollees, third-party developers, researchers, and regulators.

The Departments anticipate plans (or a TPA on behalf of plans) and issuers would incur a one-time development burden to update their systems to support the automated generation and publication of the required Text File. In addition to setting up the ability to produce the Text File, plans (or TPAs on behalf of plans) and issuers would identify a point-of-contact for the file that would be available to address inquiries and issues related to the required machine-readable files and include this point-of-contact in the Text Files. The point-of-contact identified would need to set up a mechanism to receive and respond to inquiries and issues, such as an email box or online feedback form.

The Departments estimate a one-time burden and cost for plans (or TPAs on

behalf of plans) and issuers to develop, test, and implement the automation necessary to generate and post the required Text File in the root folder of their public website as well as set up a mechanism to receive and respond to inquiries and issues. On average, each issuer or TPA would require 8 hours of

work from a Senior Application Developer (at \$143 per hour), 8 hours from a Project Manager or Team Lead (at \$153 per hour), and 8 hours from a Business Analyst (at \$120 per hour). As shown in Table 30, this results in a total estimated burden of 24 hours per entity, with an associated cost of

approximately \$3,328. Across all 1,580 issuers and TPAs, the Departments estimate a total one-time burden of 37,920 hours and a combined cost of approximately \$5,258,240, as presented in Table 31.

TABLE 30: One-Time Estimated Cost and Hour Burden per Health Insurance Issuer or TPA to Add a Text File and Identify Point-of-Contact for Inquiries to Improve Discoverability and Accessibility of Machine-Readable Files

Occupation	Burden Hours per Respondent	Labor Cost per Hour	Total Cost per Respondent
Senior Application Developer	8	\$143.00	\$1,144
Business Analyst	8	\$120.00	\$960
Project Manager/Team Lead	8	\$153.00	\$1,224
Total per Respondent	24		\$3,328

TABLE 31: One-Time Estimated Cost and Hour Burden for All Health Insurance Issuers or TPAs to Add a Text File and Identify Point-of-Contact for Inquiries to Improve Discoverability and Accessibility of Machine-Readable Files

Number of Respondents	Number of Responses	Burden Hours per Respondent	Total Burden Hours	Total Cost
1,580	1,580	24	37,920	\$5,258,240

In addition to the one-time costs estimated in Tables 30 and 31, plans (or TPAs on behalf of plans) and issuers would incur ongoing annual burden and cost to respond to inquiries and issues on the machine-readable files. The Departments assume that each issuer and TPA would establish a team to triage, review, and respond to the inquiries. The Departments estimate that, on average each year, each issuer or TPA would receive approximately 30

inquiries. Addressing each inquiry is estimated to require 10 minutes of work per inquiry from an Attorney III (totaling 300 minutes for 30 inquiries at \$143 per hour), 20 minutes per inquiry from a Senior Application Developer (totaling 600 minutes for 30 inquiries at \$143 per hour), and 30 minutes per inquiry from a Project Manager/Team Lead (totaling 900 minutes for 30 inquiries at \$153 per hour). As shown in Table 32, this results in a total

estimated annual burden of 30 hours per issuer or TPA, with an associated cost of approximately \$4,440 for each issuer or TPA. As shown in Table 33, the Departments estimate a total ongoing annual burden of 47,400 hours and a total cost of approximately \$7,015,200 for all 1,580 issuers and TPAs. The 3-year average burden hours and costs for this proposal are presented in Table 34.

TABLE 32: Estimated Annual Cost and Hour Burden per Health Insurance Issuer or TPA to Respond to Machine-Readable File Inquiries

Occupation	Burden Hours per Respondent	Labor Cost per Hour	Total Cost per Respondent
Attorney III	5	\$143.00	\$715
Senior Application Developer	10	\$143.00	\$1,430
Project Manager/Team Lead	15	\$153.00	\$2,295
Total per Respondent	30		\$4,440

TABLE 33: Estimated Annual Cost and Hour Burden for All Health Insurance Issuers or TPAs to Respond to Machine-Readable File Inquiries

Number of Respondents	Number of Responses	Burden Hours per Respondent	Total Burden Hours	Total Cost
1,580	1,580	30	47,400	\$7,015,200

TABLE 34: Estimated 3-Year Average Annual Hour Burden and Costs for All Issuers and TPAs to add a Text File and to Respond to Machine-Readable File Inquiries

Year	Number of Respondents	Number of Responses	Burden Hours per Respondent	Total Burden Hours	Total Cost
2027	1,580	1,580	54	85,320	\$12,273,440
2028	1,580	1,580	30	47,400	\$7,015,200
2029	1,580	1,580	30	47,400	\$7,015,200
3-year average	1,580	1,580	38	60,040	\$8,767,947

The Departments request comment on the estimated cost and burden hours presented in this analysis, including any additional costs or challenges that commenters may identify.

12. ICRs Regarding Requirements To Add a Price Transparency Footer Link on Website Directing Users to the Location of the Machine-Readable Files (26 CFR 54.9815–2715A3(b)(3)(iii), 29 CFR 2590.715–2715A3(b)(3)(iii), and 45 CFR 147.212(b)(3)(iii))

The Departments propose to add a new requirement at 26 CFR 54.9815–2715A3(b)(3)(iii), 29 CFR 2590.715–2715A3(b)(3)(iii), and 45 CFR 147.212(b)(3)(iii) to improve user access to machine-readable files published under paragraphs (b)(1) and (2). Specifically, plans and issuers would be required to include a link to the internet domain where the machine-readable files are hosted on the footer of their website. This link must appear on the home page and on any other page that includes a footer and must be labeled as “Price Transparency” or “Transparency in Coverage.”

The Departments anticipate that the burden associated with this proposed requirement would be minimal, as it would involve only basic website modifications.

The Departments request comment on the estimated cost and burden hours presented in this analysis, including any additional costs or challenges that commenters may identify.

E. Submission of PRA Related Comments

The burden associated with the Transparency in Coverage disclosure requirements for HHS is currently approved under OMB control number 0938–1429 (CMS–10715, Transparency in Coverage).¹⁶⁹ HHS plans to revise this information collection request to include the additional burden resulting from the proposed requirements. For the Departments of Labor and the Treasury, the related burden was submitted to OMB as Request for Common Form (RCF) submissions. Once OMB approves the RCF submissions, both DOL and Treasury will update and submit their respective information collection requests to reflect the proposed changes. The Departments have submitted a copy of these proposed rules to OMB for its review of the rule’s information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections for control number 0938–1429, please visit CMS’s website at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>. To obtain copies of the supporting statement for control number 0938–1429, please go to <https://www.RegInfo.gov> or email the request to

¹⁶⁹ Transparency in Pricing Information (CMS–10715), OMB control number 0938–1429 (October 14, 2021), https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202410-0938-006.

ebsa.opr@dol.gov and reference control number 0938–1429.

The Departments invite public comment on these potential information collection requirements. Commenters may send their views on the Department’s PRA analysis in the same way they send comments in response to these proposed rules (for example, through the www.regulations.gov website), including as part of a comment responding to the broader proposed rules.

F. Summary of Ongoing and One-Time Burden Estimates for the Proposed Requirements

As shown in Tables 35 and 36, the Departments estimate that these proposed requirements would result in an ongoing burden of approximately 1.4 million hours annually, at a cost of \$68.2 million per year for all plans (or TPAs on behalf of plans) and issuers. In addition, these proposed requirements are expected to impose one-time implementation costs, totaling approximately 6.7 million hours and \$913.7 million across all plans (TPAs on behalf of plans) and issuers. Together, this represents a first-year burden of roughly 7.8 million hours and \$982 million in associated costs. In subsequent years, the burden is estimated at about 1.4 million hours and \$68.2 million per year.

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TABLE 35: Estimated Annual Burden Hours and Costs Associated with the Proposed Requirements for All Issuers and TPAs

Information Collection Requirements (ICRs)	OMB Control Number	Number of Respondents	Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Cost (\$)
ICRs Regarding Requirements for Disclosures to Participants, Beneficiaries, or Enrollees to Provide Pricing Information via Phone (26 CFR 54.9815-2715A2, 29 CFR 2590.715-2715A2, and 45 CFR 147.211)*	0938-1372	1,580	7,800,000	658	1,300,000	\$52,000,000
ICRs Regarding Requirements to Implement the Required Utilization File Disclosures (26 CFR 54.9815-2715A3(b)(2)(ii), 29 CFR 2590.715-2715A3(b)(2)(ii), and 45 CFR 147.212(b)(2)(ii))	0938-1372	1,580	1,580	38	60,040	\$9,186,120
ICRs Regarding Requirements to Respond to Machine-Readable File Inquiries (26 CFR 54.9815-2715A3(b)(2)(iv), 29 CFR 2590.715-2715A3(b)(2)(iv), and 45 CFR 147.212(b)(2)(iv))	0938-1372	1,580	1,580	30	47,400	\$7,015,200
Total			7,803,160		1,407,440	\$68,201,320

* High-end 3-year estimated values are represented in the table and used to determine the overall 3-year average estimated figures.

TABLE 36: Estimated One-time Burden Hours and Costs Associated with the Proposed Requirements for All Issuers and TPAs

Information Collection Requirements (ICRs)	OMB Control Number	Number of Respondents	Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Cost (\$)
ICRs Regarding Requirements to Update Cost-Sharing Disclosure Reflecting Federal Balance Billing Protections (26 CFR 54.9815-2715A2, 29 CFR 2590.715-2715A2, and 45 CFR 147.211)	0938-1372	1,580	1,580	0.17	263	\$37,657
To Train Customer Service Representatives to Provide Cost-Sharing Information for ICRs Regarding Requirements for Disclosures to Participants, Beneficiaries, or Enrollees to Provide Pricing Information via Phone (26 CFR 54.9815-2715A2, 29 CFR 2590.715-2715A2, and 45 CFR 147.211)	0938-1372	1,580	1,580	10	290,720	\$13,727,040
ICRs Regarding Requirements to Organize Files by Provider Network, Allow Service Providers or Other Parties to Organize by Provider Network across Multiple Self-insured Group Health Plans, and Disclose the Common Provider Network Names (26 CFR 54.9815-2715A3(b)(1)(i) and (b)(5)(iii), 29 CFR 2590.715-2715A3(b)(1)(i) and (b)(5)(iii), and 45 CFR 147.212(b)(1)(i) and (b)(5)(iii))	0938-1372	1,580	1,580	192	303,360	\$43,810,240
ICRs Regarding Requirements to Include Product Type in Both In-network Rate and Allowed Amount Files (26 CFR 54.9815-2715A3(b)(1)(i)(B) and (b)(1)(ii)(A), 29 CFR 2590.715-2715A3(b)(1)(i)(B), and (b)(1)(ii)(A), and 45 CFR	0938-1372	1,580	1,580	32	50,560	\$7,141,600

Information Collection Requirements (ICRs)	OMB Control Number	Number of Respondents	Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Cost (\$)
147.212(b)(1)(i)(B) and (b)(1)(ii)(A))						
ICRs Regarding Requirements to Report Dollar Amounts Except for Only “Percent-of-Billed Charges” Payments (26 CFR 54.9815-2715A3(b)(1)(i)(D)(I), 29 CFR 2590.715-2715A3(b)(1)(i)(D)(I), and 45 CFR 147.212(b)(1)(i)(D)(I))*	0938-1372	1,580	1,580	32	50,560	\$7,141,600
ICRs Regarding Requirements to Report Required Enrollment Data (26 CFR 54.9815-2715A3(b)(1)(i)(E), 29 CFR 2590.715-2715A3(b)(1)(i)(E), and 45 CFR 147.212(b)(1)(i)(E))	0938-1372	1,580	1,580	32	50,560	\$7,141,600
ICRs Regarding Requirements to Exclude Certain Providers from In-network Rate Files (26 CFR 54.9815-2715A3(b)(1)(i)(F), 29 CFR 2590.715-2715A3(b)(1)(i)(F) and 45 CFR 147.212(b)(1)(i)(F))	0938-1372	1,580	1,580	192	303,360	\$42,849,600
ICRs Regarding Requirements to Aggregate Out-of-Network Allowed Amount Files by Market Type and Allow Service Providers or Other Parties to Aggregate by Market Type across Multiple Self-insured Group Health Plans (26 CFR 54.9815-2715A3(b)(1)(ii), 29 CFR 2590.715-2715A3(b)(1)(ii), and 45 CFR 147.212(b)(1)(ii) and Permit Such Aggregation at the TPA level (26 CFR 54.9815-2715A3(b)(5)(iv), 29 CFR 2590.715-2715A3(b)(5)(iv), and 45 CFR 147.212(b)(5)(iv))	0938-1372	1,580	1,580	64	101,120	\$14,283,200
ICRs Regarding Requirements to Add a	0938-1372	1,580	1,580	576	910,080	\$133,361,480

Information Collection Requirements (ICRs)	OMB Control Number	Number of Respondents	Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Cost (\$)
Change-log File related to the In-network Rate File Disclosures (26 CFR 54.9815-2715A3(b)(2)(i), 29 CFR 2590.715-2715A3(b)(2)(i), and 45 CFR 147.212(b)(2)(i))						
ICRs Regarding Requirements to Implement the Required Utilization File Disclosures (26 CFR 54.9815-2715A3(b)(2)(ii), 29 CFR 2590.715-2715A3(b)(2)(ii), and 45 CFR 147.212(b)(2)(ii))	0938-1372	1,580	1,580	2,912	4,600,960	\$638,958,320
ICRs Regarding Requirements to add a Text File to Improve Discoverability and Accessibility of Machine-Readable Files (26 CFR 54.9815-2715A3(b)(2)(iv), 29 CFR 2590.715-2715A3(b)(2)(iv), and 45 CFR 147.212(b)(2)(iv))	0938-1372	1,580	1,580	24	37,920	\$5,258,240
Total			17,380		6,699,463	\$913,710,577

* High-end estimated values are represented in the table and used to determine the overall estimated figures.

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V. Response to Comments

Because of the large number of public comments the Departments normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. The Departments will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when the Departments proceed with a subsequent document, the Departments will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

These proposed rules would amend and strengthen the existing regulations under sections 1311(e)(3) and 2715A of the PHS Act and be incorporated into section 715 of ERISA and section 9815 to the Code to enhance price transparency reporting requirements for non-grandfathered group health plans

and health insurance issuers offering non-grandfathered group and individual health insurance coverage. Consistent with the goals of Executive Order 14221, these proposed rules aim to provide patients with clear, accurate, and actionable pricing information.¹⁷⁰

More broadly, these proposed rules seek to improve the quality, accuracy, and usability of publicly available pricing disclosures and cost-sharing information for participants, beneficiaries, and enrollees. They also address new Federal protections under the No Surprises Act and reduce duplicative reporting requirements.

By making pricing data more meaningful and accessible, these changes are intended to help participants, beneficiaries, and enrollees better understand their potential costs, support more informed decision-making, and promote greater

competition among health care providers and insurers.

B. Overall Impact

The Departments have examined the impacts of these proposed rules as required by Executive Order 12866, “Regulatory Planning and Review;”¹⁷¹ Executive Order 13132, “Federalism;”¹⁷² Executive Order 13563, “Improving Regulation and Regulatory Review;”¹⁷³ Executive Order 14192, “Unleashing Prosperity Through Deregulation;”¹⁷⁴ the Regulatory Flexibility Act (RFA);¹⁷⁵ section 1102(b) of the Social Security Act; and section 202 of the Unfunded Mandates Reform

¹⁷¹ Exec. Order No. 12866, 58 FR 51735 (September 30, 1993).

¹⁷² Exec. Order No. 13132, 64 FR 43255 (August 4, 1999).

¹⁷³ Exec. Order No. 13563, 76 FR 3821 (January 18, 2011).

¹⁷⁴ Exec. Order No. 14192, 90 FR 9065 (January 31, 2025).

¹⁷⁵ Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164 (September 19, 1980).

¹⁷⁰ Exec. Order No. 14221, 90 FR 11005 (February 28, 2025).

Act of 1995 (March 22, 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, or the principles set forth in this Executive order.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under Executive Order 12866. A “significant regulatory action” is also subject to review by the Office of Management and Budget (OMB). The Departments have concluded that this rule is likely to have economic impacts of \$100 million or more in at least 1 year. The Departments have provided an assessment of the potential costs, benefits, and transfers associated with this rule. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by OMB. Additionally, tax regulatory actions issued by the U.S. Department of the Treasury are subject to the requirements of section 6 of Executive Order 12866 pursuant to the Memorandum of Agreement (MOA) (July 4, 2025) between the Treasury Department and OMB regarding review of tax regulations. As such, the Treasury portions of this rule were also reviewed by OMB and are also incorporated into this RIA.

C. Affected Entities

This section of the preamble summarizes the number of plans, issuers, and participant, beneficiaries and enrollees that would be affected by these proposed rules.

1. Group Health Plans

These proposed rules would affect ERISA-covered group health plans and non-Federal governmental group health plans. The Departments estimate there are approximately 2,600,000 ERISA-covered group health plans, of which approximately 119,000 are self-insured and 1,500,000 are fully funded.¹⁷⁶ The Departments also estimate that these proposed rules would affect 90,900 non-Federal governmental group health plans.¹⁷⁷ Of these plans, approximately 35.7 percent¹⁷⁸ (or 32,400) are self-insured,¹⁷⁹ and 64.3 percent (or 58,400) are fully funded.¹⁸⁰

2. Participants, Beneficiaries, and Enrollees

The Departments estimate that there are 135.5 million participants in ERISA-covered group health plans, of which 78.9 million are in self-insured plans and 56.6 million are in fully funded plans.¹⁸¹ There are also approximately 44.5 million participants in non-Federal governmental group health plans, of which 22.8 million are in self-insured plans and 21.5 million are in fully funded plans.¹⁸² In addition, roughly 46 million individuals are covered by

¹⁷⁶ There are 2,627,159 ERISA-covered group health plans, of which 119,485 are self-insured and 1,476,575 are fully funded. (Based on the 2023 Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and the 2021 County Business Patterns from the Census Bureau. Agency for Healthcare Research and Quality, *2023 Medical Expenditure Panel Survey Insurance Component (MEPS-IC)*, https://meps.ahrq.gov/mepsweb/data_stats/download_data_files.jsp (last visited Dec. 8, 2025); U.S. Census Bureau, *2021 County Business Patterns*, <https://www.census.gov/programs-surveys/cbp/data.html> (last visited Dec. 8, 2025).

¹⁷⁷ Based on data from the 2022 Census of Governments, there are 90,887 State and local entities. The Departments assume there is one plan per entity on average. Therefore, the Departments estimate that there are 90,887 non-Federal governmental plans. U.S. Census Bureau, *2022 Census of Governments, Organization Tables*, <https://www.census.gov/data/tables/2022/econ/gus/2022-governments.html> (last visited Dec. 8, 2025).

¹⁷⁸ Agency for Healthcare Research and Quality, *Medical Expenditure Panel Survey—Insurance Component, Table III.A.2.a.* (2023), https://www.meps.ahrq.gov/data_stats/summ_tables/insr/national/series_3/2023/ic23_iiia_g.pdf.

¹⁷⁹ This estimate is calculated as follows: 90,887 non-Federal group health plans × 35.7 percent = 32,447 self-insured, non-Federal governmental group health plans.

¹⁸⁰ This estimate is calculated as follows: 90,887 non-Federal group health plans × 64.3 percent = 58,440 fully insured, non-Federal governmental group health plans.

¹⁸¹ Employee Benefits Security Administration, *Health Insurance Coverage Bulletin: Abstract of Auxiliary Data for the March 2023 Annual Social and Economic Supplement to the Current Population Survey* (August 30, 2024), <https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2023.pdf>.

¹⁸² *Id.*

private direct-purchase health insurance.¹⁸³

3. Issuers and TPAs

Finally, the Departments estimate that these proposed rules would affect 205 TPAs¹⁸⁴ and 1,375 issuers.¹⁸⁵ The Departments assume that fully-insured group health plans would rely on health insurance issuers. In contrast, self-insured group health plans would depend on TPAs, including issuers providing administrative services only and non-issuer TPAs, to implement the proposed updates to cost-sharing disclosures to participants, beneficiaries, and enrollees, as well as to implement the amended public disclosure requirements. This assumption is based on the Departments’ understanding that most self-insured group health plans already rely on TPAs to perform core administrative functions, such as enrollment and claims processing.¹⁸⁶ The Departments use the term TPA in this section of the preamble to refer to any other party with which a self-insured group health plan has an agreement to provide services to meet the proposed requirements in these proposed rules.

D. Detailed Economic Analysis

1. Impact Estimates of the Transparency in Coverage Provisions and Accounting Table

Consistent with Executive Order 12866 and OMB Circular A–4,¹⁸⁷ Table 37 depicts an accounting statement summarizing the Departments’ assessment of the benefits, costs, and transfers associated with these proposed

¹⁸³ Congressional Research Service, *U.S. Health Care Coverage and Spending*, <https://sgp.fas.org/crs/misc/IF10830.pdf> (last updated Feb. 19, 2025).

¹⁸⁴ An “issuer/state combination” refers to a health insurance issuer and the state in which it offers coverage, such that the same issuer operating in multiple states is treated as separate issuer/state combinations. Centers for Medicare & Medicaid Services, *2023 Medical Loss Ratio Data*, <https://www.cms.gov/marketplace/resources/data/medical-loss-ratio-data-systems-resources> (last updated Dec. 23, 2024).

¹⁸⁵ The Departments’ estimate of the number of health insurance companies and the number of issuers (issuer/State combinations) is based on medical loss ratio reports submitted by issuers for the 2023 reporting year. Centers for Medicare & Medicaid Services, *Medical Loss Ratio Data and System Resources*, <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr> (last updated Dec. 23, 2024).

¹⁸⁶ Louise Norris, *What is Self-Insured Health Insurance? Most Very Large Employers Self-Insure*, Verywell Health (November 9, 2024), <https://www.verywellhealth.com/what-is-self-insured-health-insurance-and-how-is-it-regulated-4688567>.

¹⁸⁷ Office of Management and Budget, *Circular A–4: Regulatory Analysis* (2003), <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>.

regulatory actions. The Departments are unable to quantify all of the benefits and costs associated with these proposed	rules due to data limitations and uncertainty about how plans, issuers, and other interested parties may	respond to these proposed requirements. BILLING CODE 4831–GV–P; 4150–29–P; 4120–01–P

TABLE 37: Accounting Table

Benefits					
Category	Estimate	Year Dollar	Discounted Rate	Period Covered	
Annualized Monetized (\$year)	\$257,046,000	2025	3 percent	2027–2031	
Annualized Monetized (\$/year)	\$257,046,000	2025	7 percent	2027-2031	
Quantified Benefits					
Approximately \$11.2 million per year in reduced data cleaning and integration, and quarterly reporting reduction costs for third-party developers and other file users.					
Approximately \$73 million per year in storage reductions and quarterly reporting for plans, issuers, third-party developers, and other file users.					
Approximately \$171.1 million per year in egress and quarterly reporting reduction costs for plans and issuers.					
Approximately \$1.4 million per year in reduced time for third-party developers and other file users locating files by requiring a Text file and footer links to help file users more easily find the data.					
Non-Quantified Benefits					
Increases transparency of financial obligations, including coinsurance, copayments, deductibles, out-of-pocket limits, and potential balance billing.					
Helps participants, beneficiaries, and enrollees make more informed financial and health care decisions with clearer cost estimates, particularly those individuals with low computer literacy who may not be able to access the online tool.					
Promotes cost-conscious decision-making by giving participants, beneficiaries, and enrollees information to compare provider prices, so they can weigh cost alongside other important factors such as location, reputation, or quality when selecting care.					
Facilitates timely medical bill payments by giving participants, beneficiaries, and enrollees a clearer understanding of expected costs in advance.					
Fosters provider competition and potential cost savings as participants, beneficiaries, and enrollees use pricing information to shop for health care.					
Improves regulatory oversight by providing better data for assessing premium rates and tracking price trends.					
Improves data usability through standardized file requirements, enabling more effective analysis for file users and developers, as well as for academic researchers and policymakers to study health care costs.					
Helps plans and issuers negotiate more competitive rates by giving them clearer, more detailed pricing information.					
Costs					
Category	Low Estimate	High Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized (\$/year)	\$232,091,961	\$261,903,147	2025	3 percent	2027-2031
Annualized Monetized (\$/year)	\$246,565,891	\$276,468,149	2025	7 percent	2027-2031
Quantified Costs					
Ongoing annual costs to plans and issuers for making pricing information available vis phone are estimated at \$23,400,000 on the low end and \$52,000,000 on the high end.					
One-time costs to update cost-sharing disclosure reflecting Federal balance billing protections are estimated at \$37,657.					
One-time costs to plans and issuers to train customer service representatives and supervisors to provide cost-sharing information via phone are estimated at \$13,727,040.					
One-time costs to plans and issuers to organize In-network Rate Files by provider network are estimated at \$43,810,240.					
One-time costs to plans and issuers to include product type in both the In-network Rate and Allowed Amount Files are estimated at \$7,141,600.					

One-time costs to plans and issuers to report dollar amounts except for only “percent-of-billed charges” payments are estimated at \$1,428,320 on the low end and \$7,141,600 on the high end.
One-time costs to plans and issuers to disclose enrollment data are estimated at \$7,141,600.
One-time costs to plans and issuers to exclude certain providers from In-network Rate Files are estimated at \$42,849,600.
One-time costs to plans and issuers to aggregate Out-of-Network Allowed Amount files by market type and allow service providers and other parties to aggregate by market type across multiple self-insured group health plans are estimated at \$14,283,200.
One-time costs to plans and issuers to add a Change-log File related to the In-network Rate File disclosures are estimated at \$133,361,480.
One-time costs to plans and issuers to develop processes to implement the Utilization File are estimated at \$638,958,320.
Ongoing annual costs to implement the disclosures required for the Utilization File are estimated at \$9,186,120.
One-time costs to plans and issuers to add a Text File to improve discoverability and accessibility of machine-readable files is estimated at \$5,258,240.
Ongoing annual costs to plans and issuers to respond to machine-readable file inquiries estimated at \$7,015,200.
Non-Quantified Costs
Potential increase in health care costs due to price convergence, as greater transparency may lead lower-cost providers to raise prices.
Potential decrease in providers’ willingness to offer discounted rates, especially in narrow networks, due to public disclosure of negotiated prices.
Increase in difficulty for smaller issuers to sustain competitive provider networks, potentially impacting compliance with network adequacy standards.
Potential increase in risk of PHI and PII breaches, requiring investment in enhanced privacy and cybersecurity measures.
Potential increase in State regulators’ costs for monitoring and enforcing compliance with new Federal requirements.
Transfers
Non-Quantified Transfers
Potential transfer from higher-cost to lower-cost providers through market share shifts as participants, beneficiaries, and enrollees switch to providers offering more competitive pricing.
Potential transfer from providers to participants, beneficiaries, and enrollees as a result of increased price transparency through lower out-of-pocket costs if consumers select lower-cost providers.
Potential transfer from plans and issuers to consumers, participants, beneficiaries, and enrollees if increased price transparency leads to systemic shifts toward lower-cost providers and overall reductions in health care spending, which could eventually translate to decreased premiums.
Potential transfer from PTC-eligible consumers to the Federal government if there is a reduction in premiums, as a result of increased price transparency, and a subsequent reduction in PTC spending.
Potential transfer from consumers, participants, beneficiaries, and enrollees to providers if price transparency results in price convergence, leading lower-cost providers to raise their prices to align with higher-cost competitors and thereby increasing out-of-pocket costs.
Potential transfer from consumers, participants, beneficiaries, and enrollees to plans and issuers if providers raise their prices, as a result of price convergence, leading to increased premiums.
Potential transfer from the Federal government to PTC-eligible consumers if there is an increase in premiums, as a result of the provision in these rules or price convergence effects, and a subsequent increase in PTC spending.

storing, and updating very large and complex machine-readable files. The Departments acknowledge these burdens, as well as the underestimation of such burdens in the 2020 final rules and seek to address them in these proposed rules by requiring more efficient disclosure formats, clarifying data reporting structures and reducing duplicative data. While the Departments are unable to quantify the extent of the underestimation in the 2020 final rules, they seek comment on which particular burden estimates were underestimated and what data sources can be relied upon to demonstrate the impact.

The following sections outline a more detailed accounting of the quantified and non-quantified benefits and costs associated with these proposed rules.

2. Proposed Requirements for Disclosures to Participants, Beneficiaries, or Enrollees Under 45 CFR 147.211

a. Benefits

The following paragraphs describe the benefits of the proposed revisions to the requirement that plans and issuers disclose certain cost-sharing information to participants, beneficiaries, and enrollees through an internet-based self-service tool, including making pricing information available by phone, and amending the disclaimer related to balance-billing consistent with balance billing protections under the No Surprises Act.

(1) Informed Consumer

These proposed amendments would enhance consumer access to critical cost-sharing information by expanding the available delivery methods and clarifying their scope. Requiring group health plans and issuers to provide cost-sharing estimates by phone using a phone number found on any physical or electronic plan or insurance identification (ID) card issued to participants, beneficiaries, and enrollees for which a consumer may seek customer assistance would ensure broader accessibility for all participants, beneficiaries, and enrollees, including those who prefer or rely on verbal communication due to visual impairments, limited literacy, or other challenges. By expanding access to this information, more participants, beneficiaries, and enrollees would be empowered to make cost-conscious decisions about their health care. In addition, the proposed amendments to the currently required notice on balance billing would provide individuals with clearer information about the potential for out-of-network providers to charge

additional amounts not reflected in the cost-sharing information provided to the individual, including the fact that there are protections against balance bills under Federal law, as well as to ensure that plans and issuers are including this notice unless the plans or policies are offered in States that categorically prohibit balance billing.

(2) Timely Payment of Medical Bills

The proposed amended requirements are designed to make the cost-sharing information disclosed pursuant to these proposed rules more accessible to more participants, beneficiaries, and enrollees, and easier for participants, beneficiaries, and enrollees to understand and anticipate their health care costs. More transparency around potential health care costs by providing a new method for delivery of the information via the phone and clearer information about potential balance billing and out-of-pocket costs is expected to increase participants', beneficiaries', and enrollees' overall awareness of their potential health care costs. The Departments have determined that this increased transparency and awareness would help participants, beneficiaries, and enrollees better anticipate expenses and lead to more consistent and timely payment of medical bills. A TransUnion survey reported that 79 percent of individuals would be more likely to pay their medical bills promptly if they had out-of-pocket costs estimates before obtaining care.¹⁸⁸ Additionally, recent reports from hospital systems show that when patients receive clear, upfront cost estimates, they are more likely to make payments at the time of service. For example, the Surgery Center of Oklahoma achieved a 22-fold increase in point-of-service collections, from about \$900,000 in 2007 to \$20.5million in 2017, after implementing an automated cost-estimation tool that provided transparent pricing before care.¹⁸⁹ Similarly, a Florida-based hospital system that adopted real-time price estimates experienced a nearly 30 percent increase in point-of-service collections over 2 years.¹⁹⁰ This

¹⁸⁸ Beth Kutscher, *Consumers demand price transparency, but at what cost?*, Modern Healthcare (June 2015), <https://www.modernhealthcare.com/article/20150623/NEWS/150629957/consumers-demand-price-transparency-but-at-what-cost>.

¹⁸⁹ Christopher Cheney, *Cost estimation drives huge increase in POS collections*, HealthLeaders (Feb. 1, 2018), <https://www.healthleadersmedia.com/finance/cost-estimation-drives-huge-increase-pos-collections>.

¹⁹⁰ Sze-jung Wu, Gosia Sylwestrzak, Christine Shah, & Andrea DeVries, *Price transparency for MRIs increased use of less costly providers and triggered provider competition*, 33 Health Affairs

suggests that making cost-sharing information disclosures more accessible and understandable can support patients' financial planning, promote more timely payment of medical bills, and provide financial benefits for hospitals and other health care providers.

(3) Increased Competition Among Providers

The proposed amendments in these proposed rules aim to empower consumers to make cost-conscious choices among health care providers by improving the accessibility and clarity of cost-sharing information for participants, beneficiaries, and enrollees. By requiring plans and issuers to provide cost-sharing estimates over the phone, in addition to online and in paper form, these proposed rules would ensure broader access to pricing information. In addition, a clearer notice about potential balance billing by out-of-network providers would further enhance transparency and give individuals a more complete picture of the potential financial obligations associated with different providers.

Evidence suggests that price transparency can lead to reduced health care costs and increased market pressure on higher-cost providers. Studies have shown that when consumers receive pricing information, particularly in combination with incentives such as lower cost-sharing, cash rewards, or premium reductions, they are more likely to choose lower-cost options. For example, a price transparency initiative that allowed consumers to compare MRI prices across facilities resulted in nearly a 19 percent average cost reduction per scan (approximately \$220 in savings per scan) and decreased use of higher-cost hospital settings.¹⁹¹ The study also found that price variations between hospital and non-hospital facilities for MRI scans decreased by 30percent. This reduction was mainly driven by consumers switching to lower-cost options and competitive price adjustments by higher-cost facilities. Another study found that disclosure of negotiated prices stimulated provider competition and led to lower prices for shoppable services.¹⁹² These findings

¹³⁹¹, 1398 (2014), <https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.0168>.

¹⁹¹ Sze-jung Wu, Gosia Sylwestrzak, Christine Shah, & Andrea DeVries, *Price transparency for MRIs increased use of less costly providers and triggered provider competition*, 33 Health Affairs 1391, 1398 (2014), <https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.0168>.

¹⁹² Angela Zhang, Khic-Houy Prang, Nancy Devlin, Anthony Scott, et al., *The impact of price*
Continued

support the Departments' view that greater transparency can drive competition, encourage cost-conscious decision-making, reduce price disparities across the health care system, and potentially contribute to lowering overall health care costs.

The Departments acknowledge that, while price transparency may promote competition and reduce costs, some studies indicate it may lead to price convergence, where lower-cost providers raise prices toward the market average.¹⁹³ This can occur when providers observe that competitors charge substantially more for the same service and adjust their own prices upward to capture additional revenue, potentially reducing consumer savings.

(4) Reduced Deadweight Loss¹⁹⁴

Through Improved Access to Cost-Sharing Information by Phone

The Departments anticipate that requiring plans and issuers to provide cost-sharing information by phone would help reduce information asymmetry in health care markets, particularly for individuals who are less likely to use online tools, have limited internet access or feel less comfortable accessing or interpreting information over the internet. For example, according to the Pew Research Center, while 75 percent of those 65 and older use the internet generally, less than 61 percent own a smartphone,¹⁹⁵ and 22 percent of these adults report never going online at all.¹⁹⁶ By improving

access to real-time, personalized cost-sharing data for these populations, this proposed requirement could enable more consumers to compare prices and select lower-cost providers. This shift in behavior could reduce overpayment for services and better align spending with consumers' willingness to pay, thereby decreasing the deadweight loss that results from information asymmetry.

Although quantifying these efficiency gains presents methodological challenges, economic literature supports the notion that improved price transparency can lead to behavioral changes and welfare improvements.¹⁹⁷ The Departments recognize the potential for meaningful economic benefits and welcome comment and data that could inform a more robust estimate of the reduction in deadweight loss associated with these proposed provisions.

b. Costs

Section IV.C. of this preamble outlines the quantified costs associated with updating cost-sharing disclosures to reflect Federal balance billing protections, as described in 26 CFR 54.9815-2715A2(b)(1)(vii)(A), 29 CFR 2590.715-2715A2(b)(1)(vii)(A), and 45 CFR 147.211(b)(1)(vii)(A). The Departments assume that plans and issuers have already developed self-service tools and would only need to revise the disclaimer to state that out-of-network providers may engage in balance billing, subject to applicable State and Federal laws. Although these updates build on existing infrastructure, the Departments estimate that all plans (or TPAs on behalf of plans) and issuers would incur a one-time cost for minor technical modifications, with a total burden of 263 hours and an associated cost of approximately \$37,657.

Section IV. of this preamble also outlines the quantified costs associated with providing the cost-sharing information, as described in 26 CFR 54.9815-2715A2(b)(1), 29 CFR 2590.715-2715A2(b)(1), and 45 CFR 147.211(b)(1), over the phone, as proposed in new paragraph 26 CFR 54.9815-2715A2(b)(2)(iii), 29 CFR 2590.715-2715A2(b)(2)(iii), and 45 CFR 147.211(b)(2)(iii). As discussed in more detail in section IV.C. of this preamble, the Departments have provided both lower impact and higher impact cost estimates to account for varying call times. The Departments estimate that all plans (or TPAs on behalf of plans) and issuers would incur a total, low-range, annual ongoing time burden of 585,000

hours with an associated estimated cost of \$23,400,000, and a total, high-range, burden of 1,300,000 hours with and associated estimated cost of \$52,000,000, to provide pricing information by phone.

The Departments have determined that plans and issuers would leverage their existing customer service call center infrastructure to provide cost-sharing information over the phone in order to reduce or eliminate any one-time burden and cost. While the Departments have determined many plans (or TPAs on behalf of plans) and issuers already provide some level of real-time phone-based cost-sharing information, they recognize that some plans and issuers may be required to alter existing or develop new infrastructure and could incur one-time burden and cost in order to meet the proposed requirements.

The Departments also anticipate that providing phone-based access would increase call duration and require plans (or TPAs on behalf of plans) and issuers to train customer service representatives and supervisors, resulting in a one-time burden of 290,720 hours and an estimated total cost of approximately \$13,727,040.

The Departments assume that most self-insured group health plans would rely on TPAs to fulfill these newly proposed requirements and that TPAs typically serve multiple clients, allowing for economies of scale, which could result in a lower burden and cost. Additionally, the Departments acknowledge that plans and issuers might choose to upgrade their communication systems voluntarily, such as adding mobile call features or real-time texting, which could result in additional burden or cost reductions.

The Departments recognize that expanding access to personalized pricing data, particularly via phone, may increase the risk of potential exposure of personal health information (PHI) and personally identifiable information (PII). As with internet-based disclosures, additional investments in security infrastructure, staff training on data protection, and consumer privacy tools may be necessary to mitigate the risk of unauthorized access or breaches. Between 2009 and 2024, there were 6,759 health care data breaches involving 500 or more records reported to the Department of Health and Human Services Office for Civil Rights, compromising the data of over 846 million individuals (an average of more than 2.6 per member of the U.S. population). Notably, in 2024 alone, nearly 277 million individuals were affected, with an average of over

transparency on consumers and providers: A scoping review, 124 Health Policy 819, 825 (2020).

¹⁹³ Sunita Desai, Laura A. Hatfield, Andrew L. Hicks, Michael E. Chernew, et al., *Association Between Availability of a Price Transparency Tool and Outpatient Spending*, 315 JAMA 1874, 1881 (2016); Noah Tong, *Transparency has led to uniformity in healthcare costs—but not necessarily lower prices: White paper*, Fierce Healthcare (Oct. 23, 2024), <https://www.fiercehealthcare.com/providers/transparency-leading-uniformity-healthcare-costs-not-necessarily-lower-prices-study>.

¹⁹⁴ Deadweight loss refers to the economic inefficiency that arises when the consumption of a service deviates from the socially optimal level due to inaccurate pricing or insufficient information. In healthcare, lack of price transparency can lead patients to make suboptimal choices, either overpaying or postponing care, thereby decreasing overall economic welfare for both consumers and providers.

¹⁹⁵ Michelle Faverio, *Share of Those 65 and Older who are Tech Users has Grown in the Past Decade* (Jan. 13, 2022), Pew Research Center, <https://www.pewresearch.org/short-reads/2022/01/13/share-of-those-65-and-older-who-are-tech-users-has-grown-in-the-past-decade>. The share of those 65 and older who are tech users have improved at a rapid clip over the past decade and will continue to improve as more utilize online tools and resources.

¹⁹⁶ Andrew Perrin & Sara Atske, *7 percent of Americans Don't Use the internet. Who are They?*, Pew Research Center (Apr. 2, 2021), <https://www.pewresearch.org/short-reads/2021/04/02/7-of-americans-dont-use-the-internet-who-are-they>.

¹⁹⁷ Yiquan Gu & Tobias Wenzel, *Transparency, price-dependent demand and product variety*, 110 Economics Letters 216, 219 (2011).

758,000 records breached daily.¹⁹⁸ As a result, complying with these provisions may necessitate additional safeguards to protect PHI and PII during phone-based interactions.

The Departments seek comment on these burden and cost estimates, including assumptions on disclosures to reflect Federal balance billing protections, call duration, customer service staffing, and the extent to which plans (or TPAs on behalf of plans) and issuers are already equipped to provide real-time cost-sharing information by phone.

While not quantified in this analysis, the Departments acknowledge that State regulators may incur administrative costs to review, monitor, or enforce compliance with these additional requirements. The Departments seek comment on any potential State-level impacts and any other burdens and costs that could be incurred by entities that would be affected by the provision of these proposals.

3. Proposed Requirements for Public Disclosure Under 26 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212

The following paragraphs describe the quantified and non-quantified benefits of the proposed requirements to disclose information related to in-network rates and historical out-of-network allowed amounts through machine-readable files.

a. Quantified Benefits

(1) Reduced Data Cleaning and Integration Costs for Third-Party Developers and Other File Users

The Departments have determined that by reducing the complexity and inconsistency of data that currently require extensive data processing and reconciliation, these proposed rules would make machine-readable data both easier to locate and easier to process for third-party developers and other file users, such as academics, researchers, data engineers, and plans and issuers. These proposed rules would do this by requiring plans and issuers to publish contextual files including a Change-log File, Taxonomy File, and a Utilization File; report at the network rather than the plan or policy level; exclude providers that have in-network rates for items or services for which they are unlikely to be reimbursed; add enrollment numbers, common network names, and product types; and standardize file locations with a Text

File and footer links. The Departments anticipate that much of the burden currently involved in cleaning and processing the machine-readable files would be eliminated, since the files would contain more accurate data in smaller sizes. This would reduce the time and resources third-party developers and other file users spend removing duplicative and irrelevant data, which in turn would decrease the computational resources required for data cleaning and integration, further reducing overall costs.

In particular, the Departments estimate that the proposed provisions to require network-level reporting, add enrollment numbers, and specify product types would meaningfully reduce data cleaning and integration costs for approximately 300 third-party developers and other file users,¹⁹⁹ including research shops and consultancies. Specifically, network-level reporting is expected to save about 40 hours per quarterly reporting cycle, or 160 hours annually. Providing enrollment data directly in the files would remove the need for third-party sourcing and integration, saving another 40 hours each year, while the inclusion of product types would save an estimated 20 hours per quarterly cycle, or 80 hours annually. Together, these provisions would reduce about 280 hours of analyst time per year for each third-party developer or other file user. Using an average hourly wage of \$120 for a Business Analyst,²⁰⁰ the total estimated annual labor savings across all 300 third-party developers and other file users would be approximately \$10.1 million.²⁰¹

In addition, by requiring plans and issuers to exclude provider-rate combinations for items and services for which a provider would be unlikely to be reimbursed, the Departments estimate a substantial reduction in the data volume that would be disclosed, compared to current volumes, leading to lower computational costs when processing the files. Assuming industry-wide disclosures currently total roughly 1,000,000 gigabytes (GB), equivalent to

¹⁹⁹ This estimate is based on discussions with a sample of third-party developers and other file users. From these discussions, the Departments estimated a total of approximately 300 third-party developers and other file users consuming the public disclosures associated with these rules.

²⁰⁰ U.S. General Services Administration, *Pricing Intelligence Suite, CALC information and wage rates*, <https://buy.gsa.gov/pricing/> (last visited Dec. 8, 2025).

²⁰¹ The total estimated annual labor savings is calculated by multiplying the 280 hours saved per third-party developer or other file user by the 300 affected users and the average hourly wage of \$120 ($280 \times 300 \times \$120 = \$10.1$ million).

1 PB²⁰² in size per month, the proposed exclusion of these provider-rate combinations would reduce file sizes by about 70 percent²⁰³ to a new estimated size of 300,000 GBs. While most actual savings would be associated with algorithms that are processing the data, which would reflect much higher actual computation savings, an absolute baseline can still be established.

Assuming an average compute cost of \$0.015 per GB RAM-hour for general purpose usage,²⁰⁴ the baseline monthly compute cost for 1 PB is estimated at roughly \$334²⁰⁵ with an annual cost of \$4,008. With a 70 percent reduction in file size, monthly compute costs would decrease to approximately \$100, yielding a monthly savings of \$234, which corresponds to an estimated annual savings of approximately \$2,808 per third-party developer or other file user. Across 300 third-party developers and other file users, this equates to total annual savings of approximately \$842,400.

These proposed rules would also shift the reporting frequency from monthly to quarterly for In-network Rate and Allowed Amount Files, reducing the total computational needs accordingly. This change reduces total annual downloads from 3,600 (300 third-party developers and users $\times$ 12 months) to 1,200 (300 third-party developers and users $\times$ 4 months), or an average of 100 downloads per month to be processed. Under quarterly reporting, the estimated annual industry-wide computational costs for the optimized files would be \$120,000.²⁰⁶ Relative to the monthly baseline, this cadence change combined with the file-size reduction yield \$1,082,400 in total annual compute savings. Of this amount, approximately

²⁰² Christopher Whaley, Neeraj Radhakrishnan, Michael Richards, Kosali Simon, et al., *Understanding Health Care Price Variation: Evidence from Transparency-in-Coverage Data*, 3 Health Affairs Scholar 2 (2025), <https://doi.org/10.1093/haschl/qxaf011>.

²⁰³ This estimate is based on internal analysis of existing data and stakeholder feedback. External sources, such as Serif Health, report rates exceeding 80 percent. Salman Mukhi, *Zombie Hunting: Filtering Approaches for Price Transparency Data* (Sep. 20, 2024), <https://www.serifhealth.com/blog/zombie-hunting-filtering-approaches-for-price-transparency-data>.

²⁰⁴ Amazon Web Services, *Amazon EC2 On-Demand Pricing*, <https://aws.amazon.com/ec2/pricing/on-demand> (last accessed Oct. 1, 2025).

²⁰⁵ This is calculated using AWS t4g.xlarge throughput of 720 GB/hour and 16 GB of RAM. Total hours = Total data/Throughput = $1,000,000 \text{ GB} / 720 \text{ GB per hour} \approx 1,388.89$ hours; GB-RAM-hours = RAM $\times$ Hours = $16 \text{ GB} \times 1,388.89$ hours $\approx 22,222$ GB-RAM-hours; Total cost = GB-RAM-hours $\times$ Price per GB-RAM-hour = $22,222 \times \$0.015 \approx \$333.33$.

²⁰⁶ Total computational costs for new files (300,000 GB) processed quarterly are calculated as $\$100 \times 1,200$ downloads per year = \$120,000.

¹⁹⁸ Steve Adler, *Healthcare Data Breach Statistics*, The HIPAA Journal (Sept. 30, 2025), <https://www.hipaajournal.com/healthcare-data-breach-statistics/>.

\$842,400 of compute savings is attributable to file-size optimization, while an additional \$240,000 results from the reduction in reporting frequency.

The Departments have determined that together these proposed provisions would result in total annual savings of roughly \$11.2 million (\$10.1 million in labor savings plus \$1.1 million in industry-wide storage cost savings from the shift to quarterly reporting) for third-party developers and other users of price transparency data, while supporting the intended goal of making price data more usable and actionable.

The Departments seek comment on the estimated potential cost and time savings from streamlining and standardizing the machine-readable files, and on whether these proposed provisions would effectively result in reduced data processing burdens and costs for users.

(2) Reduced Storage Costs for Plans, Issuers, Third-Party Developers, and Other File Users

The proposed provisions would lead to reduced storage costs for plans, issuers, third-party developers, and other users by significantly decreasing the total volume of data needed to generate, store, and make available for download. These proposals would minimize data duplication and reduce both the number and size of the machine-readable files by changing the reporting cadence for both the In-network Rate File and the Allowed Amount File from monthly to quarterly, requiring reporting of negotiated rates at the network level rather than the plan or policy level, and excluding provider-rate combinations in the In-network Rate File for certain items and services.

The Departments have determined that these changes could lower ongoing storage, backup, and processing costs for the In-network Rate File, making it easier and more cost-effective for third-party users to download and build and manage consumer-facing price comparison tools based on the machine-readable data. Further, the Departments anticipate some users would opt not to download and store all of the new In-network Rate Files, given the Change-log File would identify changes in data from one In-network Rate File to the next, further decreasing data storage and processing costs.

Researchers have estimated that the combined monthly file sizes across industry for the In-network Rate Files are over 1 PB. The Departments estimate that the proposed changes would reduce file sizes by approximately 70 percent, lowering the monthly data volume from

about 1,000,000 GB to approximately 300,000 GB.

Using Amazon Web Services (AWS) S3 pricing as a benchmark, \$0.023 per GB for the first 50 TB, \$0.022 per GB for the next 450 TB, and \$0.021 per GB beyond that,²⁰⁷ storing 1 PB worth of data would result in an estimated baseline monthly storage cost of roughly \$22,583 with an annual cost of approximately \$270,996. With a 70 percent reduction in file size, monthly storage costs would decrease to approximately \$6,651 (\$79,812 annually), yielding a monthly savings of \$15,932 and an estimated annual savings of approximately \$191,184. These cost savings would apply for all plans and issuers.

Assuming 300 third-party developers and other file users download the files each month, total annual storage costs under current file size assumptions would be approximately \$81,298,800.²⁰⁸ With the 70 percent file-size reduction, the annual cost for all 300 third-party developers and other file users would drop to \$23,943,600.²⁰⁹ This results in an annual storage savings of roughly \$57,355,200²¹⁰ for the 300 third-party developers and other file users based on file-size optimizations.

However, because these proposed rules also shift the reporting frequency from monthly to quarterly, total storage needs and corresponding savings would be reduced accordingly. Under quarterly reporting, annual industry-wide storage cost for the reduced file size for the In-network Rate Files savings is estimated at \$7,981,200.²¹¹ Relative to the monthly baseline, this cadence change combined with the file-size reduction yield about \$73,317,600 in total annual savings.²¹² Of this amount, approximately \$57,355,200 in storage

savings can be attributed to file-size optimization, while an additional \$15,962,400 can be attributed to the reduction in reporting frequency.

The Departments seek comment on the assumptions made and the estimated storage cost savings for plans and issuers, third-party developers, and other users from reducing data volume.

(3) Reduced Network Egress Costs for Plans and Issuers

In addition to the estimated savings from reduced storage requirements, the Departments anticipate that the proposed provisions would also lead to a reduction of bandwidth network costs for plans and issuers needed with making their machine-readable files available for download.

Using the estimates developed and discussed in the preceding section for the In-network Rate File, and applying AWS egress costs, which are fees for data transferred from AWS to the public internet, as a benchmark—the first 100 GB are free, followed by \$0.09 per GB for the first 50 TB, \$0.085 per GB for the next 40 TB, \$0.07 per GB for the next 100 TB, and \$0.05 per GB for any amount exceeding 150 TB.²¹³ The Departments estimate a monthly tiered egress cost of transferring 1 PB data would be approximately \$53,800 with an estimated annual cost of roughly \$645,600. With a 70 percent reduction in file size to 300,000 GB, monthly data transfer egress costs would decrease to about \$18,795, with estimated annual costs of approximately \$225,600. This would yield a monthly savings of \$35,005 and annual cost savings of approximately \$420,060 for all plans and issuers. These cost estimates assume a single data transfer, or download, each month.

Because files would not be downloaded just once, the Departments would also estimate the number of users that would download the entire data set each month. Assuming 300 third-party developers and other file users download the files each month, total annual egress costs under current file size assumption would be nearly \$194 million.²¹⁴ With the optimized file size estimates, the costs would be reduced

²⁰⁷ Amazon Web Services, *Amazon S3 pricing*, <https://aws.amazon.com/s3/pricing/> (last accessed Oct. 1, 2025).

²⁰⁸ This is calculated by multiplying the current yearly cost to download multiplied by the number of third-party developers and other file users: $\$270,996 \times 300 = \$81,298,800$.

²⁰⁹ This figure is calculated by multiplying the annual cost per user after the file-size reduction (\$79,812) by the number of third-party developers and other file users (300): $\$79,812 \times 300 = \$23,943,600$.

²¹⁰ Annual storage savings of \$57,355,200 is calculated by subtracting the total annual cost after file-size reduction (\$23,943,600) from the total annual cost under current file-size assumptions (\$81,298,800): $\$81,298,800 - \$23,943,600 = \$57,355,200$.

²¹¹ This is calculated by multiplying the reduced monthly storage cost (\$6,651) by 4 quarterly reports and 300 third-party developers and other files: $\$6,651 \times 4 \times 300 = \$7,981,200$.

²¹² This is calculated by subtracting the total storage costs for the new, quarterly file downloads (\$7,981,200) from the total storage costs for the current monthly downloads (\$81,298,800): $\$81,298,800 - \$7,981,200 = \$73,317,600$.

²¹³ Amazon Web Services, *Amazon EC2 On-Demand Pricing*, <https://aws.amazon.com/ec2/pricing/on-demand/> (last accessed Oct. 1, 2025).

²¹⁴ At current file sizes, data transfer cost estimates are approximately \$53,800 per month for 1 PB data. The Departments assume that 300 third-party developers and other file users each download one file per month (12 annually), resulting in 3,600 total downloads per year. Based on a cost of \$53,800 per download, the estimated annual cost is approximately \$193,680,000 ($\$53,800 \times 3,600$).

by about \$68 million annually,²¹⁵ yielding total industry-wide savings of \$126 million annually.²¹⁶

Similar to reduced storage costs for plans and issuers discussed in section VI.D.3.a.(2). of this preamble, these proposed rules would also shift the reporting frequency from monthly to quarterly, which reduces total egress needs and corresponding savings. This change reduces total annual downloads from 3,600 (300 third-party developers and other file users × 12 months) to 1,200 (300 third-party developers and other file users × 4 months), or an average of 100 downloads per month. Under quarterly reporting, annual industry-wide egress costs for the optimized files would be about \$22.6 million.²¹⁷ Relative to the monthly baseline, this cadence change combined with the file-size reduction would yield about \$171 million in total annual savings.²¹⁸ Of this amount, approximately \$126 million egress savings would be attributable to file-size optimization, while an additional \$45 million would result from the reduction in reporting frequency.

The Departments seek comment on the assumptions made and anticipated egress cost savings for plans and issuers

from reducing data volume and reporting cadence.

(4) Reduced Time Locating the Files for Third-party Developers and Other File Users

The Departments' proposal to require plans and issuers to include a standardized Text File and place a direct link to the files in the website footer would make it easier for third-party developers and other file users, who currently face challenges navigating plan or issuer websites to find their machine-readable files, to more efficiently locate and access the data needed for their applications and analyses.

The time savings from locating files primarily stem from the proposed requirement that plans and issuers include a standardized Text File that includes, among other things, the source page URL for the internet website that hosts the machine-readable files, and a footer link in certain prominent locations that links directly to the web page that hosts the link to the machine-readable files. Additionally, the proposed change from monthly to quarterly reporting would reduce the number of times a file user would need to locate the In-network Rate and

Allowed Amount Files to find updated information. Together, the Departments estimate that these changes would save about 10 hours²¹⁹ of labor quarterly (or 40 hours annually) for each third-party developer or file user, reflecting the reduced need to manually track down and verify file locations. Using an average hourly wage of \$120 for a Business Analyst,²²⁰ the Departments estimate that total annual labor savings for all third-party developers and other file users would amount to approximately \$1.4 million.²²¹ The Departments seek comment on the assumptions and estimated burden and cost savings from making the machine-readable files easier to locate through standardized links.

The Departments have determined that the provisions of these proposed rules would help reduce administrative complexity and advance the objective of making price transparency data more accessible, efficient, and actionable for participants, beneficiaries, and enrollees.

As shown in Table 38, the proposed provisions are estimated to generate total annual benefits of approximately \$257 million for plans, issuers, third-party developers, and other users.

TABLE 38: Summary of Annual Quantified Benefits from the Proposed Provisions

Benefit	Annual Benefits (\$)
Reduced Data Cleaning and Integration Costs for Third-Party Developers, and Other File Users, including Changing Timing Requirements for Machine-Readable Files Reporting from Monthly to Quarterly	\$11,162,400
Reduced Storage Costs for Plans, Issuers, Third-Party Developers, and Other Files Users, including Changing Timing Requirements for Machine-Readable Files Reporting from Monthly to Quarterly	\$73,317,600
Reduced Network Egress Costs for Plans and Issuers, including Changing Timing Requirements for Machine-Readable Files Reporting from Monthly to Quarterly	\$171,126,000
Reduced Time Locating the Files for Third-party Developers and Other File Users	\$1,440,000
Total	\$257,046,000

²¹⁵ This is calculated as follows: Estimated size data transfer cost estimates for optimized files are \$18,795 per month for transferring 300,000 GB. The Departments assume that 300 third-party developers and other file users each download one file per month (3,600 downloads each year). At this rate, the total annual cost is estimated at \$67,662,000 (\$18,795 × 3,600).

²¹⁶ Estimated annual size data transfer cost savings are calculated by subtracting the total annual cost for the optimized 300TB files (\$67,662,000) from the total annual cost for the original 1PB files (\$193,680,000): \$193,680,000 – \$67,662,000 = \$126,018,000.

²¹⁷ Total network costs for transferring new files (300,000 GB) on a quarterly basis are calculated by multiplying the monthly cost per file transfer

(\$18,795) by the total annual downloads (1,200): \$18,795 × 1,200 downloads per year = \$22,554,000.

²¹⁸ Total network cost savings are calculated by subtracting the total annual network costs for the new files downloaded quarterly (\$22,554,000) from the total annual costs for the current monthly downloads (\$193,680,000): \$193,680,000 – \$22,554,000 = \$171,126,000.

²¹⁹ The estimated 10 hours saved annually per organization is based on the assumption that, for each update, organizations review the prior month's links to locate files, and only a subset of those files requires additional effort to determine their posting location.

²²⁰ U.S. General Services Administration, *Pricing Intelligence Suite, CALC information and wage rates*, <https://buy.gsa.gov/pricing/> (last visited Dec. 8, 2025).

²²¹ The total annual labor savings estimate is derived as follows: each of the approximately 300 third-party developers and other file users is estimated to save 10 hours of labor per quarterly reporting cycle as a result of the proposed standardized Text file and footer link, which facilitate easier file location. With four reporting cycles per year, this equates to 40 hours saved annually per third-party developer or other file user. Applying an average hourly wage for a Business Analyst of \$120 results in an estimated annual savings of approximately \$4,800 per third-party developer or other file user (40 hours × \$120). When aggregated across the estimated 300 third-party developers and other file users, the total annual labor savings amount to approximately \$1,440,000.

b. Non-Quantified Benefits

(1) Stronger Market Leverage for Plans and Issuers

By requiring more streamlined, meaningful, and clear disclosure of in-network rates and detailed out-of-network data, the provisions in these proposed rules would better enable plans and issuers to compare their in-network rates and out-of-network coverage with those of competitors. The addition of contextual files, including the Taxonomy File, Utilization File, and Change-log File, would enhance the practical value of this data, helping plans and issuers see not just raw prices but also provider specialties, actual in-network utilization, and historical changes in rate information. This would support plans and issuers in identifying gaps, trends, and outliers within their own networks and relative to the market. This enhanced transparency might strengthen their ability to negotiate lower reimbursement rates with providers based on knowing what those providers have negotiated with other payers that are similarly situated within the market for the same items or services with other plans and issuers that are similarly situated within the market. However, as noted in section VI.D.2.a.(3). of this preamble, the Departments also recognize the potential for this information to drive rates up if providers learn they are being paid less than other providers and use that information to seek higher negotiated rates.

By enhancing the transparency of out-of-network allowed amounts and historic billed charges, these provisions might facilitate broader adoption of private health insurance market reference-based pricing strategies. Specifically, the proposed requirements related to the Allowed Amount File would provide the public with clearer information on what out-of-network providers charge. This additional transparency could help plans and issuers, and other consumers, better identify lower-cost providers and benchmark reasonable prices, ultimately supporting strategies where participants, beneficiaries, or enrollees pay the difference when selecting higher-cost providers in circumstances where they have a meaningful choice among providers. Plans and issuers may use such reference-based pricing structures to guide participants, beneficiaries, and enrollees toward lower-cost providers. While the Departments recognize that reference-based pricing may not apply uniformly (for example, some plans offer exemptions based on clinical need or

geographic limitations), it has generally led to cost reductions. For instance, combining price transparency with reference pricing has led to significant shifts in consumer choice of facility, resulting in a 27 percent reduction in the average price paid per laboratory test and a 13 percent reduction in the average price paid per imaging test.²²²

(2) Enhanced Regulatory Oversight and Inform Policymaking

The Departments expect that State and Federal regulators could gain efficiencies and increased insights from the data reporting pursuant to the amended disclosure requirements in these proposed rules. The proposals would give regulators access to more streamlined, usable, and actionable in-network rate and out-of-network data, which may support more informed oversight of premium rate filings by enabling more effective monitoring of market trends and price variations. The proposals may also help States monitor rates to identify collusive behaviors, as well as help establish benchmarks for negotiations with providers as part of State oversight activities related to coverage programs, ultimately strengthening regulatory oversight and promoting more competitive markets.

(3) Increased Understanding and Empowered Consumers

These proposals aim to empower participants, beneficiaries, and enrollees by increasing transparency around what plans and issuers reimburse providers for covered items and services. By providing access to clearer, more streamlined, and more specific in-network rates, historical out-of-network allowed amounts, and billed charges, file users and ultimately health care consumers might be better equipped to understand how their choices of coverage and providers affect their costs. This transparency may support more informed consumer decision-making when comparing plans or selecting providers. Adding supporting contextual information to accompany the data is expected to enhance overall usability for third-party developers and other file users. As stated in the preamble to the 2020 final rules, the Departments expected third-party developers and other innovators to use the machine-readable file data to create “easy-to-use internet-based tools and mobile applications that will present information to laypersons in easy-to-

understand, plain language that is sufficiently concise and well-organized,”²²³ which would allow “consumers to consider price as a factor when making meaningful comparisons between different coverage options and providers.”²²⁴ The Departments are encouraged by the consumer-facing tools that have been built since implementation of the 2020 final rules and look forward to additional growth in this space following implementation of the enhancements in these proposed rules.

c. Costs

This section of the preamble provides both quantitative and qualitative discussion of the costs associated with the Departments’ proposed revisions to the requirements that plans and issuers make information regarding in-network negotiated rates and out-of-network allowed amounts available through machine-readable files on a public website. The Department request comment and data on how to better quantify these costs.

Section IV.D. of this preamble outlines the quantified costs associated with requirements for public disclosure of in-network rates and allowed amount data for covered items and services from in- and out-of-network providers, as described under 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212.

For In-network Rate Files, this proposal would require plans and issuers to create a separate file for each provider network, allow rates to be expressed as a percentage of billed charges when appropriate, include enrollment totals for each plan or coverage option, disclose provider network product types, and exclude providers unlikely to be reimbursed based on their scope of practice. The Departments estimate that all plans (or TPAs on behalf of plans) and issuers would incur a one-time burden of 717,952 hours on the low end and 758,400 hours on the high end, with associated costs of approximately \$102,371,360 and \$108,084,640, respectively. While these proposals would involve a one-time cost to modify existing processes, the Departments expect that, once these updates are implemented, the ongoing burden related to including product type, excluding certain providers, reporting dollar amounts (except for “percentage-of-billed-charges” payments), including enrollment data, organizing files by provider network, and allowing service

²²² Christopher Whaley, Timothy Brown, & James Robinson, *Consumer responses to price transparency alone versus price transparency combined with reference pricing*, 5 American Journal of Health Economics 227, 249 (2019).

²²³ 85 FR 72169 (November 12, 2020).

²²⁴ 85 FR 72210 (November 12, 2020).

providers to organize files across multiple self-insured plans would be minimal, beyond current costs for monitoring and maintaining these processes.

For Allowed Amount Files, the proposal includes requiring data reporting at the market level instead of the individual plan level, lowering the claims threshold from 20 to 11, extending the reporting period from 90 days to 6 months, and increasing the lookback period from 180 days to 9 months to enhance the robustness of historical data. The Departments estimate that all plans (or TPAs on behalf of plans) and issuers would incur a one-time burden of 101,120 hours, with associated costs of approximately \$14,283,200. While lowering the claims threshold to 11 is expected to require only minor system adjustments, the Departments anticipate minimal ongoing costs for maintaining and monitoring compliance. Similarly, extending the lookback period is not expected to impose a significant additional burden, as automated systems are already in place to report out-of-network allowed amounts for the 90-day reporting period beginning 180 days before publication. Ongoing costs for aggregating out-of-network Allowed Amount Files by market type are also expected to be minimal.

In addition, these proposed rules would require plans and issuers to post several contextual machine-readable files: a Change-log File, a Utilization File, a Taxonomy File, and a Text File, each with specific update and posting requirements. The Departments estimate a one-time burden of 5,548,960 hours for plans (or TPAs on behalf of plans) and issuers, with associated costs of approximately \$777,578,040 to add and implement these files, with an ongoing annual burden of 60,040 hours (costing approximately \$9,186,120) to update the Utilization File and 47,400 hours (costing approximately \$7,015,200) to address point-of-contact inquiries to improve discoverability and accessibility of the machine-readable files. The Change-log File is expected to be fully automated, and the Departments anticipate only minimal system maintenance beyond the initial generation and posting of the file. Similarly, once the initial setup for adding a Text File is complete, ongoing updates are expected to require minimal effort. The Departments also assume that including a link to the internet domain hosting the machine-readable files on the website footer would result in minimal additional burden.

(1) Non-Quantified Costs for Public Disclosure of In-Network Provider Rates

The proposed provisions are expected to introduce meaningful improvements to the quality, clarity, and usability of In-network Rate Files, such as requiring files to be organized by provider network rather than by plan or policy, allowing for percentage-of-billed charges reporting when the dollar amount is not known in advance, adding contextual files like Taxonomy, Utilization, and Change-log files, and excluding certain provider-rate combinations if it is unlikely that a provider would be reimbursed for an item or service given that provider's area of specialty. While these improvements aim to help file users, tool developers, and regulators better navigate and interpret rate data, they may also create non-quantified operational and market-level costs for plans and issuers.

Specifically, plans and issuers could face additional administrative and compliance costs from producing and maintaining stricter standardized machine-readable files. This may involve internal quality reviews, greater coordination across business units, as well as potential redesign of existing automated processes to create network-specific files and incorporate new required data fields.

There is also a risk that improving the transparency of negotiated rates may cause some providers to raise their prices if they discover they are paid less than their peers. This response could contribute to price convergence rather than sustained downward pressure on costs, an effect observed in some transparency studies, where high prices fall slightly but lower prices rise, ultimately reducing overall savings. For instance, one study found that although price transparency has helped narrow price variation in health care, it has not consistently lowered overall prices. According to the study, the highest prices fell by 6.3 percent, while the lowest prices rose by 3.4 percent, and mid-range prices decreased only slightly by 1.1 percent.²²⁵ While the study does not address the effect on average prices, these findings suggest that transparency can pressure high-cost providers to reduce prices but may also lead lower-cost providers to increase prices. A 2020 study also suggests that price transparency could facilitate tactical collusion, resulting in higher prices in

markets that are not perfectly competitive, such as health care. In these markets, there are fewer sellers and higher barriers to entry for new competitors.²²⁶

Another potential cost stemming from increased transparency due to improvements in In-network Rate Files is the impact on a plan's or issuer's ability or incentive to develop and maintain a robust provider network. A provider network consists of health care providers that have entered into agreements with plans or issuers to deliver care at a negotiated rate, which the provider accepts as full payment. Plans and issuers often prefer their participants, beneficiaries, and enrollees to use in-network providers, as these providers meet the health plan's quality standards and agree to lower rates in exchange for the patient volume they will receive by being part of the network.²²⁷ Some plans and issuers use narrow networks, which include a more limited group of providers. While these networks offer fewer in-network options to participants, beneficiaries and enrollees, they often result in lower monthly premiums and reduced out-of-pocket costs.²²⁸ The Departments recognize that publicly disclosing negotiated rates may reduce the incentive for providers to enter into such contractual agreements, particularly in narrow networks, if they know those rates will be made public or they are being offered lower than market rates. This could, in turn, limit network options available to plans and issuers.

Smaller issuers may be disproportionately affected by the improved transparency of negotiated rates, as they may be unable to match the higher rates that larger issuers can offer. In turn, smaller issuers may be forced to contract only with lower-cost providers, potentially leading to narrower networks and affecting participant, beneficiary, and enrollee access to care. Such network constraints may also make it more difficult for these issuers to fully comply with network adequacy standards described at 45 CFR 156.230 or applicable State standards. Ultimately, while the purpose of

²²⁶ Robert F. Graboyes & Jessica McBirney, *Price Transparency in Healthcare: Apply With Caution*, Mercatus Center, George Mason University (2020), <https://www.mercatus.org/system/files/graboyes-price-transparency-mercatus-research-v1.pdf>.

²²⁷ Elizabeth Davis, *Health insurance provider network overview*, Verywell Health (Feb. 9, 2025), <https://www.verywellhealth.com/health-insurance-provider-network-1738750>.

²²⁵ Forrest Xiao, *The Healthcare Cost Conundrum: Prices are Stabilizing. Why are Expenses Still Rising?*, *Turquoise Health* (Oct. 31, 2024), <https://blog.turquoise.health/the-healthcare-cost-conundrum/>.

²²⁸ Tracy Anderman, *What to know about narrow network health insurance plans*, Consumer Reports (Nov. 23, 2018), <https://www.consumerreports.org/health-insurance/what-to-know-about-narrow-network-health-insurance-plans>.

improving price transparency is to empower participants, beneficiaries, and enrollees and enhance market efficiency, the Departments acknowledge that these proposed provisions could, in some cases, reduce the ability or incentive of plans and issuers, especially smaller ones, to build and maintain robust networks that satisfy quality and access requirements.

(2) Non-Quantified Costs for Public Disclosure of Out-of-Network Allowed Amounts

The Departments recognize the potential costs arising from the proposed expansion of data in the Allowed Amount Files. These may include the increased complexity and administrative burden of managing and reporting a larger volume of data over extended reporting and lookback periods, as well as at the broader health insurance market level rather than at the plan or policy level. Additionally, to account for the expanded handling of detailed claims data, plans and issuers might face additional expenses for enhanced cybersecurity measures and compliance with data privacy regulations. These potential costs are difficult to quantify given current data limitations, but the Departments acknowledge that they represent important considerations associated with implementing these proposed provisions.

The Departments seek comment and data on the potential magnitude of these non-quantified costs, including legal, operational, and network impacts, and how they may affect plan and issuer implementation and that may assist the Departments' estimate on any related additional burden and cost.

4. Summary of Transfers

The requirements of these proposed rules, as discussed in section III. of this preamble, require plans and issuers to enhance the accuracy and usability of pricing information through improved machine-readable files, expand cost-sharing disclosure methods (including phone access), and streamline reporting requirements. As a result of the proposed requirements, the Departments expect various transfers, discussed in this section of the preamble, to occur between plans and issuers; providers; participants, beneficiaries, and enrollees; and the Federal government. While the precise magnitude of these transfers is difficult to quantify due to varying market conditions and consumer behaviors, the directional effects and distributional impacts can be analyzed conceptually.

a. Transfer From Higher-Cost to Lower-Cost Providers

If participants, beneficiaries, and enrollees gain easier access to pricing information through enhanced machine-readable files and phone-based cost-sharing estimates, some consumers might switch from higher-cost to lower-cost providers for comparable services. This transfer occurs as consumer cost preferences result in shifts from providers who charge what consumers feel are above-market rates, to those offering what the consumer feels to be more competitive pricing. The magnitude of this transfer would depend on several factors: the degree of price variation between providers, consumer price sensitivity, and the consumer's relationships between those providers.

Some evidence shows that in competitive markets, price ranges may narrow as lower-cost providers raise their prices to align with higher-cost competitors, potentially increasing costs.²²⁹ Disclosing negotiated rates can enable providers to match each other's prices, which may further limit cost reductions or even lead to higher overall prices despite the increased transparency.²³⁰ However, in some instances, increased transparency could lead higher-cost providers to face new pressure to lower costs, potentially decreasing costs.²³¹ The Departments acknowledge that this transfer may be partially offset by potential price convergence effects, where lower-cost providers may increase their prices toward market averages once pricing becomes more transparent. However, the net effect is expected to favor more efficient providers and create competitive pressure for cost reduction across the market.

b. Transfer From Providers to Consumers Through Reduced Out-of-Pocket Spending

If consumers use enhanced pricing information to select lower-cost providers, their out-of-pocket expenses for health care services are expected to decrease, representing a transfer from the provider to the consumer. This transfer is facilitated by the proposed

requirement to make cost-sharing information available by phone, which might particularly benefit populations who face barriers to using online tools, including older adults, individuals with disabilities, and those with limited internet access. By expanding access to personalized pricing information, these consumers might make more cost-conscious health care decisions, resulting in lower deductibles, copayments, and coinsurance amounts. The magnitude of this transfer could vary significantly based on individual utilization patterns, plan design, and the availability of lower-cost alternatives within their provider networks. This shift is consistent with empirical findings that greater price transparency can help consumers make more cost-effective choices and encourage market competition.²³²

c. Transfer From Plans and Issuers to Participants, Beneficiaries, and Enrollees Through Potential Premium Reductions

If enhanced price transparency leads to systematic shifts toward lower-cost providers and overall reductions in health care spending, plans and issuers may experience lower claims costs, which could eventually translate to reduced premiums for participants, beneficiaries, and enrollees. That is, as plans and issuers experience lower medical costs due to participant, beneficiary, and enrollee price shopping, competitive pressure may lead to premium reductions to attract and retain enrollees. However, the magnitude of this transfer would depend on several factors, including the degree of competition across different market segments and geographic areas (for example, urban vs. rural markets) and the rate in which consumer utilization patterns change.

d. Transfer From Premium Tax Credit (PTC) Eligible Consumers to Federal Government Through Reduced PTC

If enhanced price transparency leads to lower premiums in the individual insurance market, consumers eligible for PTCs would receive smaller subsidy amounts, resulting in a transfer from consumers to the Federal government. This transfer would occur if, through the use of transparency tools, premiums in the individual market declined

²²⁹ Forrest Xiao, *The Healthcare Cost Conundrum: Prices are Stabilizing. Why are Expenses Still Rising?*, *Turquoise Health* (Oct. 31, 2024), <https://blog.turquoise.health/the-healthcare-cost-conundrum/>.

²³⁰ David N. Bernstein & Jonathan R. Crowe, *Price Transparency in United States' Health Care: A Narrative Policy Review of the Current State and Way Forward*, 61 *INQUIRY: The Journal of Health Care Organization, Provision, and Financing* (2024).

²³¹ Yanzhi Feng, *Price Transparency in Healthcare: Bargaining Incentives and Patient Responses*, 102 *Journal of Health Economics* (2025).

²³² Zachary Y. Brown, *Equilibrium Effects of Health Care Price Information*, 101 *Review of Economics and Statistics* 4 (2019); Christopher Whaley, Zachary Brown, & John C. Robinson, *Consumer Responses to Price Transparency Alone Versus Price Transparency Combined with Reference Pricing*, 5 *American Journal of Health Economics* 227 (2019).

(including the second lowest-cost silver benchmark plan) and thus resulted in a reduction in Federal spending through reduced PTC amounts. The magnitude of this transfer would depend on the extent to which price transparency leads to substantial competitive pressure, overall premium reductions, and the number of PTC-eligible consumers affected. For subsidized consumers, the net effect may be largely neutral, since their required premium contributions are based on income rather than plan cost; however, if they choose a lower-cost plan as premiums decrease, they could experience a net benefit. On the other hand, unsubsidized consumers would generally see a positive impact from any premium reductions.

e. Transfer From Federal Government to Consumers Through Increased PTCs

If the costs associated with enhanced transparency requirements contribute to premium increases, for example, through price convergence, this could result in higher PTC payments to eligible consumers, representing a transfer from the Federal government to consumers. This transfer could also occur if the costs of implementing enhanced machine-readable file requirements, phone-based cost-sharing tools, and other transparency measures result in increased premiums. The magnitude and direction of this transfer is uncertain due to the variation in market responses; however, these proposed rules are designed to reduce administrative burden and streamline reporting requirements and thus reduce premiums and overall costs.

The Departments acknowledge uncertainty in both the magnitude and timing of these potential transfers. Market responses to price transparency efforts might vary widely based on local competitive conditions, consumer behavior patterns, provider networks, and the specific design of transparency tools. This analysis focuses on directional effects and distributional considerations rather than precise quantification, given the limited empirical evidence on the specific transparency enhancements proposed in this rule, and evidence indicates that, while transparency may create competitive pressure and encourage cost reductions, the net effects on prices and transfers remain uncertain.²³³ Price transparency can influence consumer decision-making, potentially encouraging shifts toward lower-cost

providers;²³⁴ however, in markets that are not perfectly competitive, it can sometimes lead to price alignment or collusion, which may increase prices rather than lower them.²³⁵

The Departments seek comment on the potential transfers described previously, including any potential transfers from higher-cost providers to participants, beneficiaries, and enrollees and issuers resulting from improved price transparency, as well as any possible impacts resulting from the potential for provider collusions and price convergence.

5. Uncertainty Analysis

The Departments recognize that the assumptions underlying the estimated costs and benefits described in sections VI.D.2.b. and VI.D.3.a. of this preamble involve a degree of uncertainty. Differences in plan and issuer size, internal systems, and workflows may affect the resources required to implement the proposed requirements. The quality, structure, and reporting practices of existing files could also shape the extent of savings realized by third-party developers and other users. In addition, labor costs, technical implementation needs, and the pace of adopting new practices are likely to vary across the industry. External factors, such as market behavior, regulatory changes, or shifts in the number of file users, may further influence the overall impacts. The Departments seek comment on these assumptions and uncertainties, and welcome data or information that could improve the accuracy of the estimates or help identify ways to address potential variability.

6. Regulatory Review Cost Estimation

To comply with these proposed rules, affected entities must first review and understand the regulatory requirements. While plans and issuers are ultimately responsible for meeting these proposed requirements, the Departments expect, as assumed elsewhere, that the burden of compliance would fall primarily on issuers and TPAs, with only the largest self-insured plans likely to assume this

responsibility directly. While the Departments do not have specific data on how many large self-insured plans will opt to comply independently, such plans would likely incur similar costs and burdens as issuers and TPAs in developing compliant tools and reviewing these proposed rules. Therefore, for purposes of estimating regulatory review costs, the Departments assume that a total of 1,580 issuers and TPAs would take on these responsibilities.

Additionally, the Departments expect States to review these proposed rules to prepare for oversight and enforcement duties. If these proposed rules impose administrative costs on private entities, such as the time required to review and interpret these proposed rules, the Departments should estimate the costs associated with regulatory review. Given the difficulty in precisely determining how many entities will undertake such a review, the Departments assume that all plans (or TPAs on behalf of plans) and issuers, and States would need to review these proposed rules in order to comply.

The Departments acknowledge that this assumption may overstate or understate actual costs, as not all entities may conduct an in-depth review, and some may rely on external counsel or consultants. Nonetheless, the Departments have determined that using the total number of plans, issuers, and States provides a reasonable basis for estimating the regulatory review burden.

Using data from the Bureau of Labor Statistics' Occupational Employment and Wage Statistics,²³⁶ the Departments assume that issuers and TPAs would rely on a Computer and Information Systems Manager (Code 11-3021) and a Lawyer (Code 23-1011) to review and interpret these proposed rules. For States, a Compliance Officer (Code 13-1041) is assumed to perform this task. Assuming an average reading speed of 200 words per minute and using BLS median wage data (including a 100 percent increase to account for the cost of fringe benefits and other indirect costs), the Departments estimate that each issuer or TPA would require approximately 2.9 hours of review by a Computer and Information Systems Manager (at \$164.62/hour) and 5.8 hours by a Lawyer (at \$145.34/hour). Based on these assumptions, the combined labor cost for all 1,580 issuers and TPAs is approximately \$2,068,200.

²³³ Harold A. Pollack, *Necessity for and Limitations of Price Transparency in American Health Care*, 24 *AMA Journal of Ethics* E1069 (Nov. 2022).

²³⁴ McKinsey & Company, *Consumer Decision Making in Healthcare: The Role of Information Transparency* (July, 2020), <https://www.mckinsey.com/-/media/McKinsey/Industries/Healthcare%20Systems%20and%20Services/Our%20Insights/Consumer%20decision%20making%20in%20healthcare/Consumer-decision-making-in-healthcare-The-role-of-information-transparency.pdf>.

²³⁵ Robert F. Graboyes & James McBirney, *Price Transparency in Healthcare: Apply with Caution*, Mercatus Center, George Mason University (2020), <https://www.mercatus.org/system/files/graboyes-price-transparency-mercatus-research-v1.pdf>.

²³⁶ U.S. Bureau of Labor Statistics, *National Occupational Employment and Wage Estimates* (May 2024), https://www.bls.gov/oes/current/oes_stru.htm.

For States, it is estimated that a Compliance Officer would need approximately 4.6 hours (at \$75.40/hour) to review these proposed rules, resulting in a total cost of \$22,111 across all 50 States and the District of Columbia. Accordingly, the total combined estimated cost of regulatory review for all plans and issuers, and State DOIs is approximately \$2,090,311.

E. Alternatives Considered

1. Disclosure of Claims Volume

The Departments considered adding a new content element under the In-network Rate File requirements at 26 CFR 54.9815–2715A3(b)(1), 29 CFR 2590.715–2715A3(b)(1), and 45 CFR 147.212(b)(1) requiring disclosure of claims volume for each negotiated rate for each provider for each item and service as an additional or alternative method of providing contextual plan and coverage usage information. The Departments also considered requiring the Utilization File at 26 CFR 54.9815–2715A3(b)(2)(ii), 29 CFR 2590.715–2715A3(b)(2)(ii), and 45 CFR 147.212(b)(2)(ii) to disclose the number of times that any given provider submitted a claim for any particular item or service. Claims volume could inform which providers are associated with high-volume services and the respective negotiated rates as well as help indicate the degree to which negotiated rates are used by providers to deliver actual services to health plan enrollees. However, the Departments are concerned that this additional information may impose a significant burden for plans and issuers, who would need to pull claims data for each item and service for each provider that has a negotiated rate for such item and service and update the claims count. Claims data most likely resides in different systems from contract data and would need to be imported and kept up to date in the In-network Rate File according to the cadence in which the In-network Rate File must be updated, potentially making the production of In-network Rate Files, as well as the annual Utilization File, much more burdensome. Further, this level of querying is complex and potentially always changing based on the frequency of provider groups changing (which providers are included in the TIN/NPI combination) and claims activity associated with such providers for such items and services, making the burden not only significant but ongoing. Lastly, current In-network Rate Files contain contract data which is prospective in nature and claims data is retrospective. The mixing of types of data within a file

may introduce potential data confusion. Therefore, the Departments are not proposing to require disclosure of claims-related information in the In-network Rate File or the Utilization File. The Departments seek comment on the relative benefits and burdens interested parties might anticipate with requiring claims-related information.

2. Excluded Information

As an alternative to the proposal to require plans and issuers to exclude from each In-network Rate File a provider and their negotiated rate (provider-rate combination) for an item or service, if it is unlikely that such provider would be reimbursed for the item or service given that provider's area of specialty according to the plan's or issuer's internal provider taxonomy used during the claims adjudication process, the Departments considered two alternative approaches. The first approach involved running each combination of provider and service as a mock claim and only including in the In-network Rate File those claims that passed validation edits for appropriateness of that provider to perform the service. This is different from the proposed process described in section III.C.5. of this preamble because it would require plans and issuers to process each potential provider-rate combination through its claims adjudication, rather than relying on its internal mapping of billing codes to exclude providers. This method establishes a clear standard and provides meaningful information, resulting in smaller In-network Rate Files that are far more accessible and manageable. However, there are significant drawbacks to this approach. Plans and issuers would face a high initial and ongoing administrative and financial burden, as they would need to run every provider through the claims adjudication system for every item or service with a negotiated rate, repeating this process quarterly. This method imposes the greatest engineering burden among the options considered, as it may require setting up and maintaining parallel adjudication systems specifically for this task, separate from production adjudication systems. The Departments considered the administrative burden associated with this approach to be a significant deterrent to proposing this approach as a viable option.

Second, the Departments explored the idea of requiring plans and issuers to create In-network Rate Files with negotiated rates based solely on historic claims data, identifying providers who have submitted claims for specific items

or services. This approach has several advantages. It would establish a clear standard, provide meaningful information, and ensure that negotiated rates are disclosed only for providers who have actually submitted claims for those items and services over the course of a particular period of time. However, the proposal also presented significant drawbacks. First, this approach would lack a mechanism to monitor over-filtering by plans and issuers, potentially excluding relevant providers. Also, mixing prospective and retrospective data within the In-network Rate File could confuse users about which services are available under current contracts versus historical activity. Finally, the approach might require exceptions for new providers who have not yet submitted claims, making it difficult for users to distinguish between active providers and those who are unlikely to offer specific services. As a result, the Departments determined this approach was overly complex as compared with the proposed approach of utilizing the taxonomy data discussed.

3. Data Retention

The Departments received feedback from interested parties recommending that plans and issuers be required to retain the Transparency in Coverage data required pursuant to 26 CFR 54.9815–2715A3(b), 29 CFR 2590.715–2715A3(b), 45 CFR 147.212(b) on a public website for 7 years. They argue their recommendation on the fact that, because plans and issuers are currently only required to post their machine-readable files monthly, most plans and issuers replace the files on their website each month, making the prior month's files unavailable, and consequently making it difficult for file consumers like researchers and academics to analyze pricing trends over time, verify historical rates, or assess the evolution of provider-plan relationships.

The Departments considered data retention standards of 7 years, as well as shorter durations, but are not proposing any data retention requirements at this time due to the significant cost and burden the Departments have determined it would incur on plans and issuers. Specifically, storing, maintaining, and making 7 years of machine-readable files publicly available would be costly, and the benefits, such as enabling longitudinal analysis of contractual data and historical price benchmarking, are relatively marginal especially if other proposals in these proposed rules are finalized. In particular, the recommendation would necessitate

robust additional data storage capacity—moving beyond transient monthly files to a vast archive capable of accommodating potential petabytes of historical records. Concurrently, significant network bandwidth allocations would be required to handle the consistent monthly influx of new data, as well as the eventual high-volume demands of researchers or other entities accessing and downloading years' worth of historical files. Furthermore, the ongoing maintenance and organization of the datasets would require ensuring data integrity over time, implementing efficient indexing and cataloging of systems for easy discoverability. Without careful engineering planning and dedicated resources, the archived files risk becoming digital landfills, undermining the transparency they are intended to provide.

The Departments' proposed change from a requirement to post updated In-network Rate and Allowed Amount Files every month to quarterly in redesignated 26 CFR 54.9815–2715A3(b)(4)(i), 29 CFR 2590.715–2715A3(b)(4)(i), and 45 CFR 147.212(b)(4)(i) and described in section III.C.10. of this preamble would reduce the number of files required to be retained by users for future reference and thus the associated costs of doing so. Similarly, a quarterly cadence should ease the difficulty some users have when downloading and collecting the file data monthly, thus expanding access to more users without losing any data. The Departments also expect that the proposed requirement for plans and issuers to produce a quarterly Change-log File in new 26 CFR 54.9815–2715A3(b)(2)(i), 29 CFR 2590.715–2715A3(b)(2)(i), and 45 CFR 147.212(b)(2)(i) and described in section III.C.7.a. of this preamble may help users more easily catalog and assess data changes over time, limiting the need to access all the data in prior files.

The Departments, however, seek comment on the relative burdens and benefits of requiring files to be publicly posted for a specific period of time. The Departments are particularly interested in whether interested parties believe that public retention of prior files would continue to be valuable if combined with the other changes in these proposed rules. The Departments are also interested in views from interested parties on what would be a sufficient amount of retention time that would still provide value for file users without imposing an undue burden on plans and issuers.

4. Deemed Compliance With PHS Act Section 2799A–4, ERISA Section 719, and Code Section 9819

The Departments indicated in FAQs Part 49 on August 20, 2021²³⁷ that, because the price comparison methods required by the No Surprises Act (codified in Code section 9819, ERISA section 719, and PHS Act section 2799A–4) are largely duplicative of the self-service tool described in the 2020 final rules, the Departments intended to propose rulemaking and seek public comment regarding whether compliance with the self-service tool requirements of the 2020 final rules satisfies the analogous requirements set forth in Code section 9819, ERISA section 719, and PHS Act section 2799A–4. The Departments recognized that plans and issuers had already been working to implement the self-service tool requirement of the 2020 final rules.

The Departments considered requiring plans to develop a separate cost comparison tool to fulfill the requirements of the No Surprises Act, however, such a proposal would likely impose significant costs on plans and issuers for having to build an entirely new technical infrastructure, with little additional benefits for participants, beneficiaries, and enrollees, given that the provisions of the No Surprises Act largely duplicate the requirements of the Transparency in Coverage rules. Additionally, there would be great potential for public confusion, as participants, beneficiaries, and enrollees would be unsure of which tool use, whether they had different purposes, and the potential for search results to be different. The Departments have received feedback from plans and issuers that their participants, beneficiaries, and enrollees expressed similar concerns of confusion as the plan and issuer transitioned from a legacy self-service tool to a tool that satisfied the requirements of the 2020 final rules. For these reasons, the Departments are not proposing to require an additional self-service tool.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)²³⁸ requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of a proposed rule on small entities, unless the head of the

agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The Departments have determined that the costs calculated in these proposed rules do not rise to the level of significance under the RFA. The Departments have prepared the following justification for this determination.

1. Proposed Rules

These proposed amendments aim to improve the accessibility, standardization, and utility of pricing data disclosures by refining certain requirements and aligning regulatory text with the No Surprises Act and Executive Order 14221. Key changes include clarifying the balance billing disclaimer to reflect Federal protections, requiring that cost-sharing information to also be made available by phone, and enhancing the format and usability of machine-readable files by reducing duplication and file size.

2. Affected Entities

The RFA generally defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.” The Departments use a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdiction.

a. Group Health Plans

As discussed in section VI.C.1. of this preamble, these proposed rules would affect ERISA-covered group health plans and non-Federal governmental group health plans. The Department estimates that there are approximately 2,500,000 ERISA-covered group health plans with less than 100 employees, of which 1,400,000 are fully funded.²³⁹ For purposes of the RFA, the Department of Labor continues to consider a small entity to be an employee benefit plan

²³⁷ U.S. Department of Labor, U.S. Department of Health & Human Services & U.S. Department of the Treasury, *FAQs about Affordable Care Act Implementation Part 49* (Aug. 20, 2021), <https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/downloads/faqs-part-49.pdf> and <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf>.

²³⁸ 5 U.S.C. 601, *et seq.*

²³⁹ There are 2,454,996 ERISA-covered group health plans with less than 100 employees, of which 1,423,897 are fully insured. Agency for Healthcare Research and Quality, *2023 Medical Expenditure Panel Survey Insurance Component (MEPS-IC)*, https://meps.ahrq.gov/mepsweb/data_stats/download_data_files.jsp (last visited Dec. 8, 2025); U.S. Census Bureau, *2021 County Business Patterns*, <https://www.census.gov/programs-surveys/cbp/data.html> (last visited Dec. 8, 2025).

with fewer than 100 participants.²⁴⁰ Further, while some large employers may have small plans, in general, most small plans are maintained by small employers. Thus, the Departments have determined that assessing the impact of these proposed rules on small plans is an appropriate substitute for evaluating the effect on small entities. The definition of small entity considered appropriate for this purpose differs, however, from a definition of small business that is based on size standards issued by the SBA (13 CFR 121.201) pursuant to the Small Business Act (15 U.S.C. 631, *et seq.*). Therefore, the Departments invite comments on the appropriateness of the size standard used in evaluating the impact of these proposed rules on small entities.

The Department also estimates there are approximately 90,900 non-Federal governmental group health plans.²⁴¹ Of these plans, approximately 35.7 percent²⁴² (or 32,400) are self-insured,²⁴³ and 64.3 percent (or 58,400) are fully insured.²⁴⁴ Furthermore, approximately 93.4 percent of group health plans have less than 100 employees.²⁴⁵ Therefore, the Department estimates there are approximately 84,900 non-Federal governmental health plans with less than 100 employees, of which 30,300

are self-insured²⁴⁶ and 54,600 are fully funded.²⁴⁷

b. Participants and Enrollees

The Departments estimate that there are 35.6 million participants in ERISA-covered group health plans with also 100 employees, of which 5.6 million are in self-insured plans and 30.1 million are in fully funded plans.²⁴⁸ There are also approximately 2.2 million participants in non-Federal governmental group health plans with less than 100 employees, of which one million are in self-insured plans and 1.2 million are in fully insured plans.²⁴⁹

c. Issuers and TPAs

For purposes of the RFA, the Departments have determined that health insurance companies are generally classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards,²⁵⁰ entities with average annual receipts of \$47 million or less are considered small entities within this classification. Alternatively, some may fall under NAICS code 621491 (HMO Medical Centers), which has a size standard of \$44.5 million or less.²⁵¹

Based on data from Medical Loss Ratio (MLR) annual report submissions for the 2023 reporting year, approximately 84 out of 479 (18 percent) issuers of health insurance coverage nationwide had total premium revenues of \$47 million or less.²⁵² The Departments also estimate, based on MLR data, that over 80 percent of these small companies belong to larger

holding groups, and many, if not all, of these small companies, are likely to have non-health lines of business that would result in their revenues exceeding \$47 million. The Departments have determined that the same assumptions also apply to TPAs that would be affected by these proposed rules.²⁵³ However, it should be noted that at least 76 percent of these small companies belong to larger holding groups that may not be small, and many, if not all, of these companies are likely to have non-health lines of business that would result in their revenues exceeding \$47 million.

3. Cost of These Proposed Rules

Using a threshold approach, if the total costs of these proposed rules were spread evenly across all 1,375 issuers and 205 TPAs, the high-end per-entity costs would be approximately \$578,298 in one-time first-year costs and \$43,165 in ongoing annual costs, which would also be incurred in the first year.²⁵⁴ Although the Departments are not able to apply the 3 to 5 percent change in revenues standard as a measure of significant economic impact on a substantial number of small entities due to limited data, as discussed in section VI.F.3. of this preamble, it is notable that over 80 percent of issuers and at least 76 percent of TPAs classified as small businesses are affiliated with larger holding groups that may not themselves qualify as small. Based on this information, the Departments anticipate that the costs associated with these proposed rules do not rise to the level of significance under the RFA. Therefore, the Departments conclude that an initial regulatory flexibility analysis is not required for such firms. The Departments seek comment on the assumptions and methodology underlying this analysis, including whether alternative data or approaches could better assess the impact on small plans and issuers, and on potential ways to reduce burden while meeting the objectives of these proposed rules.

Although ERISA-covered plans are often small entities, the Departments have determined that these plans would rely on the larger health insurance issuers and TPAs to comply with these proposed rules. Nevertheless, these plans may still experience increased

²⁴⁰ The Department of Labor consulted with the Small Business Administration Office of Advocacy in making this determination, as required by 5 U.S.C. 603(c) and 13 CFR 121.903(c) in a memo dated June 4, 2020.

²⁴¹ Based on data from the 2022 Census of Governments, there are 90,887 State and local entities. The Departments assume there is one plan per entity on average. Therefore, the Departments estimate that there are 90,887 non-Federal governmental plans. U.S. Census Bureau, *2022 Census of Governments, Organization Tables*, <https://www.census.gov/data/tables/2022/econ/gus/2022-governments.html> (last visited Dec. 8, 2025).

²⁴² Agency for Healthcare Research and Quality, *Medical Expenditure Panel Survey—Insurance Component, Table III.A.2.a.* (2023), <https://datatools.ahrq.gov/meps-ic/?tab=private-sector-national&dash=19> (last visited Dec. 8, 2025).

²⁴³ This estimate is calculated as follows: 90,887 non-Federal group health plans × 35.7 percent = 32,447 self-insured, non-Federal governmental group health plans.

²⁴⁴ This estimate is calculated as follows: 90,887 non-Federal group health plans × 64.3 percent = 58,440 fully insured, non-Federal governmental group health plans.

²⁴⁵ Based on the 2023 Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and the 2021 County Business Patterns from the Census Bureau. Agency for Healthcare Research and Quality, *2023 Medical Expenditure Panel Survey Insurance Component (MEPS-IC)*, https://meps.ahrq.gov/mepsweb/data_stats/download_data_files.jsp (last visited Dec. 8, 2025); U.S. Census Bureau, *2021 County Business Patterns*, <https://www.census.gov/programs-surveys/cbp/data.html> (last visited Dec. 8, 2025).

²⁴⁶ This estimate is calculated as follows: 32,447 self-insured, non-Federal governmental group health plans × 93.4 percent = 30,300 self-insured, non-Federal governmental group health plans with less than 100 employees.

²⁴⁷ This estimate is calculated as follows: 58,440 fully funded, non-Federal governmental group health plans × 93.4 percent = 54,582 fully funded, non-Federal governmental group health plans with less than 100 employees.

²⁴⁸ Employee Benefits Security Administration, *Health Insurance Coverage Bulletin: Abstract of Auxiliary Data for the March 2023 Annual Social and Economic Supplement to the Current Population Survey* (Aug. 30, 2024), <https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2023.pdf>.

²⁴⁹ *Id.*

²⁵⁰ U.S. Small Business Administration, *Table of Size Standards* (2023), <https://www.sba.gov/document/support-table-size-standards> (last updated Dec. 26, 2024).

²⁵¹ *Id.*

²⁵² Based on internal calculations. Centers for Medicare & Medicaid Services, *Medical Loss Ratio Data and System Resources* (2023), <https://www.cms.gov/marketplace/resources/data/medical-loss-ratio-data-systems-resources> (last modified Dec. 23, 2024).

²⁵³ The Departments have determined that most TPAs are or are affiliated with issuers.

²⁵⁴ The per-entity costs are estimated at \$578,298 for the first year and \$43,165 on an ongoing annual basis. These figures are derived by dividing the total estimated first-year cost of \$913,710,577 and the total estimated ongoing annual cost of \$68,201,320 by the total number of affected entities (1,375 issuers + 205 TPAs = 1,580).

costs due to the requirements, as the costs associated with implementation are likely to be passed on to them. However, the Departments are not of the view that the additional costs rise to the level of a significant economic impact. In addition, although the requirements of this proposal do not directly apply to providers, providers may experience a loss in revenue as a result of the demands of price-sensitive consumers and plans, as well as a potential unwillingness among smaller issuers to continue paying higher rates than those of larger issuers for the same items and services.

The Departments acknowledge that it may be likely that a number of small entities might enter into contracts with other entities in order to meet the requirements in these proposed rules, perhaps allowing for the development of economies of scale. However, due to limited information about how small entities may choose to meet these requirements and the potential costs associated with such contractual arrangements, the Departments seek comment on ways that these proposed rules could impose additional costs and burdens on small entities and how many such entities would likely enter into contracts to meet these proposed requirements.

Finally, section 1102(b) of the Social Security Act (SSA) (42 U.S.C. 1302) requires agencies to prepare a regulatory impact analysis if a rule is expected to have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must align with the provisions of section 603 of the RFA. For purposes of section 1102(b) of the SSA, the Departments define a small rural hospital as a hospital that is located outside of a metropolitan statistical area with fewer than 100 beds. While these proposed rules are not anticipated to directly regulate small rural hospitals, the Departments acknowledge that the transparency requirement may have indirect effects on these facilities through potential changes in negotiated rates and patient cost-sharing, behaviors that could impact hospital revenues, particularly given that rural providers typically operate with thinner profit margins than their urban counterparts. However, the Departments recognize that rural hospitals may also face lower levels of competition and any indirect effects that result from these proposed rules may have a lower impact, in some areas. Therefore, the Departments have determined that while there may be indirect effects, these do not rise to the level of a significant impact on the

operations of a substantial number of small rural hospitals.

4. Duplicate, Overlapping, or Relevant Federal Rules

There are no duplicate, overlapping, or relevant Federal rules.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires agencies to assess anticipated costs and benefits before issuing any rule that may result in expenditures of \$100 million or more in any one year (in 1995 dollars), adjusted annually for inflation. For 2025, this threshold is approximately \$187 million. These proposed rules include disclosure requirements that may impact private sector entities, such as health insurance issuers offering coverage in the individual and group health insurance markets and TPAs administering group health plans. In addition, States, local, or Tribal governments may incur costs related to enforcement of certain provisions. The Departments expect the total burden on States, local, or Tribal governments and the private sector to exceed the UMRA threshold. The regulatory impact analysis proceeding this section of the preamble constitutes the assessment of anticipated costs and benefits required by UMRA.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has federalism implications. Federal agencies issuing regulations that have federalism implications must consult with States and local officials and describe the extent of their consultation and the nature of the concerns of States and local officials in the preamble to the regulation.

In the Departments' view, these proposed rules may have federalism implications, because it would have direct effects on the States, the relationship between the Federal Government and States, or on the distribution of power and responsibilities among various levels of government relating to the disclosure of health insurance coverage information to consumers.

Under these proposed rules, all group health plans and health insurance issuers, including self-insured, non-Federal governmental group health plans as defined in section 2791 of the PHS Act, would be required to enhance

the accessibility and transparency of cost-sharing and pricing information for a participant, beneficiary, or enrollee (or an authorized representative on behalf of such individual). Specifically, plans and issuers would need to update disclaimers to reflect Federal balance billing protections, make cost-sharing estimates available by phone, and clarify how to meet the requirements for price comparison tools. These proposed rules would also require improvements to the format and accessibility of machine-readable files, expansion of required data elements, and adjustments to posting frequency and structure to ensure pricing data is more usable and understandable for consumers. Federal standards developed under section 2715A of the PHS Act preempt any related States' standards that require pricing information to be disclosed to the participant, beneficiary, or enrollee, or otherwise publicly disclosed, to the extent the State disclosure requirements would provide less information to the consumer or the public than what is required under these proposed rules.

The Departments have determined that these proposed rules may have federalism implications based on the required disclosure of pricing information, as they are aware of at least 25 States that have passed some form of price transparency legislation, such as all-payer claims databases, consumer-facing price comparison tools, and the right to shop programs, with varying requirements regarding the scope and level of disclosure.²⁵⁵ While some States provide prices for individual services, others report aggregated costs across providers or over time to reflect the cost of an episode of care. The methods of sharing this information also vary. For instance, California requires uninsured patients to receive price estimates upon request, whereas other States use websites or software applications to enable consumers to compare prices across providers. Only seven States have published pricing information of issuers on consumer-facing public websites.²⁵⁶ Therefore, these proposed rules may require plans and issuers to disclose more detailed pricing information than some State laws currently mandate.

In general, through section 514, ERISA supersedes State laws to the

²⁵⁵ National Conference of State Legislatures, *Health Costs, Coverage and Delivery State Legislation Data Base*, <https://www.ncsl.org/health/health-costs-coverage-and-delivery-state-legislation> (last updated Sep 26, 2025).

²⁵⁶ Melanie Evans, *One State's Effort to Publicize Hospital Prices Brings Mixed Results*, Wall Street Journal (June 26, 2019), <https://www.wsj.com/articles/one-states-effort-to-publicize-hospital-prices-brings-mixed-results-11561555562>.

extent that they relate to any covered employee benefit plan but preserves State laws that regulate insurance, banking, or securities. Furthermore, the preemption provisions of section 731 of ERISA and section 2724 of the PHS Act (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the provisions of Part 7 of ERISA and chapter XXVII of the PHS Act (including the amendments made by the Affordable Care Act) are not to be “construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a ‘requirement’ of a Federal standard.” The conference report accompanying HIPAA indicates that this preemption is intended to be the “narrowest” preemption of State laws.²⁵⁷ States may therefore continue to apply State law requirements to issuers so long as such requirements do not prevent the application of the Affordable Care Act requirements that are the subject of this rulemaking. Accordingly, States have significant latitude to impose requirements on issuers that are more restrictive than the Federal law.

In compliance with the requirement of Executive Order 13132, which requires agencies to examine closely any policies that may have federalism implications or limit the policy making discretion of the States, the Departments have engaged in efforts to consult with and work cooperatively with affected States. These efforts have included participation in conference calls and events hosted by the NAIC, as well as direct engagement with State insurance officials. The Departments intend to act in a similar fashion in enforcing the Affordable Care Act, including the provisions of section 2715A of the PHS Act. While drafting these proposed rules, the Departments attempted to balance the States’ interests in regulating issuers with the goal of enhancing price transparency nationwide. By doing so, the Departments have determined that they have complied with the requirements of Executive Order 13132.

The Departments request comment on any potential effects these proposed

rules may have on States. The Departments also request comment regarding any duplicative burdens that may exist between State and Federal requirements and ways such duplicative burdens can be addressed, if applicable.

In accordance with the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to these proposed rules, the Departments certify that the Department of the Treasury, Employee Benefits Security Administration, and the CMS have complied with the requirements of Executive Order 13132 for the attached proposed rules in a meaningful and timely manner.

I. Executive Order 14192, “Unleashing Prosperity Through Deregulation”

Executive Order 14192, titled “Unleashing Prosperity Through Deregulation,” was issued on January 31, 2025. Section 3(a) of Executive Order 14192 requires an agency, unless prohibited by law, to identify at least ten existing regulations to be repealed when the agency issues a new regulation. In furtherance of this requirement, section 3(c) of Executive Order 14192 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with prior regulations. A significant regulatory action (as defined in section 3(f) of Executive Order 12866) that would impose total costs greater than zero is considered an Executive Order 14192 regulatory action. This proposed rule, if finalized as proposed, is, therefore, expected to be an Executive Order 14192 regulatory action. Details on the estimated costs appear in the preceding analysis.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Child support, Employee benefit plans, Health care, Health insurance, Infants and children, Maternal and child health, Penalties, Pensions, Privacy, Reporting and recordkeeping requirements.

45 CFR Part 147

Aged, Citizenship and naturalization, Civil rights, Health care, Health insurance, Individuals with disabilities, Intergovernmental relations, Reporting

and recordkeeping requirements, Sex discrimination.

Frank J. Bisignano,

Chief Executive Officer, Internal Revenue Service.

Daniel Aronowitz,

Assistant Secretary, Employee Benefits Security Administration.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

For the reasons set forth in the preamble, the Department of the Treasury proposes to amend 26 CFR part 54 as set forth below:

PART 54—PENSION EXCISE TAXES

- 1. The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805, unless otherwise noted.

* * * * *

Sections 54.9815–2715A1, 54.9815–2715A2, and 54.9815–2715A3 are also issued under 26 U.S.C. 9833;

* * * * *

- 2. Section 54.9815–2715A1 is amended by:

■ a. Redesignating paragraphs (a)(2)(xi) through (xxii) as paragraphs (a)(2)(xii) through (xxiii); and

■ b. Adding new paragraph (a)(2)(xi).

The addition reads as follows:

§ 54.9815–2715A1 Transparency in coverage—definitions.

(a) * * *

(2) * * *

(xi) *Health insurance market* means, irrespective of the State, one of the following:

(A) The individual market, as defined in 45 CFR 144.103 (other than short-term, limited-duration insurance or individual health insurance coverage that consists solely of excepted benefits).

(B) The large group market, as defined in 45 CFR 144.103 (other than coverage that consists solely of excepted benefits).

(C) The small group market, as defined in 45 CFR 144.103 (other than coverage that consists solely of excepted benefits).

(D) For purposes of self-insured group health plans (other than account-based plans, as defined in § 54.9815–2711(d)(6)(i), and plans that consist solely of excepted benefits), all self-insured group health plans maintained by the plan sponsor.

* * * * *

- 3. Section 54.9815–2715A2 is amended by—

²⁵⁷ U.S. Department of Labor, U.S. Department of Health & Human Services & U.S. Department of the Treasury, *FAQs about Affordable Care Act Implementation Part 54* (July 28, 2022), <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-54.pdf> and <https://www.cms.gov/files/document/faqs-part-54.pdf>.

■ a. Revising paragraphs (b)(1)(i)(A) and (B), (b)(1)(vii)(A), and (b)(2)(ii) introductory text;

■ b. Redesignating paragraph (b)(2)(ii)(D) as paragraph (b)(2)(iv);

■ c. Adding paragraph (b)(2)(iii);

■ d. Revising newly redesignated paragraph (b)(2)(iv);

■ e. Revising paragraphs (b)(3)(i) and (ii);

■ f. Revising paragraph (c)(1); and

■ g. Adding paragraph (c)(7).

The revisions and additions read as follows:

§ 54.9815–2715A2 Transparency in coverage—required disclosures to participants and beneficiaries.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(A) If the request for cost-sharing information relates to items and services that are provided within a bundled payment arrangement, and the bundled payment arrangement includes items or services that have a separate cost-sharing liability, the group health plan or health insurance issuer must provide estimates of the cost-sharing liability for the requested covered item or service, as well as an estimate of the cost-sharing liability for each of the items and services in the bundled payment arrangement that have separate cost-sharing liabilities. While plans and issuers are not required to provide estimates of cost-sharing liability for a bundled payment arrangement where the cost-sharing is imposed separately for each item and service included in the bundled payment arrangement, nothing prohibits plans or issuers from providing estimates for multiple items and services in situations where such estimates could be relevant to participants or beneficiaries, as long as the plan or issuer also discloses information about the relevant items or services individually, as required in paragraph (b)(1)(v) of this section.

(B) For requested items and services that are recommended preventive services under section 2713 of the Public Health Service Act (PHS Act), if the group health plan or health insurance issuer cannot determine whether the request is for preventive or non-preventive purposes, the plan or issuer must display the cost-sharing liability that applies for non-preventive purposes. As an alternative, a plan or issuer may allow a participant or beneficiary to request cost-sharing information for the specific preventive or non-preventive item or service by including terms such as “preventive,” “non-preventive,” or “diagnostic” as a

means to request the most accurate cost-sharing information.

* * * * *

(vii) * * *

(A) A statement that the cost-sharing information provided pursuant to this paragraph (b)(1) does not account for potential additional amounts in situations where applicable State or Federal law allow out-of-network providers to bill participants or beneficiaries for the difference between a provider's billed charges and the sum of the amount collected from the group health plan or health insurance issuer and from the participants or beneficiaries in the form of a copayment, coinsurance, or deductible amount (the difference referred to as balance billing). This statement is not required if the State in which the item or service was furnished prohibits all out-of-network providers from balance billing for all items and services payable by the plan or issuer.

* * * * *

(2) * * *

(i) *Paper method.* Information provided under this paragraph (b) must be made available in plain language, without a fee, in paper form at the request of the participant or beneficiary. In responding to such a request, the group health plan or health insurance issuer may limit the number of providers with respect to which cost-sharing information for covered items and services is provided to no fewer than 20 providers per request. The plan or issuer is required to:

* * * * *

(iii) *Phone method.* Information provided under this paragraph (b) must be made available at the request of the participant or beneficiary via a telephone number through which a consumer may seek customer assistance that Code section 9816(e) requires be indicated on any physical or electronic plan or insurance identification card issued to a participant, beneficiary, or enrollee. Such information must be accurate at the time of the request and must be provided at the time of the request. In responding to such a request, the group health plan or health insurance issuer may limit the number of providers with respect to which cost-sharing information for covered items and services is provided to no fewer than 20 providers per day. The plan or issuer is required to:

(A) Disclose the applicable provider-per-day limit; and

(B) Provide the cost-sharing information, in accordance with the requirements in paragraphs (b)(2)(i)(A) through (C) of this section.

(iv) *Alternative method.* In circumstances where participants and beneficiaries request disclosure other than by the internet-based self-service tool, paper, or phone (for example, by email) group health plans and health insurance issuers may provide the disclosure through alternative means and satisfy the requirements of this section, provided the participant or beneficiary agrees that such disclosure through such means is sufficient to satisfy the request and the plan or issuer meets the timing requirements established under paragraph (b)(2)(ii)(C) of this section for paper method disclosure.

(3) * * *

(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information required by this paragraph (b) in compliance with this section pursuant to a written agreement. Accordingly, if an issuer and a plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a pharmacy benefit manager or other third-party) provides the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a plan or issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(c) * * *

(1)(i) The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after January 1, 2023 with respect to the 500 items and services to be posted on a publicly available website, and with respect to all covered items and services, for plan years (in the individual market, for policy years) beginning on or after January 1, 2024.

(ii) Notwithstanding paragraph (c)(1)(i) of this section, paragraphs

(b)(1)(vii)(A), (b)(2)(iii) and (iv), and (c)(7) of this section apply for plan years (in the individual market, for policy years) beginning on or after January 1, 2027. Until such time, the current provisions of paragraph (b) of this section continue to apply.

* * * * *

(7) A group health plan or health insurance issuer that provides to the participant or beneficiary the information required under paragraph (b)(1) of this section, in accordance with the method and format requirements set forth in paragraph (b)(2) of this section, satisfies the requirements set forth in Code section 9819, ERISA section 719, and PHS Act section 2799A–4.

* * * * *

■ 4. Section § 54.9815–2715A3 is amended by—

- a. Revising paragraph (b) heading and introductory text;
- b. Revising paragraphs (b)(1)(i) and (ii);
- c. Redesignating paragraphs (b)(2) and (3) as paragraphs (b)(3) and (4), respectively;
- d. Adding new paragraph (b)(2);
- e. Revising newly redesignated paragraphs (b)(3) and (4);
- f. Redesignating paragraphs (b)(4)(i) and (ii) as paragraphs (b)(5)(i) and (ii), respectively;
- g. Revising newly redesignated paragraphs (b)(5)(i) and (ii);
- h. Redesignating paragraph (b)(4)(iii) as paragraph (b)(5)(iv);
- i. Adding new paragraph (b)(5)(iii);
- j. Revising newly redesignated paragraph (b)(5)(iv); and
- k. Revising paragraph (c)(1).

The revisions and additions read as follows:

§ 54.9815–2715A3 Transparency in coverage—requirements for public disclosure.

* * * * *

(b) *Requirements for public disclosure of in-network provider rates for covered items and services, out-of-network allowed amounts and billed charges for covered items and services, negotiated rates and historical net prices for covered prescription drugs, and contextual information.* A group health plan or health insurance issuer must make available on an internet website the information required under paragraphs (b)(1) and (2) of this section in machine-readable files, in accordance with the method and format requirements described in paragraph (b)(3) of this section, and that are updated as required under paragraph (b)(4) of this section.

(1) * * *

(i) An in-network rate machine-readable file for each provider network

maintained or contracted by a group health plan or health insurance issuer that includes the required information under this paragraph (b)(1)(i) for all covered items and services under each coverage option offered by the plan or issuer that uses such provider network, except for prescription drugs that are subject to a fee-for-service reimbursement arrangement, which must be reported in the prescription drug machine-readable file pursuant to paragraph (b)(1)(iii) of this section. Each in-network rate machine-readable file must include:

(A) The common provider network name;

(B) For each coverage option offered by a group health plan or health insurance issuer that uses such provider network, the name; the Health Insurance Oversight System (HIOS) identifier, or, if no HIOS identifier is available, the Employer Identification Number (EIN); and the product type (for example, Health Maintenance Organization, Preferred Provider Organization);

(C) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service included in the machine-readable file;

(D) For each covered item or service included in the machine-readable file, all applicable rates, which may include one or more of the following: Negotiated rates, underlying fee schedule rates, or derived amounts. If a group health plan or health insurance issuer does not use negotiated rates for provider reimbursement, then the plan or issuer should disclose derived amounts to the extent these amounts are already calculated in the normal course of business. If the plan or issuer uses underlying fee schedule rates for calculating cost sharing, then the plan or issuer should include the underlying fee schedule rates in addition to the negotiated rate or derived amount. Applicable rates, including for both individual items and services and items and services in a bundled payment arrangement, must be:

(1) Reflected as dollar amounts, with respect to each covered item or service that is furnished by an in-network provider. If the negotiated rate is subject to change based upon participant or beneficiary-specific characteristics, these dollar amounts should be reflected as the base negotiated rate applicable to the item or service prior to adjustments for participant or beneficiary-specific characteristics. For contractual arrangements under which a group health plan or health insurance issuer agrees to pay an in-network provider a

percentage of billed charges and is not able to assign a dollar amount to an item or service prior to a bill being generated, plans and issuers must report a percentage number, in lieu of a dollar amount, in a form and manner as specified in guidance issued by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services.

(2) Associated with the National Provider Identifier (NPI), Tax Identification Number (TIN), and Place of Service Code for each in-network provider, except those specified in paragraph (b)(1)(i)(F) of this section;

(3) Associated with the last date of the contract term or expiration date for each provider-specific applicable rate that applies to each covered item or service; and

(4) Indicated with a notation where a reimbursement arrangement other than a standard fee-for-service model (such as capitation or a bundled payment arrangement) applies.

(E) Current numerical enrollment totals, as of the date the file is posted, for each coverage option offered by a group health plan or health insurance issuer that uses such provider network. Such numerical enrollment totals must include the number of participants and beneficiaries (including all dependents) in the coverage option offered by a plan or issuer.

(F) A group health plan or health insurance issuer must exclude from each file under paragraph (b)(1)(i) of this section a provider and their negotiated rate (provider-rate combination) for an item or service if the plan or issuer determines it is unlikely that the provider would be reimbursed for the item or service given that provider's area of specialty according to the plan's or issuer's internal provider taxonomy used during the claims adjudication process.

(ii) For each health insurance market, as defined in § 54.9815–2715A1(a)(2)(xi), in which a group health plan or health insurance issuer offers a plan or coverage, an out-of-network allowed amount machine-readable file, including:

(A) For each coverage option offered by a group health plan or health insurance issuer in such health insurance market, the name and the HIOS identifier, or, if no HIOS identifier is available, the EIN; and the product type (for example, Health Maintenance Organization, Preferred Provider Organization);

(B) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for

each billing code for each covered item or service under any coverage option offered by a group health plan or health insurance issuer in such health insurance market; and

(C) Aggregated unique out-of-network allowed amounts and billed charges with respect to each covered item or service under any coverage option offered by a group health plan or health insurance issuer in such health insurance market furnished by out-of-network providers during the 6-month time period that begins 9 months prior to the publication date of the machine-readable file (except that a plan or issuer must omit such data in relation to a particular item or service when compliance with this paragraph (b)(1)(ii)(C) would require the plan or issuer to report payment of out-of-network allowed amounts in connection with fewer than 11 different claims for payment of that item or service in a single health insurance market). Consistent with paragraph (c)(3) of this section, nothing in this paragraph (b)(1)(ii)(C) requires the disclosure of information that would violate any applicable health information privacy law. Each unique out-of-network allowed amount must be:

(1) Reflected as a dollar amount, with respect to each covered item or service that is furnished by an out-of-network provider; and

(2) Associated with the NPI, TIN, and Place of Service Code for each out-of-network provider.

* * * *

(2) *Required contextual files.* A group health plan or health insurance issuer must make available in a machine-readable format:

(i) A change-log file, for each in-network rate machine-readable file specified in paragraph (b)(1)(i) of this section, that identifies any changes made to the required information described in paragraph (b)(1)(i) of this section since the immediately preceding published in-network rate machine-readable file.

(ii) A utilization file, for each in-network rate machine-readable file specified in paragraph (b)(1)(i) of this section, that includes, for the 12-month period that ends 6 months prior to the publication date of each utilization file:

(A) Items and services covered under the plans or policies included in the files prepared as specified in paragraph (b)(1)(i) of this section for which a claim has been submitted and reimbursed, in whole or in part; and

(B) Each in-network provider identified by the NPI, TIN, and Place of Service Code who was reimbursed, in

whole or in part, for a claim for each covered item or service included as specified in paragraph (b)(2)(ii)(A) of this section.

(iii) A taxonomy file, for each in-network rate machine-readable file prepared as specified in paragraph (b)(1)(i) of this section, which includes the group health plan's or health insurance issuer's internal provider taxonomy that matches items and services (represented by a billing code) with provider specialties (represented by specialty codes which are derived from the Health Care Provider Taxonomy code set established by the National Uniform Claim Committee (NUCC)) to determine if the plan or issuer should deny reimbursement for an item or service because it was not furnished by a provider in an appropriate specialty. Plans and issuers must use their internal provider taxonomy to determine whether to exclude certain provider-rate combinations from the in-network rate machine-readable file as specified in paragraph (b)(1)(i)(F) of this section.

(iv) A plain text file in a .txt format in the root folder (that is, the top-level directory on an electronic file system) of a group health plan's or health insurance issuer's website that includes:

(A) The source page URL for the internet website that hosts the machine-readable files required under paragraphs (b)(1) and (2) of this section;

(B) A direct link to the URL for the machine-readable files required under paragraphs (b)(1) and (2) of this section; and

(C) Point-of-contact information, including an up-to-date name, title, and email address for an individual who can address inquiries and issues related to the machine-readable files required under paragraphs (b)(1) and (2) of this section. This contact information must be prominently displayed on the same website where the machine-readable files are made available and be kept updated per the requirements in paragraph (b)(4)(vi) of this section.

(3) *Required method and format for disclosing information to the public.* (i) The machine-readable files described in paragraphs (b)(1) and (2) of this section must be available in a form and manner as specified in guidance issued by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services.

(ii) The machine-readable files must be publicly available and accessible to any person, automated scripts, or web crawlers free of charge and without conditions, such as establishment of a user account, password, submission of

personally identifiable information or other credentials, or blocking server configurations or firewalls to access the file.

(iii) The source page URL for the internet website that hosts the machine-readable files required under paragraphs (b)(1) and (2) of this section must be included as a link in the footer on the home page of the group health plan's or health insurance issuer's website, as well as any page of the website that features a footer, that is labeled "Price Transparency" or "Transparency in Coverage" and links directly to the publicly available web page that hosts the link to the machine-readable files.

(iv) The group health plan or health insurance issuer may satisfy the requirements of paragraph (b)(3)(iii) of this section by entering into a written agreement under which another party (such as a third-party administrator) posts the machine-readable files on its public website on behalf of the plan or issuer, including if the plan or issuer does not have a website. However, if the files are posted on a service provider's website, and the plan or issuer maintains a public website but chooses not to host the files separately on its own public website, it must provide a link on its own public website to the location where the files are made publicly available.

(4) *Timing.* A group health plan or health insurance issuer must update the machine-readable files in accordance with the following timeframes and clearly indicate the date that the files were most recently updated:

(i) The in-network rate and out-of-network allowed amount machine-readable files required by paragraphs (b)(1)(i) and (ii) of this section must be updated and posted quarterly beginning on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1) of this section;

(ii) The prescription drug machine-readable file required by paragraph (b)(1)(iii) of this section must be updated monthly;

(iii) The change-log machine-readable file required by paragraph (b)(2)(i) of this section must be updated and posted quarterly beginning on the first day of the calendar-year quarter following the date on which the first in-network rate machine-readable file is required to be posted under paragraph (b)(4)(i) of this section in accordance with the applicability date of the amendments to paragraph (b)(1) of this section as specified in paragraph (c)(1) of this section. If there are no changes to the in-network rate machine-readable file described in paragraph (b)(1)(i) of this section since the last such file was

updated, a change-log machine-readable file must still be updated and posted quarterly indicating there are no changes;

(iv) The utilization machine-readable file required under paragraph (b)(2)(ii) of this section must be updated and posted annually beginning on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1) of this section;

(v) The taxonomy machine-readable file required under paragraph (b)(2)(iii) of this section must be updated and posted quarterly beginning on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1) of this section. If there are no changes to the taxonomy that affect the information required in the machine-readable file required under paragraph (b)(1)(i) of this section in a subsequent quarter, the posted taxonomy file is not required to be updated that quarter; and

(vi) The text file required by paragraph (b)(2)(iv) of this section must be posted beginning on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1) of this section and subsequently updated and posted as soon as practicable but no later than 7 calendar days following a change in any of the information required under paragraph (b)(2)(iv) of this section.

(5) *Special rules to prevent unnecessary duplication*—(i) *Special rule for insured group health plans*. To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information pursuant to a written agreement. Accordingly, if an issuer and a plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements*. A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a third-party administrator or health care claims clearinghouse) will provide the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a plan or issuer chooses to enter into such an agreement and the

party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(iii) *Special rule for self-insured group health plans with respect to the disclosure of in-network rate machine-readable files*. A self-insured group health plan that enters into an agreement with another party described in paragraph (b)(5)(ii) of this section may permit such other party to make available in a single in-network rate machine readable file as required under paragraph (b)(1)(i) of this section the information required under paragraph (b)(1)(i) for each provider network used by more than one plan, insurance policy, or contract (including those offered by different plan sponsors with which the other party has an agreement) and across different health insurance markets, provided that—

(A) Each in-network rate machine-readable file made available for a provider network includes the required information under paragraph (b)(1)(i) of this section for all covered items and services under each plan, insurance policy, or contract that uses the same provider network for which the in-network rate machine-readable file is made available; and

(B) Each of the self-insured group health plan's change-log, utilization, and taxonomy machine-readable files include the information required under paragraphs (b)(2)(i), (ii), and (iii) of this section, respectively, for the same plans, insurance policies, or contracts (including those offered by different plan sponsors and across different health insurance markets, if applicable) represented in the corresponding in-network rate machine-readable files specified in paragraph (b)(1)(i) of this section.

(iv) *Special rule for self-insured group health plans with respect to the disclosure of out-of-network allowed amount machine-readable files*. A self-insured group health plan that enters into an agreement with another party described in paragraph (b)(5)(ii) of this section may permit such other party to make available the information required under paragraph (b)(1)(ii) of this section in a single out-of-network allowed amount file for more than one self-insured group health plan (including those offered by different plan sponsors with which the other party has an agreement), provided that the out-of-network allowed amount and billed charge data described in paragraph (b)(1)(ii)(C) of this section in relation to a particular item or service is omitted if

it would require disclosure of out-of-network allowed amounts in connection with fewer than 11 different claims for payment of such item or service across all of the plans (including those offered by different plan sponsors) included in the out-of-network machine-readable file.

(c) * * *

(1)(i) Beginning on or after January 2, 2022, the requirements of this section apply for plan years (in the individual market, for policy years).

(ii) Notwithstanding paragraph (c)(1)(i) of this section, paragraph (b)(1) of this section applies on [DATE 12 MONTHS AFTER PUBLICATION OF FINAL REGULATIONS IN THE FEDERAL REGISTER]. Until such time, the current provisions of paragraph (b) of this section continue to apply.

* * * * *

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons stated in the preamble, the Department of Labor proposes to amend 29 CFR part 2590 as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 5. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a–n, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Pub. L. 116–260, 134 Stat. 1182; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 6. Section 2590.715–2715A1 is amended by—

■ a. Redesignating paragraphs (a)(2)(x) through (xxi) as paragraphs (a)(2)(xi) through (xxii); and

■ b. Adding new paragraph (a)(2)(x).

The addition reads as follows:

§ 2590.715–2715A1 Transparency in coverage—definitions.

(a) * * *

(2) * * *

(x) *Health insurance market* means, irrespective of the State, one of the following:

(A) The individual market, as defined in 45 CFR 144.103 (other than short-term, limited-duration insurance or individual health insurance coverage that consists solely of excepted benefits).

(B) The large group market, as defined in 45 CFR 144.103 (other than coverage that consists solely of excepted benefits).

(C) The small group market, as defined in 45 CFR 144.103 (other than coverage that consists solely of excepted benefits).

(D) For purposes of self-insured group health plans (other than account-based plans, as defined in § 2590.715–2711(d)(6)(i), and plans that consist solely of excepted benefits), all self-insured group health plans maintained by the plan sponsor.

* * * * *

■ 7. Section 2590.715–2715A2 is amended by—

■ a. Revising paragraphs (b)(1)(i)(A) and (B), (b)(1)(vii)(A), and (b)(2)(ii) introductory text;

■ b. Redesignating paragraph (b)(2)(ii)(D) as paragraph (b)(2)(iv);

■ c. Adding paragraph (b)(2)(iii);

■ d. Revising newly redesignated paragraph (b)(2)(iv);

■ e. Revising paragraphs (b)(3)(i) and (ii);

■ f. Revising paragraph (c)(1); and

■ g. Adding paragraph (c)(7).

The revisions and additions read as follows:

§ 2590.715–2715A2 Transparency in coverage—required disclosures to participants and beneficiaries.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(A) If the request for cost-sharing information relates to items and services that are provided within a bundled payment arrangement, and the bundled payment arrangement includes items or services that have a separate cost-sharing liability, the group health plan or health insurance issuer must provide estimates of the cost-sharing liability for the requested covered item or service, as well as an estimate of the cost-sharing liability for each of the items and services in the bundled payment arrangement that have separate cost-sharing liabilities. While plans and issuers are not required to provide estimates of cost-sharing liability for a bundled payment arrangement where the cost-sharing is imposed separately for each item and service included in the bundled payment arrangement, nothing prohibits plans or issuers from providing estimates for multiple items and services in situations where such estimates could be relevant to participants or beneficiaries, as long as the plan or issuer also discloses information about the relevant items or services individually, as required in paragraph (b)(1)(v) of this section.

(B) For requested items and services that are recommended preventive services under section 2713 of the Public Health Service Act (PHS Act), if the group health plan or health insurance issuer cannot determine whether the request is for preventive or non-preventive purposes, the plan or issuer must display the cost-sharing liability that applies for non-preventive purposes. As an alternative, a plan or issuer may allow a participant or beneficiary to request cost-sharing information for the specific preventive or non-preventive item or service by including terms such as “preventive,” “non-preventive,” or “diagnostic” as a means to request the most accurate cost-sharing information.

* * * * *

(vii) * * *

(A) A statement that the cost-sharing information provided pursuant to this paragraph (b)(1) does not account for potential additional amounts in situations where applicable State or Federal law allow out-of-network providers to bill participants or beneficiaries for the difference between a provider’s billed charges and the sum of the amount collected from the group health plan or health insurance issuer and from the participants or beneficiaries in the form of a copayment, coinsurance, or deductible amount (the difference referred to as balance billing). This statement is not required if the State in which the item or service was furnished prohibits all out-of-network providers from balance billing for all items and services payable by the plan or issuer;

* * * * *

(2) * * *

(i) *Paper method.* Information provided under this paragraph (b) must be made available in plain language, without a fee, in paper form at the request of the participant or beneficiary. In responding to such a request, the group health plan or health insurance issuer may limit the number of providers with respect to which cost-sharing information for covered items and services is provided to no fewer than 20 providers per request. The plan or issuer is required to:

* * * * *

(iii) *Phone method.* Information provided under this paragraph (b) must be made available at the request of the participant or beneficiary via a telephone number through which a consumer may seek customer assistance that ERISA section 716(e) requires be indicated on any physical or electronic plan or insurance identification card issued to a participant, beneficiary, or

enrollee. Such information must be accurate at the time of the request and must be provided at the time of the request. In responding to such a request, the group health plan or health insurance issuer may limit the number of providers with respect to which cost-sharing information for covered items and services is provided to no fewer than 20 providers per day. The plan or issuer is required to:

(A) Disclose the applicable provider-per-day limit; and

(B) Provide the cost-sharing information, in accordance with the requirements in paragraphs (b)(2)(i)(A) through (C) of this section.

(iv) *Alternative method.* In circumstances where participants and beneficiaries request disclosure other than by the internet-based self-service tool, paper, or phone (for example, by email) group health plans and health insurance issuers may provide the disclosure through alternative means and satisfy the requirements of this section, provided the participant or beneficiary agrees that such disclosure through such means is sufficient to satisfy the request and the plan or issuer meets the timing requirements established under paragraph (b)(2)(ii)(C) of this section for paper method disclosure.

(3) * * *

(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information required by this paragraph (b) in compliance with this section pursuant to a written agreement. Accordingly, if an issuer and a plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a pharmacy benefit manager or other third-party) provides the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a plan or issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in

compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(c) * * *

(1)(i) The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after January 1, 2023 with respect to the 500 items and services to be posted on a publicly available website, and with respect to all covered items and services, for plan years (in the individual market, for policy years) beginning on or after January 1, 2024.

(ii) Notwithstanding paragraph (c)(1)(i) of this section, paragraphs (b)(1)(vii)(A), (b)(2)(iii) and (iv), and (c)(7) of this section apply for plan years (in the individual market, for policy years) beginning on or after January 1, 2027. Until such time, the current provisions of paragraph (b) of this section continue to apply.

* * * * *

(7) A group health plan or health insurance issuer that provides to the participant or beneficiary the information required under paragraph (b)(1) of this section, in accordance with the method and format requirements set forth in paragraph (b)(2) of this section, satisfies the requirements set forth in Code section 9819, ERISA section 719, and PHS Act section 2799A-4.

* * * * *

■ 8. Section 2590.715–2715A3 is amended by—

- a. Revising paragraph (b) heading and introductory text;
- b. Revising paragraphs (b)(1)(i) and (ii);
- c. Redesignating paragraphs (b)(2) and (3) as paragraphs (b)(3) and (4), respectively;
- d. Adding new paragraph (b)(2);
- e. Revising newly redesignated paragraphs (b)(3) and (4);
- f. Redesignating paragraphs (b)(4)(i) and (ii) as paragraphs (b)(5)(i) and (ii), respectively;
- g. Revising newly redesignated paragraphs (b)(5)(i) and (ii);
- h. Redesignating paragraph (b)(4)(iii) as paragraph (b)(5)(iv);
- i. Adding new paragraph (b)(5)(iii);
- j. Revising newly redesignated paragraph (b)(5)(iv); and
- k. Revising paragraph (c)(1).

The revisions and additions read as follows:

§ 2590.715–2715A3 Transparency in coverage—requirements for public disclosure.

* * * * *

(b) *Requirements for public disclosure of in-network provider rates for covered items and services, out-of-network*

allowed amounts and billed charges for covered items and services, negotiated rates and historical net prices for covered prescription drugs, and contextual information. A group health plan or health insurance issuer must make available on an internet website the information required under paragraphs (b)(1) and (2) of this section in machine-readable files, in accordance with the method and format requirements described in paragraph (b)(3) of this section, and that are updated as required under paragraph (b)(4) of this section.

(1) * * *

(i) An in-network rate machine-readable file for each provider network maintained or contracted by a group health plan or health insurance issuer that includes the required information under this paragraph (b)(1)(i) for all covered items and services under each coverage option offered by the plan or issuer that uses such provider network, except for prescription drugs that are subject to a fee-for-service reimbursement arrangement, which must be reported in the prescription drug machine-readable file pursuant to paragraph (b)(1)(iii) of this section. Each in-network rate machine-readable file must include:

(A) The common provider network name;

(B) For each coverage option offered by a group health plan or health insurance issuer that uses such provider network, the name; the Health Insurance Oversight System (HIOS) identifier, or, if no HIOS identifier is available, the Employer Identification Number (EIN); and the product type (for example, Health Maintenance Organization, Preferred Provider Organization);

(C) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service included in the machine-readable file;

(D) For each covered item or service included in the machine-readable file, all applicable rates, which may include one or more of the following: Negotiated rates, underlying fee schedule rates, or derived amounts. If a group health plan or health insurance issuer does not use negotiated rates for provider reimbursement, then the plan or issuer should disclose derived amounts to the extent these amounts are already calculated in the normal course of business. If the plan or issuer uses underlying fee schedule rates for calculating cost sharing, then the plan or issuer should include the underlying fee schedule rates in addition to the negotiated rate or derived amount.

Applicable rates, including for both individual items and services and items and services in a bundled payment arrangement, must be:

(1) Reflected as dollar amounts, with respect to each covered item or service that is furnished by an in-network provider. If the negotiated rate is subject to change based upon participant or beneficiary-specific characteristics, these dollar amounts should be reflected as the base negotiated rate applicable to the item or service prior to adjustments for participant or beneficiary-specific characteristics. For contractual arrangements under which a group health plan or health insurance issuer agrees to pay an in-network provider a percentage of billed charges and is not able to assign a dollar amount to an item or service prior to a bill being generated, plans and issuers must report a percentage number, in lieu of a dollar amount, in a form and manner as specified in guidance issued by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services.

(2) Associated with the National Provider Identifier (NPI), Tax Identification Number (TIN), and Place of Service Code for each in-network provider, except those specified in paragraph (b)(1)(i)(F) of this section;

(3) Associated with the last date of the contract term or expiration date for each provider-specific applicable rate that applies to each covered item or service; and

(4) Indicated with a notation where a reimbursement arrangement other than a standard fee-for-service model (such as capitation or a bundled payment arrangement) applies.

(E) Current numerical enrollment totals, as of the date the file is posted, for each coverage option offered by a group health plan or health insurance issuer that uses such provider network. Such numerical enrollment totals must include the number of participants and beneficiaries (including all dependents) in the coverage option offered by a plan or issuer.

(F) A group health plan or health insurance issuer must exclude from each file under paragraph (b)(1)(i) of this section a provider and their negotiated rate (provider-rate combination) for an item or service if the plan or issuer determines it is unlikely that the provider would be reimbursed for the item or service given that provider's area of specialty according to the plan's or issuer's internal provider taxonomy used during the claims adjudication process.

(ii) For each health insurance market, as defined in § 2590.715–2715A1(a)(2)(x), in which a group health plan or health insurance issuer offers a plan or coverage, an out-of-network allowed amount machine-readable file, including:

(A) For each coverage option offered by a group health plan or health insurance issuer in such health insurance market, the name and the HIOS identifier, or, if no HIOS identifier is available, the EIN; and the product type (for example, Health Maintenance Organization, Preferred Provider Organization);

(B) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service under any coverage option offered by a group health plan or health insurance issuer in such health insurance market; and

(C) Aggregated unique out-of-network allowed amounts and billed charges with respect to each covered item or service under any coverage option offered by a group health plan or health insurance issuer in such health insurance market furnished by out-of-network providers during the 6-month time period that begins 9 months prior to the publication date of the machine-readable file (except that a plan or issuer must omit such data in relation to a particular item or service when compliance with this paragraph (b)(1)(ii)(C) would require the plan or issuer to report payment of out-of-network allowed amounts in connection with fewer than 11 different claims for payment of that item or service in a single health insurance market). Consistent with paragraph (c)(3) of this section, nothing in this paragraph (b)(1)(ii)(C) requires the disclosure of information that would violate any applicable health information privacy law. Each unique out-of-network allowed amount must be:

(1) Reflected as a dollar amount, with respect to each covered item or service that is furnished by an out-of-network provider; and

(2) Associated with the NPI, TIN, and Place of Service Code for each out-of-network provider.

* * * *

(2) *Required contextual files.* A group health plan or health insurance issuer must make available in a machine-readable format:

(i) A change-log file, for each in-network rate machine-readable file specified in paragraph (b)(1)(i) of this section, that identifies any changes made to the required information

described in paragraph (b)(1)(i) of this section since the immediately preceding published in-network rate machine-readable file.

(ii) A utilization file, for each in-network rate machine-readable file specified in paragraph (b)(1)(i) of this section, that includes, for the 12-month period that ends 6 months prior to the publication date of each utilization file:

(A) Items and services covered under the plans or policies included in the files prepared as specified in paragraph (b)(1)(i) of this section for which a claim has been submitted and reimbursed, in whole or in part; and

(B) Each in-network provider identified by the NPI, TIN, and Place of Service Code who was reimbursed, in whole or in part, for a claim for each covered item or service included as specified in paragraph (b)(2)(ii)(A) of this section.

(iii) A taxonomy file, for each in-network rate machine-readable file prepared as specified in paragraph (b)(1)(i) of this section, which includes the group health plan's or health insurance issuer's internal provider taxonomy that matches items and services (represented by a billing code) with provider specialties (represented by specialty codes which are derived from the Health Care Provider Taxonomy code set established by the National Uniform Claim Committee (NUCC)) to determine if the plan or issuer should deny reimbursement for an item or service because it was not furnished by a provider in an appropriate specialty. Plans and issuers must use their internal provider taxonomy to determine whether to exclude certain provider-rate combinations from the in-network rate machine-readable file as specified in paragraph (b)(1)(i)(F) of this section.

(iv) A plain text file in a .txt format in the root folder (that is, the top-level directory on an electronic file system) of a group health plan's or health insurance issuer's website that includes:

(A) The source page URL for the internet website that hosts the machine-readable files required under paragraphs (b)(1) and (2) of this section;

(B) A direct link to the URL for the machine-readable files required under paragraphs (b)(1) and (2) of this section; and

(C) Point-of-contact information, including an up-to-date name, title, and email address for an individual who can address inquiries and issues related to the machine-readable files required under paragraphs (b)(1) and (2) of this section. This contact information must be prominently displayed on the same website where the machine-readable

files are made available and be kept updated per the requirements in paragraph (b)(4)(vi) of this section.

(3) *Required method and format for disclosing information to the public.* (i) The machine-readable files described in paragraphs (b)(1) and (2) of this section must be available in a form and manner as specified in guidance issued by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services.

(ii) The machine-readable files must be publicly available and accessible to any person, automated scripts, or web crawlers free of charge and without conditions, such as establishment of a user account, password, submission of personally identifiable information or other credentials, or blocking server configurations or firewalls to access the file.

(iii) The source page URL for the internet website that hosts the machine-readable files required under paragraphs (b)(1) and (2) of this section must be included as a link in the footer on the home page of the group health plan's or health insurance issuer's website, as well as any page of the website that features a footer, that is labeled "Price Transparency" or "Transparency in Coverage" and links directly to the publicly available web page that hosts the link to the machine-readable files.

(iv) The group health plan or health insurance issuer may satisfy the requirements of paragraph (b)(3)(iii) of this section by entering into a written agreement under which another party (such as a third-party administrator) posts the machine-readable files on its public website on behalf of the plan or issuer, including if the plan or issuer does not have a website. However, if the files are posted on a service provider's website, and the plan or issuer maintains a public website but chooses not to host the files separately on its own public website, it must provide a link on its own public website to the location where the files are made publicly available.

(4) *Timing.* A group health plan or health insurance issuer must update the machine-readable files in accordance with the following timeframes and clearly indicate the date that the files were most recently updated:

(i) The in-network rate and out-of-network allowed amount machine-readable files required by paragraphs (b)(1)(i) and (ii) of this section must be updated and posted quarterly beginning on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1) of this section;

(ii) The prescription drug machine-readable file required by paragraph (b)(1)(iii) of this section must be updated monthly;

(iii) The change-log machine-readable file required by paragraph (b)(2)(i) of this section must be updated and posted quarterly beginning on the first day of the calendar-year quarter following the date on which the first in-network rate machine-readable file is required to be posted under paragraph (b)(4)(i) of this section in accordance with the applicability date of the amendments to paragraph (b)(1) of this section as specified in paragraph (c)(1) of this section. If there are no changes to the in-network rate machine-readable file described in paragraph (b)(1)(i) of this section since the last such file was updated, a change-log machine-readable file must still be updated and posted quarterly indicating there are no changes;

(iv) The utilization machine-readable file required under paragraph (b)(2)(ii) of this section must be updated and posted annually beginning on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1) of this section;

(v) The taxonomy machine-readable file required under paragraph (b)(2)(iii) of this section must be updated and posted quarterly beginning on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1) of this section. If there are no changes to the taxonomy that affect the information required in the machine-readable file required under paragraph (b)(1)(i) of this section in a subsequent quarter, the posted taxonomy file is not required to be updated that quarter; and

(vi) The text file required by paragraph (b)(2)(iv) of this section must be posted beginning on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1) of this section and subsequently updated and posted as soon as practicable but no later than 7 calendar days following a change in any of the information required under paragraph (b)(2)(iv) of this section.

(5) *Special rules to prevent unnecessary duplication*—(i) *Special rule for insured group health plans*. To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information pursuant to a written agreement. Accordingly, if an issuer and a plan sponsor enter into a written agreement under which the issuer

agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements*. A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a third-party administrator or health care claims clearinghouse) will provide the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a plan or issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(iii) *Special rule for self-insured group health plans with respect to the disclosure of in-network rate machine-readable files*. A self-insured group health plan that enters into an agreement with another party described in paragraph (b)(5)(ii) of this section may permit such other party to make available in a single in-network rate machine-readable file as required under paragraph (b)(1)(i) of this section the information required under paragraph (b)(1)(i) for each provider network used by more than one plan, insurance policy, or contract (including those offered by different plan sponsors with which the other party has an agreement) and across different health insurance markets, provided that—

(A) Each in-network rate machine-readable file made available for a provider network includes the required information under paragraph (b)(1)(i) of this section for all covered items and services under each plan, insurance policy, or contract that uses the same provider network for which the in-network rate machine-readable file is made available; and

(B) Each of the self-insured group health plan's change-log, utilization, and taxonomy machine-readable files include the information required under paragraphs (b)(2)(i), (ii), and (iii) of this section, respectively, for the same plans, insurance policies, or contracts (including those offered by different plan sponsors and across different health insurance markets, if applicable) represented in the corresponding in-network rate machine-readable files specified in paragraph (b)(1)(i) of this section.

(iv) *Special rule for self-insured group health plans with respect to the disclosure of out-of-network allowed amount machine-readable files*. A self-insured group health plan that enters into an agreement with another party described in paragraph (b)(5)(ii) of this section may permit such other party to make available the information required under paragraph (b)(1)(ii) of this section in a single out-of-network allowed amount file for more than one self-insured group health plan (including those offered by different plan sponsors with which the other party has an agreement), provided that the out-of-network allowed amount and billed charge data described in paragraph (b)(1)(ii)(C) of this section in relation to a particular item or service is omitted if it would require disclosure of out-of-network allowed amounts in connection with fewer than 11 different claims for payment of such item or service across all of the plans (including those offered by different plan sponsors) included in the out-of-network machine-readable file.

(c) * * *

(1)(i) Beginning on or after January 2, 2022, the requirements of this section apply for plan years (in the individual market, for policy years).

(ii) Notwithstanding paragraph (c)(1)(i) of this section, paragraph (b)(1) of this section applies on [DATE 12 MONTHS AFTER PUBLICATION OF FINAL REGULATIONS IN THE **FEDERAL REGISTER**]. Until such time, the current provisions of paragraph (b) of this section continue to apply.

* * * * *

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons stated in the preamble, the Department of Health and Human Services proposes to amend 45 CFR part 147 as set forth below:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 9. The authority citation for part 147 is revised to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92, and 300gg–114, as amended.

■ 10. Section 147.210 is amended by—

■ a. Redesignating paragraphs (a)(2)(xi) through (xxii) as paragraphs (a)(2)(xii) through (xxiii), respectively; and

■ b. Adding new paragraph (a)(2)(xi).

The addition reads as follows:

§ 147.210 Transparency in coverage—definitions.

- (a) * * *
- (2) * * *

(xi) *Health insurance market* means, irrespective of the State, one of the following:

(A) The individual market, as defined in 45 CFR 144.103 (other than short-term, limited-duration insurance or individual health insurance coverage that consists solely of excepted benefits).

(B) The large group market, as defined in 45 CFR 144.103 (other than coverage that consists solely of excepted benefits).

(C) The small group market, as defined in 45 CFR 144.103 (other than coverage that consists solely of excepted benefits).

(D) For purposes of self-insured group health plans (other than account-based plans, as defined in § 147.126(d)(6)(i), and plans that consist solely of excepted benefits), all self-insured group health plans maintained by the plan sponsor.

* * * * *

■ 11. Section 147.211 is amended by—

■ a. Revising paragraphs (b)(1)(i)(A) and (B), (b)(1)(vii)(A), and (b)(2)(ii) introductory text;

■ b. Redesignating paragraph (b)(2)(ii)(D) as paragraph (b)(2)(iv);

■ c. Adding paragraph (b)(2)(iii);

■ d. Revising newly redesignated paragraph (b)(2)(iv);

■ e. Revising paragraphs (b)(3)(i) and (ii);

■ f. Revising paragraph (c)(1); and

■ g. Adding paragraph (c)(7).

The revisions and additions read as follows:

§ 147.211 Transparency in coverage—required disclosures to participants, beneficiaries, or enrollees.

* * * * *

- (b) * * *

- (1) * * *

- (i) * * *

(A) If the request for cost-sharing information relates to items and services that are provided within a bundled payment arrangement, and the bundled payment arrangement includes items or services that have a separate cost-sharing liability, the group health plan or health insurance issuer must provide estimates of the cost-sharing liability for the requested covered item or service, as well as an estimate of the cost-sharing liability for each of the items and services in the bundled payment arrangement that have separate cost-sharing liabilities. While plans and issuers are not required to provide estimates of cost-sharing liability for a bundled payment arrangement where

the cost-sharing is imposed separately for each item and service included in the bundled payment arrangement, nothing prohibits plans or issuers from providing estimates for multiple items and services in situations where such estimates could be relevant to participants or beneficiaries, as long as the plan or issuer also discloses information about the relevant items or services individually, as required in paragraph (b)(1)(v) of this section.

(B) For requested items and services that are recommended preventive services under section 2713 of the Public Health Service Act (PHS Act), if the group health plan or health insurance issuer cannot determine whether the request is for preventive or non-preventive purposes, the plan or issuer must display the cost-sharing liability that applies for non-preventive purposes. As an alternative, a plan or issuer may allow a participant, beneficiary, or enrollee to request cost-sharing information for the specific preventive or non-preventive item or service by including terms such as “preventive,” “non-preventive,” or “diagnostic” as a means to request the most accurate cost-sharing information.

* * * * *

- (vii) * * *

(A) A statement that the cost-sharing information provided pursuant to this paragraph (b)(1) does not account for potential additional amounts in situations where applicable State or Federal law allow out-of-network providers to bill participants, beneficiaries, or enrollees for the difference between a provider's billed charges and the sum of the amount collected from the group health plan or health insurance issuer and from the participants, beneficiaries, or enrollees in the form of a copayment, coinsurance, or deductible amount (the difference referred to as balance billing). This statement is not required if the State in which the item or service was furnished prohibits all out-of-network providers from balance billing for all items and services payable by the plan or issuer;

* * * * *

- (2) * * *

(ii) *Paper method.* Information provided under this paragraph (b) must be made available in plain language, without a fee, in paper form at the request of the participant, beneficiary, or enrollee. In responding to such a request, the group health plan or health insurance issuer may limit the number of providers with respect to which cost-sharing information for covered items and services is provided to no fewer

than 20 providers per request. The plan or issuer is required to:

* * * * *

(iii) *Phone method.* Information provided under this paragraph (b) must be made available at the request of the participant, beneficiary, or enrollee via a telephone number through which a consumer may seek customer assistance that PHS Act section 2799A–1(e) required be indicated on any physical or electronic plan or insurance identification card issued to a participant, beneficiary, or enrollee. Such information must be accurate at the time of the request and must be provided at the time of the request. In responding to such a request, the group health plan or health insurance issuer may limit the number of providers with respect to which cost-sharing information for covered items and services is provided to no fewer than 20 providers per day. The plan or issuer is required to:

(A) Disclose the applicable provider-per-day limit; and

(B) Provide the cost-sharing information, in accordance with the requirements in paragraphs (b)(2)(i)(A) through (C) of this section.

(iv) *Alternative method.* In circumstances where participants, beneficiaries, and enrollees request disclosure other than by the internet-based self-service tool, paper, or phone (for example, by email) group health plans and health insurance issuers may provide the disclosure through alternative means and satisfy the requirements of this section, provided the participant, beneficiary, or enrollee agrees that such disclosure through such means is sufficient to satisfy the request and the plan or issuer meets the timing requirements established under paragraph (b)(2)(ii)(C) of this section for paper method disclosure.

(3) * * *

(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information required by this paragraph (b) in compliance with this section pursuant to a written agreement. Accordingly, if an issuer and a plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a pharmacy benefit manager or other third-party) provides the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a plan or issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(c) * * *

(1)(i) The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after January 1, 2023 with respect to the 500 items and services to be posted on a publicly available website, and with respect to all covered items and services, for plan years (in the individual market, for policy years) beginning on or after January 1, 2024.

(ii) Notwithstanding paragraph (c)(1)(i) of this section, paragraphs (b)(1)(vii)(A), (b)(2)(iii) and (iv), and (c)(7) of this section apply for plan years (in the individual market, for policy years) beginning on or after January 1, 2027. Until such time, the current provisions of paragraph (b) of this section continue to apply.

* * * * *

(7) A group health plan or health insurance issuer that provides to the participant, beneficiary or enrollee the information required under paragraph (b)(1) of this section, in accordance with the method and format requirements set forth in paragraph (b)(2) of this section, satisfies the requirements set forth in Code section 9819, ERISA section 719, and PHS Act section 2799A-4.

* * * * *

■ 12. Section 147.212 is amended by—
 ■ a. Revising paragraph (b) heading and introductory text;
 ■ b. Revising paragraphs (b)(1)(i) and (ii);
 ■ c. Redesignating paragraphs (b)(2) and (3) as paragraphs (b)(3) and (4), respectively;
 ■ d. Adding new paragraph (b)(2);
 ■ e. Revising newly redesignated paragraphs (b)(3) and (4);
 ■ f. Redesignating paragraphs (b)(4)(i) and (ii) as paragraphs (b)(5)(i) and (ii), respectively;
 ■ g. Revising newly redesignated paragraphs (b)(5)(i) and (ii);
 ■ h. Redesignating paragraph (b)(4)(iii) as paragraph (b)(5)(iv);

■ i. Adding new paragraph (b)(5)(iii);
 ■ j. Revising newly redesignated paragraph (b)(5)(iv); and
 ■ k. Revising paragraph (c)(1).

The revisions and additions read as follows:

147.212 Transparency in coverage—requirements for public disclosure.

* * * * *

(b) *Requirements for public disclosure of in-network provider rates for covered items and services, out-of-network allowed amounts and billed charges for covered items and services, negotiated rates and historical net prices for covered prescription drugs, and contextual information.* A group health plan or health insurance issuer must make available on an internet website the information required under paragraphs (b)(1) and (2) of this section in machine-readable files, in accordance with the method and format requirements described in paragraph (b)(3) of this section, and that are updated as required under paragraph (b)(4) of this section.

(1) * * *

(i) An in-network rate machine-readable file for each provider network maintained or contracted by a group health plan or health insurance issuer that includes the required information under this paragraph (b)(1)(i) for all covered items and services under each coverage option offered by the plan or issuer that uses such provider network, except for prescription drugs that are subject to a fee-for-service reimbursement arrangement, which must be reported in the prescription drug machine-readable file pursuant to paragraph (b)(1)(iii) of this section. Each in-network rate machine-readable file must include:

(A) The common provider network name;

(B) For each coverage option offered by a group health plan or health insurance issuer that uses such provider network, the name; the Health Insurance Oversight System (HIOS) identifier, or, if no HIOS identifier is available, the Employer Identification Number (EIN); and the product type (for example, Health Maintenance Organization, Preferred Provider Organization);

(C) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service included in the machine-readable file;

(D) For each covered item or service included in the machine-readable file, all applicable rates, which may include one or more of the following: Negotiated rates, underlying fee schedule rates, or

derived amounts. If a group health plan or health insurance issuer does not use negotiated rates for provider reimbursement, then the plan or issuer should disclose derived amounts to the extent these amounts are already calculated in the normal course of business. If the plan or issuer uses underlying fee schedule rates for calculating cost sharing, then the plan or issuer should include the underlying fee schedule rates in addition to the negotiated rate or derived amount. Applicable rates, including for both individual items and services and items and services in a bundled payment arrangement, must be:

(1) Reflected as dollar amounts, with respect to each covered item or service that is furnished by an in-network provider. If the negotiated rate is subject to change based upon participant, beneficiary, or enrollee-specific characteristics, these dollar amounts should be reflected as the base negotiated rate applicable to the item or service prior to adjustments for participant, beneficiary, or enrollee-specific characteristics. For contractual arrangements under which a group health plan or health insurance issuer agrees to pay an in-network provider a percentage of billed charges and is not able to assign a dollar amount to an item or service prior to a bill being generated, plans and issuers must report a percentage number, in lieu of a dollar amount, in a form and manner as specified in guidance issued by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services.

(2) Associated with the National Provider Identifier (NPI), Tax Identification Number (TIN), and Place of Service Code for each in-network provider, except those specified in paragraph (b)(1)(i)(F) of this section;

(3) Associated with the last date of the contract term or expiration date for each provider-specific applicable rate that applies to each covered item or service; and

(4) Indicated with a notation where a reimbursement arrangement other than a standard fee-for-service model (such as capitation or a bundled payment arrangement) applies.

(E) Current numerical enrollment totals, as of the date the file is posted, for each coverage option offered by a group health plan or health insurance issuer that uses such provider network. Such numerical enrollment totals must include the number of participants, beneficiaries, and enrollees (including all dependents) in the coverage option offered by a plan or issuer.

(F) A group health plan or health insurance issuer must exclude from each file under paragraph (b)(1)(i) of this section a provider and their negotiated rate (provider-rate combination) for an item or service if the plan or issuer determines it is unlikely that the provider would be reimbursed for the item or service given that provider's area of specialty according to the plan's or issuer's internal provider taxonomy used during the claims adjudication process.

(ii) For each health insurance market, as defined in § 147.210(a)(2)(xi), in which a group health plan or health insurance issuer offers a plan or coverage, an out-of-network allowed amount machine-readable file, including:

(A) For each coverage option offered by a group health plan or health insurance issuer in such health insurance market, the name and the HIOS identifier, or, if no HIOS identifier is available, the EIN; and the product type (for example, Health Maintenance Organization, Preferred Provider Organization);

(B) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service under any coverage option offered by a group health plan or health insurance issuer in such health insurance market; and

(C) Aggregated unique out-of-network allowed amounts and billed charges with respect to each covered item or service under any coverage option offered by a group health plan or health insurance issuer in such health insurance market furnished by out-of-network providers during the 6-month time period that begins 9 months prior to the publication date of the machine-readable file (except that a plan or issuer must omit such data in relation to a particular item or service when compliance with this paragraph (b)(1)(ii)(C) would require the plan or issuer to report payment of out-of-network allowed amounts in connection with fewer than 11 different claims for payment of that item or service in a single health insurance market). Consistent with paragraph (c)(3) of this section, nothing in this paragraph (b)(1)(ii)(C) requires the disclosure of information that would violate any applicable health information privacy law. Each unique out-of-network allowed amount must be:

(1) Reflected as a dollar amount, with respect to each covered item or service that is furnished by an out-of-network provider; and

(2) Associated with the NPI, TIN, and Place of Service Code for each out-of-network provider.

* * * * *

(2) *Required contextual files.* A group health plan or health insurance issuer must make available in a machine-readable format:

(i) A change-log file, for each in-network rate machine-readable file specified in paragraph (b)(1)(i) of this section, that identifies any changes made to the required information described in paragraph (b)(1)(i) of this section since the immediately preceding published in-network rate machine-readable file.

(ii) A utilization file, for each in-network rate machine-readable file specified in paragraph (b)(1)(i) of this section, that includes, for the 12-month period that ends 6 months prior to the publication date of each utilization file:

(A) Items and services covered under the plans or policies included in the files prepared as specified in paragraph (b)(1)(i) of this section for which a claim has been submitted and reimbursed, in whole or in part; and

(B) Each in-network provider identified by the NPI, TIN, and Place of Service Code who was reimbursed, in whole or in part, for a claim for each covered item or service included as specified in paragraph (b)(2)(ii)(A) of this section.

(iii) A taxonomy file, for each in-network rate machine-readable file prepared as specified in paragraph (b)(1)(i) of this section, which includes the group health plan's or health insurance issuer's internal provider taxonomy that matches items and services (represented by a billing code) with provider specialties (represented by specialty codes which are derived from the Health Care Provider Taxonomy code set established by the National Uniform Claim Committee (NUCC)) to determine if the plan or issuer should deny reimbursement for an item or service because it was not furnished by a provider in an appropriate specialty. Plans and issuers must use their internal provider taxonomy to determine whether to exclude certain provider-rate combinations from the in-network rate machine-readable file as specified in paragraph (b)(1)(i)(F) of this section. (iv) A plain text file in a .txt format in the root folder (that is, the top-level directory on an electronic file system) of a group health plan's or health insurance issuer's website that includes:

(A) The source page URL for the internet website that hosts the machine-readable files required under paragraphs (b)(1) and (2) of this section;

(B) A direct link to the URL for the machine-readable files required under paragraphs (b)(1) and (2) of this section; and

(C) Point-of-contact information, including an up-to-date name, title, and email address for an individual who can address inquiries and issues related to the machine-readable files required under paragraphs (b)(1) and (2) of this section. This contact information must be prominently displayed on the same website where the machine-readable files are made available and be kept updated per the requirements in paragraph (b)(4)(vi) of this section.

(3) *Required method and format for disclosing information to the public.* (i) The machine-readable files described in paragraphs (b)(1) and (2) of this section must be available in a form and manner as specified in guidance issued by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services.

(ii) The machine-readable files must be publicly available and accessible to any person, automated scripts, or web crawlers free of charge and without conditions, such as establishment of a user account, password, submission of personally identifiable information or other credentials, or blocking server configurations or firewalls to access the file.

(iii) The source page URL for the internet website that hosts the machine-readable files required under paragraphs (b)(1) and (2) of this section must be included as a link in the footer on the home page of the group health plan's or health insurance issuer's website, as well as any page of the website that features a footer, that is labeled "Price Transparency" or "Transparency in Coverage" and links directly to the publicly available web page that hosts the link to the machine-readable files.

(iv) The group health plan or health insurance issuer may satisfy the requirements of paragraph (b)(3)(iii) of this section by entering into a written agreement under which another party (such as a third-party administrator) posts the machine-readable files on its public website on behalf of the plan or issuer, including if the plan or issuer does not have a website. However, if the files are posted on a service provider's website, and the plan or issuer maintains a public website but chooses not to host the files separately on its own public website, it must provide a link on its own public website to the location where the files are made publicly available.

(4) *Timing.* A group health plan or health insurance issuer must update the

machine-readable files in accordance with the following timeframes and clearly indicate the date that the files were most recently updated:

(i) The in-network rate and out-of-network allowed amount machine-readable files required by paragraphs (b)(1)(i) and (ii) of this section must be updated and posted quarterly beginning on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1) of this section;

(ii) The prescription drug machine-readable file required by paragraph (b)(1)(iii) of this section must be updated monthly;

(iii) The change-log machine-readable file required by paragraph (b)(2)(i) of this section must be updated and posted quarterly beginning on the first day of the calendar-year quarter following the date on which the first in-network rate machine-readable file is required to be posted under paragraph (b)(4)(i) of this section in accordance with the applicability date of the amendments to paragraph (b)(1) of this section as specified in paragraph (c)(1) of this section. If there are no changes to the in-network rate machine-readable file described in paragraph (b)(1)(i) of this section since the last such file was updated, a change-log machine-readable file must still be updated and posted quarterly indicating there are no changes;

(iv) The utilization machine-readable file required under paragraph (b)(2)(ii) of this section must be updated and posted annually beginning on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1) of this section;

(v) The taxonomy machine-readable file required under paragraph (b)(2)(iii) of this section must be updated and posted quarterly beginning on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1) of this section. If there are no changes to the taxonomy that affect the information required in the machine-readable file required under paragraph (b)(1)(i) of this section in a subsequent quarter, the posted taxonomy file is not required to be updated that quarter; and

(vi) The text file required by paragraph (b)(2)(iv) of this section must be posted beginning on the first day of the calendar-year quarter following the applicability date under paragraph (c)(1) of this section and subsequently updated and posted as soon as practicable but no later than 7 calendar

days following a change in any of the information required under paragraph (b)(2)(iv) of this section.

(5) *Special rules to prevent unnecessary duplication*—(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information pursuant to a written agreement. Accordingly, if an issuer and a plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a third-party administrator or health care claims clearinghouse) will provide the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a plan or issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(iii) *Special rule for self-insured group health plans with respect to the disclosure of in-network rate machine-readable files.* A self-insured group health plan that enters into an agreement with another party described in paragraph (b)(5)(ii) of this section may permit such other party to make available in a single in-network rate machine-readable file as required under paragraph (b)(1)(i) of this section the information required under paragraph (b)(1)(i) for each provider network used by more than one plan, insurance policy, or contract (including those offered by different plan sponsors with which the other party has an agreement) and across different health insurance markets, provided that—

(A) Each in-network rate machine-readable file made available for a provider network includes the required information under paragraph (b)(1)(i) of

this section for all covered items and services under each plan, insurance policy, or contract that uses the same provider network for which the in-network rate machine-readable file is made available; and

(B) Each of the self-insured group health plan's change-log, utilization, and taxonomy machine-readable files include the information required under paragraphs (b)(2)(i), (ii), and (iii) of this section, respectively, for the same plans, insurance policies, or contracts (including those offered by different plan sponsors and across different health insurance markets, if applicable) represented in the corresponding in-network rate machine-readable files specified in paragraph (b)(1)(i) of this section.

(iv) *Special rule for self-insured group health plans with respect to the disclosure of out-of-network allowed amount machine-readable files.* A self-insured group health plan that enters into an agreement with another party described in paragraph (b)(5)(ii) of this section may permit such other party to make available the information required under paragraph (b)(1)(ii) of this section in a single out-of-network allowed amount file for more than one self-insured group health plan (including those offered by different plan sponsors with which the other party has an agreement), provided that the out-of-network allowed amount and billed charge data described in paragraph (b)(1)(ii)(C) of this section in relation to a particular item or service is omitted if it would require disclosure of out-of-network allowed amounts in connection with fewer than 11 different claims for payment of such item or service across all of the plans (including those offered by different plan sponsors) included in the out-of-network machine-readable file.

(c) * * *

(1)(i) Beginning on or after January 2, 2022, the requirements of this section apply for plan years (in the individual market, for policy years).

(ii) Notwithstanding paragraph (c)(1)(i) of this section, paragraph (b)(1) of this section applies on [DATE 12 MONTHS AFTER PUBLICATION OF FINAL REGULATIONS IN THE **FEDERAL REGISTER**]. Until such time, the current provisions of paragraph (b) of this section continue to apply.

* * * * *

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Part V

The President

Executive Order 14368—Adjustments of Certain Rates of Pay

Executive Order 14369—Ensuring American Space Superiority

Executive Order 14370—Increasing Medical Marijuana and Cannabidiol Research

Executive Order 14371—Providing for the Closing of Executive Departments and Agencies of the Federal Government on December 24, 2025, and December 26, 2025

Presidential Documents

Title 3—**Executive Order 14368 of December 18, 2025****The President****Adjustments of Certain Rates of Pay**

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. *Statutory Pay Systems.* The rates of basic pay or salaries of the statutory pay systems (as defined in 5 U.S.C. 5302(1)), as adjusted under 5 U.S.C. 5303, are set forth on the schedules attached hereto and made a part hereof:

(a) The General Schedule (5 U.S.C. 5332(a)) at Schedule 1;

(b) The Foreign Service Schedule (22 U.S.C. 3963) at Schedule 2; and

(c) The schedules for the Veterans Health Administration of the Department of Veterans Affairs (38 U.S.C. 7306, 7401, 7404; section 301(a) of Public Law 102–40) at Schedule 3.

Sec. 2. *Senior Executive Service.* The ranges of rates of basic pay for senior executives in the Senior Executive Service, as established pursuant to 5 U.S.C. 5382, are set forth on Schedule 4 attached hereto and made a part hereof.

Sec. 3. *Certain Executive, Legislative, and Judicial Salaries.* The rates of basic pay or salaries for the following offices and positions are set forth on the schedules attached hereto and made a part hereof:

(a) The Executive Schedule (5 U.S.C. 5311–5318) at Schedule 5;

(b) The Vice President (3 U.S.C. 104) and the Congress (2 U.S.C. 4501) at Schedule 6; and

(c) Justices and judges (28 U.S.C. 5, 44(d), 135, 252, and 461(a)) at Schedule 7.

Sec. 4. *Uniformed Services and Other.* The rates of monthly basic pay (37 U.S.C. 203(a)) for members of the uniformed services, as adjusted under 37 U.S.C. 1009, and the rate of monthly cadet or midshipman pay (37 U.S.C. 203(c)) are set forth on Schedule 8 attached hereto and made a part hereof. Additionally, the Director of the Office of Personnel Management (Director) is directed to assess whether to provide up to a total increase of 3.8 percent (inclusive of the increase provided under Section 1) to the rates of pay of certain Federal civilian law enforcement personnel, as determined by the Director following coordination with agencies and consistent with 5 U.S.C. 5305.

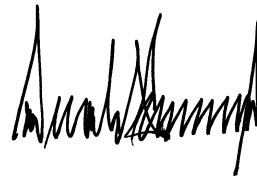
Sec. 5. *Locality-Based Comparability Payments.* (a) Pursuant to section 5304 of title 5, United States Code, and my authority to implement an alternative level of comparability payments under section 5304a of title 5, United States Code, locality-based comparability payments shall be paid in accordance with Schedule 9 attached hereto and made a part hereof.

(b) The Director shall take such actions as may be necessary to implement these payments and to publish appropriate notice of such payments in the *Federal Register*.

Sec. 6. *Administrative Law Judges.* Pursuant to section 5372 of title 5, United States Code, the rates of basic pay for administrative law judges are set forth on Schedule 10 attached hereto and made a part hereof.

Sec. 7. *Effective Dates.* Schedule 8 is effective January 1, 2026. The other schedules contained herein are effective on the first day of the first applicable pay period beginning on or after January 1, 2026.

Sec. 8. *Prior Order Superseded.* Executive Order 14132 of December 23, 2024 (Adjustments of Certain Rates of Pay), is superseded as of the effective dates specified in section 7 of this order.



THE WHITE HOUSE,
December 18, 2025.

Schedule 1-General Schedule

(Effective on the first day of the first applicable pay period beginning on or after January 1, 2026)

Grade	1	2	3	4	5	6	7	8	9	10
GS-1	\$22,584	\$23,341	\$24,092	\$24,840	\$25,589	\$26,028	\$26,771	\$27,519	\$27,550	\$28,248
GS-2	25,393	25,997	26,839	27,550	27,858	28,677	29,496	30,315	31,134	31,953
GS-3	27,708	28,632	29,556	30,480	31,404	32,328	33,252	34,176	35,100	36,024
GS-4	31,103	32,140	33,177	34,214	35,251	36,288	37,325	38,362	39,399	40,436
GS-5	34,799	35,959	37,119	38,279	39,439	40,599	41,759	42,919	44,079	45,239
GS-6	38,791	40,084	41,377	42,670	43,963	45,256	46,549	47,842	49,135	50,428
GS-7	43,106	44,543	45,980	47,417	48,854	50,291	51,728	53,165	54,602	56,039
GS-8	47,738	49,329	50,920	52,511	54,102	55,693	57,284	58,875	60,466	62,057
GS-9	52,727	54,485	56,243	58,001	59,759	61,517	63,275	65,033	66,791	68,549
GS-10	58,064	59,999	61,934	63,869	65,804	67,739	69,674	71,609	73,544	75,479
GS-11	63,795	65,922	68,049	70,176	72,303	74,430	76,557	78,684	80,811	82,938
GS-12	76,463	79,012	81,561	84,110	86,659	89,208	91,757	94,306	96,855	99,404
GS-13	90,925	93,956	96,987	100,018	103,049	106,080	109,111	112,142	115,173	118,204
GS-14	107,446	111,028	114,610	118,192	121,774	125,356	128,938	132,520	136,102	139,684
GS-15	126,384	130,597	134,810	139,023	143,236	147,449	151,662	155,875	160,088	164,301

Schedule 2-Foreign Service Schedule

(Effective on the first day of the first applicable pay period beginning on or after January 1, 2026)

Step	Class 1	Class 2	Class 3	Class 4	Class 5	Class 6	Class 7	Class 8	Class 9
1	\$126,384	\$102,409	\$82,982	\$67,240	\$54,485	\$48,708	\$43,543	\$38,926	\$34,799
2	130,176	105,481	85,471	69,257	56,120	50,169	44,849	40,094	35,843
3	134,081	108,646	88,036	71,335	57,803	51,674	46,195	41,297	36,918
4	138,103	111,905	90,677	73,475	59,537	53,225	47,581	42,535	38,026
5	142,246	115,262	93,397	75,679	61,323	54,821	49,008	43,812	39,167
6	146,514	118,720	96,199	77,950	63,163	56,466	50,478	45,126	40,342
7	150,909	122,282	99,085	80,288	65,058	58,160	51,993	46,480	41,552
8	155,436	125,950	102,057	82,697	67,010	59,905	53,552	47,874	42,798
9	160,099	129,729	105,119	85,178	69,020	61,702	55,159	49,310	44,082
10	164,301	133,621	108,273	87,733	71,091	63,553	56,814	50,790	45,405
11	164,301	137,629	111,521	90,365	73,223	65,459	58,518	52,313	46,767
12	164,301	141,758	114,866	93,076	75,420	67,423	60,274	53,883	48,170
13	164,301	146,011	118,312	95,868	77,683	69,446	62,082	55,499	49,615
14	164,301	150,391	121,862	98,744	80,013	71,529	63,944	57,164	51,104

**Schedule 3-Veterans Health Administration Schedules
Department of Veterans Affairs**

(Effective on the first day of the first applicable pay period
beginning on or after January 1, 2026)

**Schedule for the Office of the Under Secretary for Health
(38 U.S.C. 7306) and Directors of Medical Centers and Directors of
Veterans Integrated Service Networks (38 U.S.C. 7401(4)) ***

Minimum	Maximum
\$151,661	\$228,000**

Physician, Podiatrist, Optometrist, and Dentist Base and Longevity Pay Schedule***	Minimum	Maximum
Physician Grade	\$124,308	\$182,324
Podiatrist Grade	124,308	182,324
Optometrist Grade	124,308	182,324
Dentist Grade	124,308	182,324

Clinical Chiropractor Schedule****	Minimum	Maximum
Chief Grade	\$126,384	\$164,301
Senior Grade	107,446	139,684
Intermediate Grade	90,925	118,204
Full Grade	76,463	99,404
Associate Grade	63,795	82,938

Expanded-Function Dental Auxiliary Schedule*****	Minimum	Maximum
Director Grade	\$126,384	\$164,301
Assistant Director Grade	107,446	139,684
Chief Grade	90,925	118,204
Senior Grade	76,463	99,404
Intermediate Grade	63,795	82,938
Full Grade	52,727	68,549
Associate Grade	45,373	58,981
Junior Grade	38,791	50,428

* Pursuant to 38 U.S.C. 7404(a)(2)(A) and (e), this schedule does not apply to the Director of Nursing Service or any incumbents who are physicians, podiatrists, optometrists or dentists. Pursuant to 38 U.S.C. 7404(a)(2)(B), this schedule also does not apply to the basic pay of any incumbents who are registered nurses or physician assistants if that basic pay is determined by the Secretary under subchapter IV of chapter 74 of title 38, United States Code.

** Pursuant to 38 U.S.C. 7404(a)(3)(B), for positions that are covered by a certified performance appraisal system, the maximum rate of basic pay may not exceed the rate of basic pay payable for level II of the Executive Schedule. For positions that are not covered by a certified performance appraisal system, the maximum rate of basic pay may not exceed the rate of basic pay payable for level III of the Executive Schedule.

*** Pursuant to 38 U.S.C. 7431, Veterans Health Administration physicians, podiatrists, optometrists and dentists paid under the Physician, Podiatrist, Optometrist, and Dentist Base and Longevity Pay schedule may also be paid market pay and performance pay.

**** Pursuant to section 142 of Public Law 118-210, Veterans Health Administration optometrists are to be removed from the 38 U.S.C. 7404 Salary Table for Clinical Chiropractors and converted to the Physician, Podiatrist, Optometrist, and Dentist pay system under 38 U.S.C. 7431.

***** Pursuant to section 301(a) of Public Law 102-40, these positions are paid according to the Nurse Schedule in 38 U.S.C. 4107(b), as in effect on August 14, 1990, with subsequent adjustments.

Schedule 4-Senior Executive Service

(Effective on the first day of the first applicable pay period
beginning on or after January 1, 2026)

	Minimum	Maximum
Agencies with a Certified SES Performance Appraisal System	\$151,661	\$228,000
Agencies without a Certified SES Performance Appraisal System	\$151,661	\$209,600

Schedule 5-Executive Schedule

(Effective on the first day of the first applicable pay period
beginning on or after January 1, 2026)

Level I	\$253,100
Level II	228,000
Level III	209,600
Level IV	197,200
Level V	184,900

Schedule 6-Vice President and Members Of Congress

(Effective on the first day of the first applicable pay period
beginning on or after January 1, 2026)

Vice President	\$292,300
Senators	174,000
Members of the House of Representatives	174,000
Delegates to the House of Representatives	174,000
Resident Commissioner from Puerto Rico	174,000
President pro tempore of the Senate	193,400
Majority leader and minority leader of the Senate	193,400
Majority leader and minority leader of the House of Representatives	193,400
Speaker of the House of Representatives	223,500

Schedule 7-Judicial Salaries

(Effective on the first day of the first applicable pay period
beginning on or after January 1, 2026)

Chief Justice of the United States	\$320,700
Associate Justices of the Supreme Court	306,600
Circuit Judges	264,900
District Judges	249,900
Judges of the Court of International Trade	249,900

Schedule 8-Pay of the Uniformed Services

(Effective January 1, 2026)

Part I-Monthly Basic Pay

Years of Service (Computed Under 37 U.S.C. 205)

Commissioned Officers

Pay Grade	2 or less	Over 2	Over 3	Over 4	Over 6	Over 8	Over 10	Over 12	Over 14	Over 16	Over 18
O-10*	-	-	-	-	-	-	-	-	-	-	-
O-9*	-	-	-	-	-	-	-	-	-	-	-
O-8*	\$13,888.50	\$14,343.90	\$14,645.40	\$14,729.40	\$15,106.50	\$15,735.30	\$15,882.00	\$16,479.60	\$16,651.80	\$17,166.60	\$17,911.80
O-7	11,540.10	12,076.20	12,324.30	12,522.00	12,878.70	13,231.80	13,639.20	14,045.70	14,454.30	15,735.30	16,817.70
O-6**	8,751.30	9,613.80	10,245.00	10,245.00	10,284.30	10,725.00	10,783.50	10,783.50	11,396.40	12,479.70	13,115.40
O-5	7,295.40	8,218.20	8,787.00	8,894.10	9,249.60	9,461.40	9,928.50	10,271.70	10,715.10	11,391.30	11,713.80
O-4	6,294.60	7,286.40	7,773.60	7,881.00	8,332.20	8,816.40	9,420.00	9,888.30	10,214.40	10,401.60	10,509.90
O-3***	5,534.10	6,273.90	6,770.40	7,382.70	7,737.00	8,125.50	8,375.70	8,788.20	9,004.20	9,004.20	9,004.20
O-2***	4,782.00	5,446.20	6,272.40	6,484.50	6,617.70	6,617.70	6,617.70	6,617.70	6,617.70	6,617.70	6,617.70
O-1***	4,150.20	4,320.00	5,222.40	5,222.40	5,222.40	5,222.40	5,222.40	5,222.40	5,222.40	5,222.40	5,222.40

* Basic pay is limited to the rate of basic pay for level II of the Executive Schedule in effect during calendar year 2026, which is \$18,899.90 per month, for officers at pay grades O-7 through O-10. This includes officers serving as Chairman or Vice Chairman of the Joint Chiefs of Staff, Chief of Staff of the Army, Chief of Naval Operations, Chief of Staff of the Air Force, Commandant of the Marine Corps, Chief of Space Operations, Commandant of the Coast Guard, Chief of the National Guard Bureau, or commander of a unified or specified combatant command (as defined in 10 U.S.C. 161(c)).

** Basic pay is limited to the rate of basic pay for level V of the Executive Schedule in effect during calendar year 2026, which is \$15,408.30 per month, for officers at pay grades O-6 and below.

*** Does not apply to commissioned officers who have been credited with over 4 years of active duty service as an enlisted member or warrant officer.

Commissioned Officers with Over 4 Years Active Duty Service as an Enlisted Member or Warrant Officer****

Pay Grade	2 or less	Over 2	Over 3	Over 4	Over 6	Over 8	Over 10	Over 12	Over 14	Over 16	Over 18
O-3E	-	-	-	\$7,382.70	\$7,737.00	\$8,125.50	\$8,375.70	\$8,788.20	\$9,137.10	\$9,336.90	\$9,609.60
O-2E	-	-	-	6,484.50	6,617.70	6,828.00	7,183.80	7,458.90	7,663.50	7,663.50	7,663.50
O-1E	-	-	-	5,222.40	5,576.70	5,783.10	5,993.70	6,200.70	6,484.50	6,484.50	6,484.50

Warrant Officers

Pay Grade	2 or less	Over 2	Over 3	Over 4	Over 6	Over 8	Over 10	Over 12	Over 14	Over 16	Over 18
W-5	-	-	-	-	-	-	-	-	-	-	-
W-4	\$5,719.80	\$6,152.10	\$6,328.50	\$6,502.20	\$6,801.90	\$7,098.00	\$7,398.00	\$7,848.30	\$8,243.70	\$8,619.90	\$8,928.60
W-3	5,223.30	5,440.50	5,664.30	5,736.90	5,970.90	6,431.10	6,910.50	7,136.40	7,397.70	7,665.90	8,150.40
W-2	4,621.80	5,058.90	5,193.30	5,286.00	5,585.40	6,051.00	6,282.60	6,509.40	6,787.50	7,005.00	7,201.50
W-1	4,056.60	4,493.70	4,611.00	4,859.10	5,152.20	5,584.20	5,786.10	6,069.30	6,346.50	6,564.90	6,766.20

**** Reservists also qualify for these rates, provided that they have at least 1,460 points as an enlisted member, a warrant officer, or a warrant officer and an enlisted member, and that those points are creditable toward reserve retirement.

Schedule 8-Pay of the Uniformed Services

(Effective January 1, 2026)

Part I-Monthly Basic Pay

Years of Service (Computed Under 37 U.S.C. 205)

Commissioned Officers

Pay Grade	Over 20	Over 22	Over 24	Over 26	Over 28	Over 30	Over 32	Over 34	Over 36	Over 38	Over 40
O-10*	\$18,999.90	\$18,999.90	\$18,999.90	\$18,999.90	\$18,999.90	\$18,999.90	\$18,999.90	\$18,999.90	\$18,999.90	\$18,999.90	\$18,999.90
O-9*	18,999.90	18,999.90	18,999.90	18,999.90	18,999.90	18,999.90	18,999.90	18,999.90	18,999.90	18,999.90	18,999.90
O-8*	18,598.20	18,999.90	18,999.90	18,999.90	18,999.90	18,999.90	18,999.90	18,999.90	18,999.90	18,999.90	18,999.90
O-7	16,817.70	16,817.70	16,817.70	16,904.40	16,904.40	17,242.20	17,242.20	17,242.20	17,242.20	17,242.20	17,242.20
O-6**	13,751.10	14,112.90	14,479.20	15,188.70	15,188.70	15,408.30	15,408.30	15,408.30	15,408.30	15,408.30	15,408.30
O-5	12,032.70	12,394.80	12,394.80	12,394.80	12,394.80	12,394.80	12,394.80	12,394.80	12,394.80	12,394.80	12,394.80
O-4	10,509.90	10,509.90	10,509.90	10,509.90	10,509.90	10,509.90	10,509.90	10,509.90	10,509.90	10,509.90	10,509.90
O-3***	9,004.20	9,004.20	9,004.20	9,004.20	9,004.20	9,004.20	9,004.20	9,004.20	9,004.20	9,004.20	9,004.20
O-2***	6,617.70	6,617.70	6,617.70	6,617.70	6,617.70	6,617.70	6,617.70	6,617.70	6,617.70	6,617.70	6,617.70
O-1***	5,222.40	5,222.40	5,222.40	5,222.40	5,222.40	5,222.40	5,222.40	5,222.40	5,222.40	5,222.40	5,222.40

* Basic pay is limited to the rate of basic pay for level II of the Executive Schedule in effect during calendar year 2026, which is \$18,899.90 per month, for officers at pay grades O-7 through O-10. This includes officers serving as Chairman or Vice Chairman of the Joint Chiefs of Staff, Chief of Staff of the Army, Chief of Naval Operations, Chief of Staff of the Air Force, Commandant of the Marine Corps, Chief of Space Operations, Commandant of the Coast Guard, Chief of the National Guard Bureau, or commander of a unified or specified combatant command (as defined in 10 U.S.C. 161(c)).

** Basic pay is limited to the rate of basic pay for level V of the Executive Schedule in effect during calendar year 2026, which is \$15,408.30 per month, for officers at pay grades O-6 and below.

*** Does not apply to commissioned officers who have been credited with over 4 years of active duty service as an enlisted member or warrant officer.

Commissioned Officers with Over 4 Years Active Duty Service As An Enlisted Member Or Warrant Officer****

Pay Grade	Over 20	Over 22	Over 24	Over 26	Over 28	Over 30	Over 32	Over 34	Over 36	Over 38	Over 40
O-3E	\$9,609.60	\$9,609.60	\$9,609.60	\$9,609.60	\$9,609.60	\$9,609.60	\$9,609.60	\$9,609.60	\$9,609.60	\$9,609.60	\$9,609.60
O-2E	7,663.50	7,663.50	7,663.50	7,663.50	7,663.50	7,663.50	7,663.50	7,663.50	7,663.50	7,663.50	7,663.50
O-1E	6,484.50	6,484.50	6,484.50	6,484.50	6,484.50	6,484.50	6,484.50	6,484.50	6,484.50	6,484.50	6,484.50

Warrant Officers

Pay Grade	Over 20	Over 22	Over 24	Over 26	Over 28	Over 30	Over 32	Over 34	Over 36	Over 38	Over 40
W-5	10,169.70	10,685.70	11,070.30	11,495.10	11,495.10	12,070.80	12,070.80	12,673.50	12,673.50	13,308.30	13,308.30
W-4	9,228.90	9,669.60	10,032.00	10,445.40	10,445.40	10,653.60	10,653.60	10,653.60	10,653.60	10,653.60	10,653.60
W-3	8,476.50	8,671.80	8,879.70	9,162.60	9,162.60	9,162.60	9,162.60	9,162.60	9,162.60	9,162.60	9,162.60
W-2	7,437.00	7,591.50	7,714.20	7,714.20	7,714.20	7,714.20	7,714.20	7,714.20	7,714.20	7,714.20	7,714.20
W-1	7,010.10	7,010.10	7,010.10	7,010.10	7,010.10	7,010.10	7,010.10	7,010.10	7,010.10	7,010.10	7,010.10

**** Reservists with at least 1,460 points as an enlisted member, a warrant officer, or a warrant officer and an enlisted member which are creditable toward reserve retirement also qualify for these rates.

Schedule 8-Pay of the Uniformed Services

(Effective January 1, 2026)

Part I-Monthly Basic Pay

Years of Service (Computed Under 37 U.S.C. 205)

Enlisted Members

Pay Grade	2 or less	Over 2	Over 3	Over 4	Over 6	Over 8	Over 10	Over 12	Over 14	Over 16	Over 18
E-9*	-	-	-	-	-	-	\$6,910.20	\$7,066.50	\$7,263.60	\$7,496.10	\$7,730.70
E-8	-	-	-	-	-	\$5,656.50	5,907.00	6,061.80	6,247.20	6,448.20	6,811.20
E-7	\$3,932.10	\$4,291.50	\$4,456.20	\$4,673.10	\$4,843.80	5,135.70	5,300.40	5,591.70	5,835.00	6,000.90	6,177.30
E-6	3,401.10	3,743.10	3,908.10	4,068.90	4,235.70	4,612.80	4,759.50	5,043.30	5,130.30	5,193.60	5,267.70
E-5	3,342.90	3,598.20	3,775.80	3,946.80	4,110.00	4,299.90	4,395.30	4,421.70	4,421.70	4,421.70	4,421.70
E-4	3,142.20	3,303.00	3,482.40	3,658.50	3,815.40	3,815.40	3,815.40	3,815.40	3,815.40	3,815.40	3,815.40
E-3	2,836.80	3,015.00	3,198.00	3,198.00	3,198.00	3,198.00	3,198.00	3,198.00	3,198.00	3,198.00	3,198.00
E-2	2,697.90	2,697.90	2,697.90	2,697.90	2,697.90	2,697.90	2,697.90	2,697.90	2,697.90	2,697.90	2,697.90
E-1**	2,407.20	2,407.20	2,407.20	2,407.20	2,407.20	2,407.20	2,407.20	2,407.20	2,407.20	2,407.20	2,407.20
E-1***	2,225.70	-	-	-	-	-	-	-	-	-	-

* For noncommissioned officers serving as Sergeant Major of the Army, Master Chief Petty Officer of the Navy or Coast Guard, Chief Master Sergeant of the Air Force, Sergeant Major of the Marine Corps, Chief Master Sergeant of the Space Force, Senior Enlisted Advisor to the Chairman of the Joint Chiefs of Staff, or Senior Enlisted Advisor to the Chief of the National Guard Bureau, basic pay for this grade is \$11,166.90 per month, regardless of cumulative years of service under 37 U.S.C. 205.

** Applies to personnel who have served 4 months or more on active duty.

*** Applies to personnel who have served less than 4 months on active duty.

Schedule 8-Pay of the Uniformed Services

(Effective January 1, 2026)

Part I-Monthly Basic Pay

Years of Service (Computed Under 37 U.S.C. 205)

Enlisted Members

Pay Grade	Over 20	Over 22	Over 24	Over 26	Over 28	Over 30	Over 32	Over 34	Over 36	Over 38	Over 40
E-9*	\$8,105.10	\$8,423.10	\$8,756.70	\$9,267.90	\$9,267.90	\$9,730.20	\$9,730.20	\$10,217.40	\$10,217.40	\$10,729.20	\$10,729.20
E-8	6,995.40	7,308.30	7,481.70	7,908.90	7,908.90	8,067.30	8,067.30	8,067.30	8,067.30	8,067.30	8,067.30
E-7	6,245.70	6,475.20	6,598.20	7,067.40	7,067.40	7,067.40	7,067.40	7,067.40	7,067.40	7,067.40	7,067.40
E-6	5,267.70	5,267.70	5,267.70	5,267.70	5,267.70	5,267.70	5,267.70	5,267.70	5,267.70	5,267.70	5,267.70
E-5	4,421.70	4,421.70	4,421.70	4,421.70	4,421.70	4,421.70	4,421.70	4,421.70	4,421.70	4,421.70	4,421.70
E-4	3,815.40	3,815.40	3,815.40	3,815.40	3,815.40	3,815.40	3,815.40	3,815.40	3,815.40	3,815.40	3,815.40
E-3	3,198.00	3,198.00	3,198.00	3,198.00	3,198.00	3,198.00	3,198.00	3,198.00	3,198.00	3,198.00	3,198.00
E-2	2,697.90	2,697.90	2,697.90	2,697.90	2,697.90	2,697.90	2,697.90	2,697.90	2,697.90	2,697.90	2,697.90
E-1**	2,407.20	2,407.20	2,407.20	2,407.20	2,407.20	2,407.20	2,407.20	2,407.20	2,407.20	2,407.20	2,407.20
E-1***	-	-	-	-	-	-	-	-	-	-	-

* For noncommissioned officers serving as Sergeant Major of the Army, Master Chief Petty Officer of the Navy or Coast Guard, Chief Master Sergeant of the Air Force, Sergeant Major of the Marine Corps, Chief Master Sergeant of the Space Force, Senior Enlisted Advisor to the Chairman of the Joint Chiefs of Staff, or Senior Enlisted Advisor to the Chief of the National Guard Bureau, basic pay for this grade is \$11,166.90 per month, regardless of cumulative years of service under 37 U.S.C. 205.

** Applies to personnel who have served 4 months or more on active duty.

*** Applies to personnel who have served less than 4 months on active duty.

Schedule 8-Pay of the Uniformed Services

Part II-Rate of Monthly Cadet or Midshipman Pay

The rate of monthly cadet or midshipman pay authorized by 37 U.S.C. 203(c) is \$1,452.90.

Schedule 9-Locality-Based Comparability Payments

(Effective on the first day of the first applicable pay period
beginning on or after January 1, 2026)

Locality Pay Area	Rate
Alaska	32.36%
Albany-Schenectady, NY-MA	20.77%
Albuquerque-Santa Fe-Las Vegas, NM	18.33%
Atlanta-Athens-Clarke County-Sandy Springs, GA-AL	23.79%
Austin-Round Rock-Georgetown, TX	20.35%
Birmingham-Hoover-Talladega, AL	18.24%
Boston-Worcester-Providence, MA-RI-NH-CT-ME-VT	32.58%
Buffalo-Cheektowaga-Olean, NY	22.41%
Burlington-South Burlington-Barre, VT	19.45%
Charlotte-Concord, NC-SC	19.67%
Chicago-Naperville, IL-IN-WI	30.86%
Cincinnati-Wilmington-Maysville, OH-KY-IN	21.93%
Cleveland-Akron-Canton, OH-PA	22.23%
Colorado Springs, CO	20.15%
Columbus-Marion-Zanesville, OH	22.15%
Corpus Christi-Kingsville-Alice, TX	17.63%
Dallas-Fort Worth, TX-OK	27.26%
Davenport-Moline, IA-IL	18.93%
Dayton-Springfield-Kettering, OH	21.42%
Denver-Aurora, CO	30.52%
Des Moines-Ames-West Des Moines, IA	18.01%
Detroit-Warren-Ann Arbor, MI	29.12%
Fresno-Madera-Hanford, CA	17.65%
Harrisburg-Lebanon, PA	19.43%
Hartford-East Hartford, CT-MA	32.08%
Hawaii	22.21%
Houston-The Woodlands, TX	35.00%
Huntsville-Decatur, AL-TN	21.91%
Indianapolis-Carmel-Muncie, IN	18.15%
Kansas City-Overland Park-Kansas City, MO-KS	18.97%
Laredo, TX	21.59%
Las Vegas-Henderson, NV-AZ	19.57%
Los Angeles-Long Beach, CA	36.47%
Miami-Port St. Lucie-Fort Lauderdale, FL	24.67%
Milwaukee-Racine-Waukesha, WI	22.42%
Minneapolis-St. Paul, MN-WI	27.62%
New York-Newark, NY-NJ-CT-PA	37.95%
Omaha-Council Bluffs-Fremont, NE-IA	18.23%
Palm Bay-Melbourne-Titusville, FL	17.93%
Philadelphia-Reading-Camden, PA-NJ-DE-MD	28.99%
Phoenix-Mesa, AZ	22.45%
Pittsburgh-New Castle-Weirton, PA-OH-WV	21.03%
Portland-Vancouver-Salem, OR-WA	26.13%
Raleigh-Durham-Cary, NC	22.24%
Reno-Fernley, NV	17.52%
Richmond, VA	22.28%
Rochester-Batavia-Seneca Falls, NY	17.88%
Sacramento-Roseville, CA-NV	29.76%
San Antonio-New Braunfels-Pearsall, TX	18.78%
San Diego-Chula Vista-Carlsbad, CA	33.72%
San Jose-San Francisco-Oakland, CA	46.34%
Seattle-Tacoma, WA	31.57%
Spokane-Spokane Valley-Coeur d'Alene, WA-ID	17.67%
St. Louis-St. Charles-Farmington, MO-IL	20.03%
Tucson-Nogales, AZ	19.28%
Virginia Beach-Norfolk, VA-NC	18.80%
Washington-Baltimore-Arlington, DC-MD-VA-WV-PA	33.94%
Rest of U.S.	17.06%

Locality Pay Areas are defined in 5 CFR 531.603.

Schedule 10-Administrative Law Judges

(Effective on the first day of the first applicable pay period
beginning on or after January 1, 2026)

AL-3/A	\$131,700
AL-3/B	141,700
AL-3/C	151,900
AL-3/D	162,200
AL-3/E	172,500
AL-3/F	182,400
AL-2	192,400
AL-1*	197,200

* Pursuant to 5 U.S.C. 5372(b)(1)(C), the rate of basic pay for AL-1 may not exceed the rate for level IV of the Executive Schedule.

Presidential Documents

Executive Order 14369 of December 18, 2025

Ensuring American Space Superiority

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. Purpose. Superiority in space is a measure of national vision and willpower, and the technologies Americans develop to achieve it contribute substantially to the Nation's strength, security, and prosperity. The United States must therefore pursue a space policy that will extend the reach of human discovery, secure the Nation's vital economic and security interests, unleash commercial development, and lay the foundation for a new space age.

Sec. 2. Policy. My Administration will focus its space policy on achieving the following priorities:

(a) Leading the world in space exploration and expanding human reach and American presence in space by:

(i) returning Americans to the Moon by 2028 through the Artemis Program, to assert American leadership in space, lay the foundations for lunar economic development, prepare for the journey to Mars, and inspire the next generation of American explorers;

(ii) establishing initial elements of a permanent lunar outpost by 2030 to ensure a sustained American presence in space and enable the next steps in Mars exploration; and

(iii) enhancing sustainability and cost-effectiveness of launch and exploration architectures, including enabling commercial launch services and prioritizing lunar exploration;

(b) Securing and defending American vital national and economic security interests in, from, and to space by:

(i) developing and demonstrating prototype next-generation missile defense technologies by 2028 to progressively and materially enhance America's air and missile defenses pursuant to Executive Order 14186 of January 27, 2025 (The Iron Dome for America);

(ii) ensuring the ability to detect, characterize, and counter threats to United States space interests from very low-Earth orbit and through cislunar space, including any placement of nuclear weapons in space;

(iii) creating a responsive and adaptive national security space architecture by accelerating acquisition reform, integrating commercial space capabilities, and enabling new market entrants; and

(iv) strengthening ally and partner contributions to United States and collective space security, including through increased space security spending, operational cooperation, basing agreements, and ally and partner investments in America's space industrial base;

(c) Growing a vibrant commercial space economy through the power of American free enterprise by:

(i) fostering economic growth, attracting at least \$50 billion of additional investment in American space markets by 2028, and increasing launch and reentry cadence through new and upgraded facilities, improved efficiency, and policy reforms;

- (ii) demonstrating spectrum leadership across space applications to promote United States technology competitiveness, spectrum management efficiency, and global market access; and
- (iii) spurring private sector initiative and a commercial pathway to replace the International Space Station by 2030; and
- (d) Developing and deploying advanced capabilities and approaches to enable the next century of space achievements by:
 - (i) optimizing space research-and-development investments to achieve my Administration's near-term space objectives, use emerging technologies and scientific discoveries to advance mission capabilities, and enable scientific discovery for America's long-term science and technology leadership;
 - (ii) enabling near-term utilization of space nuclear power by deploying nuclear reactors on the Moon and in orbit, including a lunar surface reactor ready for launch by 2030;
 - (iii) improving high-value space and Earth weather forecasting and operations to meet needs on Earth and beyond, utilizing improved business approaches such as firm fixed-price contracts and as-a-service models for both space and ground-based segments;
 - (iv) enabling the sustainability of space operations through effective and responsible approaches to space traffic management; orbital debris mitigation and remediation; and terrestrial and cislunar positioning, navigation, and timing, including by establishing the United States as the standards and services leader in these areas; and
 - (v) establishing ground, space, and lunar infrastructure and standards that enable implementation of space priorities and a robust space industrial base.

Sec. 3. *Implementation.* (a) The Assistant to the President for Science and Technology (APST) shall coordinate the overall implementation of this order, including:

- (i) within 60 days of the date of this order, issuing guidance on establishing a National Initiative for American Space Nuclear Power to achieve the nuclear power policy priorities directed in this order, in coordination with the heads of relevant executive departments and agencies (agencies) identified by the APST; and
 - (ii) within 120 days of the date of this order, propose revisions to Presidential Policy Directive 26 of November 21, 2013 (National Space Transportation Policy), to support implementation of this order.
- (b) Within 90 days of the date of this order, the APST shall coordinate development of and integrate into one submission to the President the following:
- (i) a plan from the Administrator of the National Aeronautics and Space Administration (NASA), in coordination with the Director of the Office of Management and Budget (OMB) and the Assistant to the President for Domestic Policy (APDP), for achieving the policy objectives in this order regarding leading the world in space exploration and expanding human reach and American presence in space, including plans for mitigating any technology, supply chain, or industrial capacity gaps relevant to achieving those goals within available funding;
 - (ii) the results of comprehensive reviews by the Secretary of Commerce and the Administrator of NASA, in consultation with the Director of OMB, of their respective major space acquisition programs to identify any such programs that are more than 30 percent behind schedule based on the program's acquisition baseline, 30 percent over cost based on the program's baseline, unable to meet any key performance parameters, or unaligned with the priorities in this order, along with a description of their planned mitigation or remediation efforts; and

(iii) a report from the Secretary of War, in coordination with the Director of National Intelligence (DNI) and the Assistant to the President for National Security Affairs (APNSA), of any technology, supply chain, or industrial capacity gaps relevant to this order's directive to progressively and materially enhance America's air and missile defenses, and plans for mitigating such gaps within available funding.

(c) Within 180 days of the date of this order, the Secretary of Commerce and the Administrator of NASA shall each reform their respective agency's space acquisition processes to support the space priorities in this order, and to further Executive Order 14271 of April 15, 2025 (Ensuring Commercial, Cost-Effective Solutions in Federal Contracts). These reforms shall incorporate the following:

(i) use of existing authorities to improve efficiency and expedite space acquisitions, including a first preference for commercial solutions and a general preference for Other Transactions Authority or Space Act Agreements, customary commercial terms, or any other pathways to promote effective or streamlined acquisitions;

(ii) a detailed review of each functional support role within the agency's Federal and contract workforce, to eliminate unnecessary tasks, reduce duplication, and accelerate decision-making;

(iii) for the Department of Commerce, strengthening capabilities for conducting space acquisition and sustainment activities in a manner that supports collaboration with, but does not require acquisition assistance from, NASA, including by recommending legislative reforms as necessary; and

(iv) for NASA, aligning space-focused acquisition and procurement processes across NASA centers and activities to improve efficiency.

(d) Within 180 days of the date of this order, the APNSA shall, in coordination with the Secretary of War, the DNI, the APST, and the heads of other relevant agencies:

(i) implement a space security strategy that accounts for United States interests in, from, and to space; addresses current and projected threats to United States space interests from very low-Earth orbit through cislunar space; and incorporates a technology plan for detecting, characterizing, and countering potential adversary placement of nuclear weapons in space; and

(ii) implement a plan for a responsive and adaptive national security space architecture to support the space security strategy and other relevant priorities established in this order.

(e) Within 180 days of the date of this order, the Secretary of State, in coordination with the Secretary of War and the DNI, shall implement a plan to strengthen ally and partner contributions to United States and collective space security.

(f) Within 120 days of the date of this order, the Secretary of Commerce shall coordinate with the APST, the Assistant to the President for Economic Policy, the APDP, and the heads of relevant agencies to assert spectrum leadership, which shall include considering opportunities for reapportioning and sharing spectrum, as appropriate.

(g) Within 120 days of the date of this order, the Administrator of NASA, in coordination with the Secretary of State and the APST, shall ensure that international civil space cooperation arrangements involving NASA support the policy priorities in this order, including by initiating new arrangements and modifying or terminating existing arrangements where appropriate and consistent with existing authorities and legal obligations.

Sec. 4. Rescission. (a) This order supersedes Executive Order 14056 of December 1, 2021 (The National Space Council), which is hereby revoked.

(b) Space Policy Directive 3 of June 18, 2018 (National Space Traffic Management Policy), is hereby revised as follows:

(i) by replacing “free of direct user fees” with “for commercial and other relevant use” in subsections 3(b) and 4(d); and

(ii) by replacing “provided free of direct user fees” with “available for commercial and other relevant use” in subsections 5(a)(ii) and 5(b)(ii).

(c) To the extent this order is inconsistent with any provision of any previous Executive Order, Presidential Memorandum, or Presidential Directive, this order shall control.

Sec. 5. Definitions. (a) The term “commercial solutions” means any of the methods for procurement of a commercial product or service described in part 12 of the Federal Acquisition Regulation, or other industry solutions funded by private investment that meet agency needs.

(b) The term “Other Transactions Authority” means the ability of the United States Government to enter into contracts other than standard contracts, grants, or cooperative agreements.

Sec. 6. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

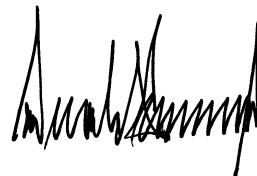
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of OMB relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order 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.

(d) The costs for publication of this order shall be borne by the National Aeronautics and Space Administration.



THE WHITE HOUSE,
December 18, 2025.

Presidential Documents

Executive Order 14370 of December 18, 2025

Increasing Medical Marijuana and Cannabidiol Research

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. *Purpose and Policy.* Americans deserve access to the best medical treatments and research infrastructure in the world. In 2023, the Food and Drug Administration (FDA) completed a review of the landscape of medical use of marijuana and found scientific support for its use to treat anorexia related to a medical condition, nausea and vomiting, and pain. Chronic pain affects nearly 1 in 4 United States adults and more than 1 in 3 United States seniors, and 6 in 10 people who use medical marijuana report doing so to manage pain. Forty States plus the District of Columbia have State- or locally-sanctioned, regulated medical marijuana programs. Yet decades of Federal drug control policy have neglected marijuana's medical uses. That oversight has limited the ability of scientists and manufacturers to complete the necessary research on safety and efficacy to inform doctors and patients.

Marijuana is currently controlled under Schedule I of the Controlled Substances Act (CSA). In 2023, the Department of Health and Human Services (HHS) recommended to the Drug Enforcement Agency that marijuana be controlled under Schedule III of the CSA. Schedule I drugs are defined as drugs with no currently accepted medical use, a high potential for abuse, and a lack of accepted safety for use of the drug under medical supervision. Schedule III drugs are classified as having a potential for abuse less than the drugs or other substances in Schedules I and II, a currently accepted medical use in treatment in the United States, and a potential for moderate or low physical dependence or high psychological dependence in the event of drug abuse.

The recommendation from HHS included a determination that medical marijuana has a currently accepted medical use. That determination was based in part on a finding by the HHS Office of the Assistant Secretary of Health that more than 30,000 licensed healthcare practitioners across 43 United States jurisdictions are authorized to recommend the medical use of marijuana for more than 6 million registered patients to treat at least 15 medical conditions. It was also based on a finding by the FDA of credible scientific support to substantiate the use of marijuana in the treatment of pain, anorexia related to certain medical conditions, and nausea and vomiting induced by chemotherapy. The National Institute on Drug Abuse concurred with the FDA's recommendation that marijuana be rescheduled from Schedule I to Schedule III of the CSA. In May 2024, the Department of Justice issued a proposed rule to reschedule marijuana to Schedule III. The proposed rule received nearly 43,000 public comments and is currently awaiting an administrative law hearing.

The Federal Government's long delay in recognizing the medical use of marijuana does not serve the Americans who report health benefits from the medical use of marijuana to ease chronic pain and other various medically recognized ailments. Americans who often seek alternative relief from chronic pain symptoms are particularly impacted. For example, in one research survey, 20 percent of participating United States veterans reported using fewer opioids as a result of their medical marijuana use. One in 10 seniors used marijuana in the last year and some evidence shows improvements

in seniors' health-related quality of life and pain with medical marijuana use. However, the current Schedule I position of marijuana has impeded research. The lack of appropriate research on medical marijuana and consequent lack of FDA approval leaves American patients and doctors without adequate guidance on appropriate prescribing and utilization. One patient survey showed that just 56 percent of older Americans using marijuana have discussed the usage with their healthcare provider. This places patients, especially seniors who may be on multiple medications, at increased risk of drug interactions or other adverse events. The Federal Government must improve the research infrastructure for medical marijuana to better serve Americans.

In addition to medical marijuana, which is primarily made up of two cannabinoids—cannabidiol (CBD) and tetrahydrocannabinol (THC)—hemp-derived cannabinoid products, defined by section 297A of the Agricultural Marketing Act of 1946 (7 U.S.C. 1639o), have shown potential to improve patient symptoms for common ailments and are frequently used by Americans. One in 5 United States adults and nearly 15 percent of seniors reported using CBD in the past year, and chronic pain patients have reported improvements with CBD use in clinical studies. Furthermore, evidence suggests that the amount of THC in hemp-derived cannabinoid products can affect both pain treatment efficacy and adverse events. Hemp-derived cannabinoids, as defined in 7 U.S.C. 1639o, are not controlled substances under the CSA but are subject to the same authorities and requirements as FDA-regulated products containing any other substance. Adding complexity is the fact that some full-spectrum CBD products will once again be controlled as marijuana under the CSA when section 781 of Public Law 119–37 goes into effect because they contain THC levels above the per-container threshold set by that law. Further, a recent study found that some commercially available CBD products evaluated were inaccurately labeled regarding CBD isolate, broad-spectrum, or full-spectrum composition, posing safety risks for consumers. In short, the current legal landscape leaves American patients and doctors without adequate guidance or product safeguards for CBD.

It is the policy of my Administration to increase medical marijuana and CBD research to better inform patients and doctors. It is critical to close the gap between current medical marijuana and CBD use and medical knowledge of risks and benefits, including for specific populations and conditions. Research methods and models should include real-world evidence and should facilitate affordable access in order to rapidly assess the health outcomes of medical marijuana and legal CBD products while focusing on long-term health effects in vulnerable populations like adolescents and young adults.

Sec. 2. *Rescheduling Medical Marijuana and Improving Access to Cannabidiol Products.* (a) The Attorney General shall take all necessary steps to complete the rulemaking process related to rescheduling marijuana to Schedule III of the CSA in the most expeditious manner in accordance with Federal law, including 21 U.S.C. 811.

(b) The Assistant to the President and Deputy Chief of Staff for Legislative, Political, and Public Affairs shall work with the Congress to update the statutory definition of final hemp-derived cannabinoid products to allow Americans to benefit from access to appropriate full-spectrum CBD products while preserving the Congress's intent to restrict the sale of products that pose serious health risks. This will include consultation with appropriate executive departments and agencies and authorities to develop a regulatory framework for hemp-derived cannabinoid products, including development of guidance on an upper limit on milligrams of THC per serving with considerations on per container limits and CBD to THC ratio requirements. The Secretary of Health and Human Services, the Commissioner of Food and Drugs, the Administrator of the Centers for Medicare and Medicaid Services, and the Director of the National Institutes of Health shall develop research methods and models utilizing real-world evidence to improve access

to hemp-derived cannabinoid products in accordance with Federal law and to inform standards of care.

Sec. 3. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

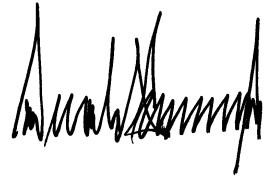
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order 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.

(d) The costs for publication of this order shall be borne by the Department of Health and Human Services.

A handwritten signature in black ink, appearing to be 'Donald Trump', located on the right side of the page.

THE WHITE HOUSE,
December 18, 2025.

Presidential Documents

Executive Order 14371 of December 18, 2025

Providing for the Closing of Executive Departments and Agencies of the Federal Government on December 24, 2025, and December 26, 2025

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. All executive departments and agencies of the Federal Government shall be closed and their employees excused from duty on Wednesday, December 24, 2025, and Friday, December 26, 2025, the day before and the day following Christmas Day, respectively.

Sec. 2. The heads of executive departments and agencies may determine that certain offices and installations of their organizations, or parts thereof, must remain open and that certain employees must report for duty on December 24, 2025, or December 26, 2025, or both, for reasons of national security, defense, or other public need.

Sec. 3. December 24, 2025, and December 26, 2025, shall be considered as falling within the scope of Executive Order 11582 of February 11, 1971, and of 5 U.S.C. 5546 and 6103(b) and other similar statutes insofar as they relate to the pay and leave of employees of the United States.

Sec. 4. The Director of the Office of Personnel Management shall take such actions as may be necessary to implement this order.

Sec. 5. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

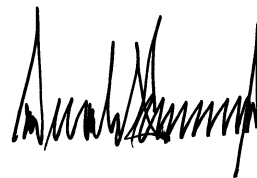
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order 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.

(d) The costs for publication of this order shall be borne by the Office of Personnel Management.

A handwritten signature in black ink, appearing to be "Donald Trump", located in the upper right quadrant of the page.

THE WHITE HOUSE,
December 18, 2025.

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