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

## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 150

**[NRC–2026–1387]**

## State of Indiana: Discontinuance of Certain Commission Regulatory Authority Within the State, Notice of Agreement Between the Nuclear Regulatory Commission and the State of Indiana

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Final state agreement.

**SUMMARY:** This notice is announcing that on September 24, 2026, Ho K. Nieh, Chairman of the U.S. Nuclear Regulatory Commission (NRC or Commission), and Governor Michael Braun of the State of Indiana, signed an Agreement as authorized by Section 274b. of the Atomic Energy Act of 1954, as amended (the Act or AEA).

Under the Agreement, the Commission discontinues its regulatory authority, and the State of Indiana assumes regulatory authority over byproduct materials, source materials, and special nuclear materials in quantities not sufficient to form a critical mass, as defined in Sections 11e.(1), 11e.(3), and 11e(4) of the AEA.

**DATES:** The effective date of the Agreement is September 30, 2026.

**ADDRESSES:** Please refer to Docket ID NRC–2026–1387 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–2026–1387. 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.
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**FOR FURTHER INFORMATION CONTACT:** Sherrie Flaherty, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–7288; email: *Sherrie.Flaherty@nrc.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Additional Background Information on Indiana Agreement

The NRC published the proposed Agreement in the **Federal Register** for comment once each week for four consecutive weeks on May 15, 2026 (91 FR 27987), Corrected version May 21, 2026 (91 FR 29988), May 22, 2026 (91 FR 30333), May 29, 2026 (91 FR 32129), and June 5, 2026 (91 FR 34251), as required by the Act. The comment period ended on June 15, 2026. The NRC received one comment from the Organization of Agreement States in support of the Agreement. No changes in the proposed Agreement or the staff's conclusions in the draft staff assessment of the State's program were made in response to the comment. The NRC staff determined that the Indiana Agreement State program is adequate to protect the public health and safety and compatible with the NRC's program. The Indiana Agreement is consistent with Commission policy and thus meets the criteria for an Agreement with the Commission.

After considering the request for an Agreement by the Governor of Indiana, the supporting documentation submitted with the request for an Agreement, and its interactions with the staff of the Indiana Department of Homeland Security, the NRC staff completed an assessment of the Indiana program. The agency made a copy of the staff assessment available in the NRC's PDR and electronically on the NRC's website. Based on the staff's assessment, the Commission determined on September 30, 2026, that the Indiana program for control of radiation hazards is adequate to protect the public health and safety and compatible with the Commission's program. As of the effective date of the Agreement, a person in Indiana possessing these materials is exempt from certain Commission regulations. The exemptions have been previously published in the **Federal Register** and are codified in the Commission's regulations. The Agreement is published here as required by Section 274e. of the Act.

This Agreement is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). The Office of Management and Budget has found that this action does not meet the criteria at 5 U.S.C. 804(2). The Office of Information and Regulatory Affairs has determined that this Agreement is not a significant regulatory action under Executive Order 12866.

### II. Availability of Documents

The ADAMS Accession numbers for the request for an Agreement by the Governor of Indiana, including all information and documentation submitted in support of the request, and the NRC staff assessment are identified in the following table.

| Document description | ADAMS Accession No. |
|---|---|
| Final Indiana Application Section 4.1 Legal Elements (Revised), dated January 29, 2026 | ML26068A234 |

| Document description | ADAMS Accession No. |
|---|---|
| Final Indiana Application Section 4.2 Regulatory Requirements Program Elements (Revised), dated January 29, 2026. | ML26068A235 |
| Final Indiana Application Section 4.3 Licensing Program Elements (Revised), dated January 29, 2026 | ML26068A236 |
| Final Indiana Application Section 4.4 Inspection Program Elements (Revised), dated January 21, 2026 | ML26068A237 |
| Final Indiana Application Section 4.5 Enforcement Program Elements (Revised), dated January 29, 2026 | ML26068A238 |
| Final Indiana Application Section 4.6 Technical Staffing and Training Program Elements (Revised), dated January 29, 2026. | ML26068A239 |
| Final Indiana Application Section 4.7 Event and Allegation Response Program Elements (Revised), dated January 29, 2026. | ML26068A240 |
| Indiana Application Request for Additional Information, dated February 27, 2026 | ML26068A127 |
| Receipt from C. Eckstein Acknowledging Indiana Revisions to Regulations 290 IAC 3–1 through 3–18, dated January 26, 2026. | ML26026A076 |
| Letter from C. Eckstein re: Indiana Revisions to Regulations 290 IAC 3–1 through 3–18, dated February 27, 2026 | ML26068A068 |
| Indiana Response to RAI, dated March 9, 2026 | ML26068A126 |
| Letter from Governor Mike Braun, Indiana, to Chairman Nieh requesting agreement be established between the NRC and State of Indiana, received January 29, 2026. | ML26033A182 |
| Staff Requirements Memorandum for SECY–26–0053 ''Proposed Agreement Between the State of Indiana and the Commission Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended,'' dated May 5, 2026. | ML26125A146 (package) |
| SECY–26–0053 ''Proposed Agreement Between the State of Indiana and the Commission Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended,'' dated April 10, 2026. | ML26069A564 |
| Draft Staff Assessment of the Proposed Indiana Program, dated April 10, 2026 | ML26069A567 |
| State Agreement (SA)-700 Processing an Agreement final, dated June 15, 2022 | ML22138A414 |
| SA–700 Handbook for Processing an Agreement Procedure final, dated June 17, 2022 | ML22140A396 |
| SECY–26–0098, includes final NRC staff assessment | ML26173A182 (package). |

**Authority:** 42 U.S.C. 2011 *et seq.*

Dated: September 30, 2026.

For the Nuclear Regulatory Commission.

**Jody Martin,**

*Secretary of the Commission.*

[FR Doc. 2026–20276 Filed 10–1–26; 8:45 am]

**BILLING CODE 7590–01–P**

## FEDERAL RESERVE SYSTEM

### 12 CFR Parts 225, 238, and 252

**[Regulations Y, LL, and YY; Docket No. R–1866]**

**RIN 7100–AG92**

## Modifications to the Capital Plan Rule and Stress Capital Buffer Requirement

**AGENCY:** Board of Governors of the Federal Reserve System (Board).

**ACTION:** Final rule.

**SUMMARY:** The Board is adopting a final rule to amend the calculation of the Board's stress capital buffer requirement applicable to certain large bank holding companies, savings and loan holding companies, U.S. intermediate holding companies of foreign banking organizations, and nonbank financial companies supervised by the Board to reduce the volatility of the stress capital buffer requirement. The final rule uses the average of the maximum common equity tier 1 capital ratio declines projected in each of the Board's prior two annual supervisory stress tests to inform a firm's stress capital buffer requirement. The final rule also extends the annual effective date of the stress capital buffer requirement by one quarter, to January 1, to provide additional time for firms to comply with the requirement. In addition, the Board is adopting changes to the FR Y–14A/Q/M reports to collect additional net income data that would improve the accuracy of the stress capital buffer requirement calculation. The final rule also amends the Stress Testing Policy Statement to remove the phase-in of highly material supervisory model changes.

**DATES:** The final rule is effective December 1, 2026.

**FOR FURTHER INFORMATION CONTACT:** Doriana Ruffino, Associate Director (202) 452–5235, Hillel Kipnis, Assistant Director, (202) 452–2924, John Simone, Manager (202) 245–4256, Alice Moore, Senior Financial Institution Policy Analyst II, (202) 360–0155, and Mehdi Beyhaghi, Principal Economist, (202) 973–6909, Division of Supervision and Regulation; Asad Kudiya, Associate General Counsel, (202) 360–6887, Julie Anthony, Senior Special Counsel, (202) 658–9400, and Kirin Walsh, Senior Counsel, (202) 391–1963, Legal Division. Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551. For users of TDD–TYY, please call 711 from any telephone, anywhere in the United States. Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

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## I. Changes to the Stress Capital Buffer Requirement

### *A. Introduction*

#### 1. Background on Stress Testing and the Stress Capital Buffer Requirement

Stress testing is a fundamental element of the Board's regulatory framework and supervisory program for large firms. It enables the Board to assess whether large bank holding companies, savings and loan holding companies, U.S. intermediate holding companies of foreign banking organizations, and nonbank financial companies supervised by the Board (collectively, firms) have sufficient capital to absorb potential losses under hypothetical stress scenarios and continue lending under severely adverse conditions, although it is not designed or intended to be predictive of future economic conditions.

In March 2020, the Board established the stress capital buffer requirement

framework.[1] Under the stress capital buffer requirement framework, the Board calculates each firm's preliminary stress capital buffer requirement as the difference between the firm's starting and minimum projected common equity tier 1 capital ratio under the severely adverse scenario in the supervisory stress test (stress capital decline component), plus four quarters of planned common stock dividends as a percentage of risk-weighted assets (dividend add-on component).[2] The stress capital buffer requirement has a minimum value of 2.5 percent of a firm's risk-weighted assets.[3] A firm can adjust the amount of its planned dividends after receiving its preliminary stress capital buffer requirement. A firm can also request reconsideration of the calculation of its preliminary stress capital buffer requirement. The final stress capital buffer requirement, which includes adjusted dividends and any revisions to a firm's stress capital decline component following a reconsideration of its preliminary stress capital buffer requirement, becomes part of the firm's ongoing capital requirements.[4] A firm subject to Category I–III standards must participate in the supervisory stress test every year, whereas a firm subject to Category IV standards is generally required to participate every other year, unless the firm chooses, or is otherwise required, to be subject to the supervisory stress test on a more frequent basis.[5]

As described in the proposal issued on April 22, 2025 (proposal or proposed rule), supervisory stress test results can vary based on changes in a firm's balance sheet, economic conditions, the severely adverse scenario, and supervisory models used in the stress test.[6] Standard economic theory holds that abrupt changes in capital requirements can be costly. Significant year-over-year variation in capital requirements may impact the provision of banking services. Abrupt changes in capital requirements could influence decision-making regarding investment and expansion, create challenges in long-term capital planning, and impact the supply of credit to households and businesses. In particular, when a firm's new stress capital buffer requirement is substantially higher than expected, the firm might choose to raise equity quickly, which can be complex and more costly than retaining earnings over time. As described further in the Section II.D.2 of this **SUPPLEMENTARY INFORMATION**, the results of the 2025 supervisory stress test further demonstrated volatility in the results for individual firms.[7]

In October 2025, the Board issued additional proposals to increase the transparency of the supervisory stress test (''enhanced transparency and public accountability proposal'').[8] These proposals sought to improve the transparency and public accountability of the supervisory stress test while ensuring that the test remains an effective tool for understanding and assessing risk and retaining appropriate risk sensitivity and risk capture in capital requirements. Final action related to those proposals is addressed in a separate **Federal Register** notice (''enhanced transparency and public accountability final rule'').

Statutory Authorities for the Board's Stress Testing and Stress Capital Buffer Framework

The International Lending Supervision Act of 1983 provides the Board with broad discretionary authority to set minimum capital levels for state member banks and certain affiliates of insured depository institutions, including holding companies, supervised by the Board.[9] Under section 5(b) of the Bank Holding Company Act of 1956 (Bank Holding Company Act), the Board may issue such regulations and orders relating to capital requirements of bank holding companies as may be necessary for the Board to carry out the purposes of the Bank Holding Company Act.[10] Foreign banking organizations with a U.S. branch, agency, or commercial lending company subsidiary are made subject by the International Banking Act of 1978 (International Banking Act) to the provisions of the Bank Holding Company Act in the same manner as bank holding companies;[11] therefore, the Board is also authorized under section 5(b) of the Bank Holding Company Act to impose these requirements on those foreign banking organizations, including on their U.S. operations. Similarly, with regard to savings and loan holding companies, section 10(g) of the Home Owners' Loan Act authorizes the Board to issue such regulations and orders relating to capital requirements as the Board deems necessary and appropriate to carry out the purposes of the Home Owners' Loan Act.[12]

Section 165 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act),[13] as amended by section 401 of the Economic Growth, Regulatory Relief, and Consumer Protection Act,[14] requires the Board to establish risk-based capital requirements for bank holding companies with $250 billion or more in total consolidated assets and nonbank financial companies supervised by the Board.[15] Additionally, section 165(i)(1) of the Dodd-Frank Act, as amended by section 401 of the Economic Growth, Regulatory Relief, and Consumer Protection Act, requires the Board to conduct an annual supervisory stress test of bank holding companies with $250 billion or more in total consolidated assets.[16] Section 401(e) of the Economic Growth, Regulatory Relief, and Consumer Protection Act requires the Board to conduct periodic stress tests for bank holding companies with total consolidated assets between $100 billion and $250 billion.[17]

Section 401 of the Economic Growth, Regulatory Relief, and Consumer Protection Act also added section 165(a)(2)(C) of the Dodd-Frank Act, which authorizes the Board to apply any prudential standard established under section 165 to any bank holding company or bank holding companies with $100 billion or more in total consolidated assets to which the prudential standard does not otherwise apply, provided that the Board (1) determines that application of the prudential standard is appropriate to

[1] *See* 85 FR 15576 (March 18, 2020).

[2] 12 CFR 217.11(a)(2)(vi), 12 CFR 225.8(f)(2)(i), and 12 CFR 238.170(f)(2)(i).

[3] 12 CFR 225.8(f)(2)(ii) and 12 CFR 238.170(f)(2)(ii).

[4] 12 CFR 217.11(c)(1)(iii).

[5] *See* 12 CFR 217.2; 12 CFR 238.10; 12 CFR 252.5; 84 FR 59032 (Nov. 1, 2019).

[6] *See* 90 FR 16843 (April 22, 2025).

[7] Because the Board did not use the results of the 2026 supervisory stress test to update firms' stress capital buffer requirements, 2026 results are not included in the impact analysis. *See* Board, Press Release (Feb. 4, 2026), *https://www.federalreserve.gov/newsevents/pressreleases/bcreg20260204a.htm.*

[8] *See* 90 FR 51856 (Nov. 18, 2025), available at *https://www.federalregister.gov/d/2025-20211.*

[9] *See* 12 U.S.C. 3902(1); 3907(a); 3909(a)(2).

[10] 12 U.S.C. 1844(b).

[11] *See* 12 U.S.C. 3106.

[12] *See* 12 U.S.C. 1467a(g)(1).

[13] Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010).

[14] Economic Growth, Regulatory Relief, and Consumer Protection Act, Public Law 115–174, 132 Stat. 1296 (2018).

[15] *See* 12 U.S.C. 5365(b)(1)(A)(i). The term bank holding company as used in section 165 of the Dodd-Frank Act includes a foreign bank or company treated as a bank holding company for purposes of the Bank Holding Company Act, pursuant to section 8(a) of the International Banking Act. *See* 12 U.S.C. 3106(a); 12 U.S.C. 5311(a)(1). *See also* section 401(g) of the Economic Growth, Regulatory Relief, and Consumer Protection Act (regarding the Board's authority to establish enhanced prudential standards for foreign banking organizations with total consolidated assets of $100 billion or more).

[16] *See* 12 U.S.C. 5365(i)(1).

[17] 12 U.S.C. 5365 note.

prevent or mitigate risks to the financial stability of the United States, or to promote the safety and soundness of such firm(s); and (2) takes into consideration the capital structure, riskiness, complexity, financial activities (including financial activities of subsidiaries), size, and any other risk-related factors of such firm(s) that the Board deems appropriate.[18]

2. Overview of the Proposed Rule

On April 22, 2025, the Board issued a proposed rule that would have amended the calculation of the stress capital buffer requirement to reduce the volatility of the stress capital buffer requirements.[19] Specifically, under the proposal, for a firm participating in two consecutive annual supervisory stress tests, the stress capital decline component projected in each of the Board's prior two annual supervisory stress tests would be averaged to inform a firm's stress capital buffer requirement (results averaging).[20] The proposal would also have extended the annual effective date of the stress capital buffer requirement from October 1 to January 1. The proposal also introduced revisions to the FR Y–14A/Q/M (Capital Assessments and Stress Testing) reporting forms to collect data that would provide greater insight into the net income composition of reporting firms and to eliminate data fields that are no longer needed to conduct the supervisory stress test. The proposed rule provided that, in the event of a material change to a firm's risk profile, financial condition, or corporate structure (material change) that resulted in a recalculation of the firm's stress capital buffer requirements, a firm's recalculated stress capital buffer requirement would not be subject to results averaging.[21] In addition, the proposed rule would have amended the Board's Stress Testing Policy Statement to remove the phase-in of highly material supervisory model changes.

3. Summary of Comments

The Board received sixteen comments on the proposal from banking organizations, trade associations, public interest groups, private individuals, and a member of the U.S. Senate.[22] Most commenters were supportive of the proposal's objective to reduce volatility in the stress capital buffer requirement by averaging the results of supervisory stress tests. Commenters provided a range of views on the proposed averaging approach, with several commenters expressing support for and opposition to an asymmetrical averaging approach, which was included as an alternative in the proposal.

Commenters were also broadly supportive of the proposal's extension of the annual effective date of the stress capital buffer requirement from October 1 to January 1 and the proposed modifications to the FR Y–14A/Q/M reports. Some commenters objected to the proposal, asserting that reducing volatility through averaging of stress test results is not necessary and would reduce capital levels. Some such commenters asserted that a supervisory stress test should at times produce large changes in results for individual firms due to changes in firm risk profiles and economic conditions. One commenter encouraged the Board to consider the safety and soundness implications of any changes to the capital requirements of large firms, noting the potential impact of the failures of such firms on the Deposit Insurance Fund.[23]

In response to a question about the dividend add-on component, several commenters supported removing it from the stress capital buffer requirement, whereas other commenters supported maintaining the dividend add-on component or modifying it to include additional planned capital actions. Commenters provided a variety of suggestions for the implementation timeline for the stress capital buffer requirement associated with the 2025 supervisory stress test.

In response to a question about the Board's authority to require capital plan resubmissions due to changing market conditions, a commenter asserted that eliminating this authority would represent a major overhaul of the stress testing framework and would, therefore, require a separate proposal with its own public comment process.

Several commenters opposed the proposed amendment to the Board's Stress Testing Policy Statement that would remove the phase-in of highly material supervisory model changes.

Several commenters recommended that the Board publish the annual supervisory stress test scenarios for public comment prior to finalizing them. In addition, several commenters also highlighted specific concerns with the transparency and adequacy of the supervisory stress test models and supported issuing those models for public comment. Some commenters also provided specific suggestions on how to improve the supervisory stress test models and assumptions. Several commenters provided suggestions regarding the interaction of the proposal with other elements of the Board's capital framework and outstanding proposals on regulatory capital for large firms.

4. Overview of the Final Rule

The Board is finalizing the rule as proposed, with results averaging to go into effect for stress capital buffer requirements following the 2028 stress test, as discussed below. For a firm participating in two consecutive annual supervisory stress tests, the final rule averages the stress capital decline component projected in each of the Board's prior two annual supervisory stress tests to inform a firm's stress capital buffer requirement. The averaging calculation does not include the dividend add-on component, which will continue to be updated on an annual basis for all firms subject to the supervisory stress test.[24] Consistent with current requirements, for a firm that is not participating in two consecutive annual stress tests, the final rule does not apply results averaging, and the stress capital decline component of such a firm's stress capital buffer requirement is informed by the results of its most recent supervisory stress test.

The final rule extends the annual effective date of the stress capital buffer requirement from October 1 to January 1 for all firms subject to the stress capital buffer requirement. Consistent with the changes in the effective date of the stress capital buffer requirement, the final rule updates the definition of the dividend add-on component to cover dividends issued in quarters five

[18] 12 U.S.C. 5365(a)(2)(C).

[19] *Supra* note 8.

[20] The proposal would have included changes to the timing of the planned dividends included in the dividend add-on component but would not have included any other changes to the component.

[21] In the event of a material change determination, if a recalculation of the stress capital buffer requirement were not required, results averaging would have continued to apply for applicable firms.

[22] *See* Modifications to the Capital Plan Rule and Stress Capital Buffer Requirements [R–1866], *https://www.federalreserve.gov/apps/proposals/FR-2025-0026-01/comments.* Some comments related to the volatility proposal were also included in responses to the enhanced transparency and public accountability proposal. Those comments are addressed in a separate rulemaking. *See* Enhanced Transparency and Public Accountability of the Supervisory Stress Test Models and Scenarios; Modifications to the Capital Planning and Stress Capital Buffer Requirement Rule, Enhanced Prudential Standards Rule, and Regulation LL [R–1873], *https://www.federalreserve.gov/apps/proposals/FR-2025-0063-01/comments.*

[23] This commenter also noted that supervision for community banks should be tailored to their specific size, characteristics, and risk profile, rather than applying the requirements for larger institutions. The commenter specifically noted capital planning and supervisory stress testing requirements as examples of requirements to maintain tailoring.

[24] *See* 12 CFR 225.8(f)(1); 12 CFR 225.8(f)(4); 12 CFR 238.170(f)(1); 12 CFR 238.170(f)(4).

through eight of the planning horizon of the supervisory stress test.

The Board has adopted revisions to the FR Y–14A/Q/M reports consistent with the proposal. The revisions were largely adopted as proposed, except that the Board amended the FR Y–14Q instructions from the proposal to clarify the definition of one line item in response to a comment. Additionally, the Board is not adopting the proposed removal of items related to pre-provision net revenue (PPNR) from FR Y–14A, Schedule A.7.a (PPNR Projections Sub-schedule) and FR Y–14Q, Schedule G.1 (PPNR Submission Worksheet), as certain of these items are used in the PPNR model proposed for use in the 2027 stress test.[25] Further, consistent with the proposal, the final rule provides that if a firm experiences a material change resulting in a recalculated stress capital buffer requirement, the Board generally will not use results averaging for the recalculation.[26] In addition, the final rule revises the Board's Stress Testing Policy Statement to no longer specify that a material supervisory model change will be phased in over a two-year period.

The final rule will be effective 60 days after publication in the **Federal Register**. Results averaging will begin starting with the stress capital buffer requirements effective on January 1, 2029. The revisions to the FR Y–14A/Q/M reporting forms will be effective for the June 30, 2027, report date.

*B. Changes to the Calculation of the Stress Capital Buffer Requirement*

1. Results Averaging

Under the proposal, for firms participating in two consecutive annual supervisory stress tests, the stress capital decline component of the stress capital buffer requirement calculation would have been averaged over the supervisory stress tests, with the current year and the prior year weighted equally in the averaging calculation. The averaging would have been symmetric, meaning that the stress capital decline component would have been averaged regardless of whether it resulted in an increase or decrease.

The Board received a number of comments recommending that the final rule adopt an asymmetric averaging approach, whereby only increases in the stress capital decline component would be averaged over two stress tests. These commenters argued that such an approach would reflect that the costs of volatility are more pronounced as requirements increase and that implementing a reduction in requirements more quickly would be consistent with the approach of other capital buffer requirements, such as the countercyclical capital buffer requirement framework and the GSIB surcharge requirement framework. Several commenters opposed incorporating an asymmetric approach, arguing that it would mechanically lead to a reduction in capital requirements over time. Two commenters supported applying a higher weight in the averaging calculation to the most recent results of the supervisory stress test relative to the prior year's results.[27] Conversely, one commenter asserted that weighted averaging would introduce unnecessary complexity to the averaging framework.

The Board received some comments opposing the concept of averaging for the stress capital buffer requirement. These commenters argued that additional certainty in stress capital buffer requirements from averaging is not necessary and would result in lower capital levels as firms would likely distribute more capital.

Consistent with the proposal, the final rule averages the stress capital decline component symmetrically over the prior two annual supervisory stress tests.[28] By averaging the stress capital declines symmetrically over the prior two stress tests, the final rule would most effectively and directly reduce volatility for both increases and decreases in stress test results.

Asymmetric averaging would result in more stress capital buffer requirement volatility than symmetric averaging. It would also mechanically reduce capital requirements, which would be inconsistent with the purposes of the proposal. The countercyclical capital buffer requirement framework and GSIB surcharge requirement framework noted by commenters serve distinct purposes from the stress capital buffer requirement framework. Further, the capital buffer requirements associated with those frameworks have generally been more predictable. Conversely, given the volatility observed in stress capital buffer requirements, this final rule aims to mitigate such volatility by implementing symmetric averaging of stress capital declines.

The Board considered but chose not to adopt an averaging approach that would place a higher weight on a firm's most recent stress capital decline. While applying a higher weight to the most recent year's stress capital decline in the averaging approach could increase the risk sensitivity of stress capital buffer requirements in certain circumstances, it would also increase the complexity of the regulatory capital framework and, depending on the weighting for each year, would reduce volatility by less than the approach taken in the final rule. Further analysis of the alternatives supported by commenters is included in Section II.E of this **SUPPLEMENTARY INFORMATION**.

2. Application of 2027 and 2028 Stress Capital Buffer Requirements Under the Final Rule

Under the proposal, the changes to the calculation of the stress capital buffer requirement would have been effective beginning with the stress capital buffer requirement calculated using the 2025 stress test. Those stress capital buffer requirements would have been calculated using the average of the stress capital decline components from the 2024 and 2025 supervisory stress test for applicable firms.

One commenter asserted that, if the final rule became effective in 2025 or on January 1, 2026, the rule would undermine the objective of the proposal because it would introduce additional uncertainty into capital planning for firms. Several commenters recommended allowing firms to operate under the existing stress capital buffer requirement through September 30, 2026, to reduce uncertainty in the capital planning process and permit firms to opt in to the revised averaging framework.[29] Other commenters recommended that the final rule clarify that the stress capital buffer requirement

[25] The model documentation is available on the Board's website at: *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2027.htm.*

[26] In addition to a material change, the Board, or the appropriate Reserve Bank with the concurrence of the Board, may direct a firm to resubmit its capital plan where the capital plan is incomplete or contains material weaknesses. 12 CFR 225.8(e)(4)(i)(B)(*1*); 12 CFR 238.170(e)(4)(i)(B)(*1*). In circumstances where the Board recalculates a firm's stress capital buffer requirement following such a resubmission, the Board would use results averaging, because the risk profile of the firm is less likely to have changed materially over the period being averaged.

[27] One of these commenters objected to the proposal overall but noted that, should the Board apply averaging, it should do so by applying a higher weight to the most recent stress test results.

[28] To calculate a firm's stress capital buffer requirement, the final rule (1) averages the stress capital declines from the two most recent annual supervisory stress tests; then (2) adds the four quarters of planned dividends for the year in which the requirement will be effective; and (3) applies, as applicable, the 2.5 percent floor, in that order.

[29] These commenters also submitted a comment letter earlier in the comment period asserting that the proposal created uncertainty for the 2025 supervisory stress test cycle and recommended that Board issue a public statement confirming the existing stress capital buffer requirement framework would apply through September 30, 2026, or issue an interim final rule to that effect.

effective through September 30 in the year that the rule takes effect would apply through December 31 of that year.[30]

In February 2026, the Board voted to maintain the current stress capital buffer requirements until 2027, when new requirements can be calculated based on models that take public feedback into consideration.[31] As a result, absent further action from the Board, each firm is subject to its current stress capital buffer requirement until it receives a new requirement, which, under this final rule, will be effective on January 1, 2028. The dividend add-on component of the requirements that take effect on January 1, 2028, would be shifted forward in time by one quarter, consistent with this final rule. Firms subject to Category IV standards that do not participate in the 2027 supervisory stress test will still receive stress capital buffer requirements that are adjusted to account for updated planned common stock dividends in 2027. Until January 1, 2029, firms will be subject to the stress capital buffer requirement without results averaging.

Beginning on January 1, 2029, through December 31, 2029, the stress capital buffer requirement for firms subject to results averaging will incorporate the average of the 2027 and 2028 stress capital decline components, consistent with this final rule. The final rule delays results averaging until the stress capital buffer requirements effective on January 1, 2029, to ensure that results used to calculate the stress capital buffer requirement have been calculated using only models informed by public input. However, other aspects of this final rule, including the change in the annual effective date of the stress capital buffer requirement, the shift forward by one quarter of the dividend add-on component, and the removal of the phase-in of highly material model changes, take effect for the stress capital buffer requirements that would be calculated following the 2027 stress test.

The Board considered comments requesting that firms have an option to opt into results averaging before the averaging goes into effect for all firms. However, in order to ensure that future stress capital buffer requirements are calculated solely using models that have been subject to public input, this final rule does not allow firms to opt into results averaging at an earlier date. Further, implementing results on the same timeline for all firms ensures consistency and fairness.

3. Dividend Add-On Component

Under the proposal, the stress capital buffer requirement would have continued to include a firm's stress capital decline component (under the proposed results averaging) and the dividend add-on component (updated annually). The proposal would have updated the definition of the dividend add-on component to cover dividends issued in quarters five through eight of the planning horizon of the supervisory stress test to be consistent with the change in the annual effective date of the stress capital buffer requirement. The proposal's averaging calculation would not have included the dividend add-on component, because the dividend add-on component is intended to equal planned dividends for the year that the stress capital buffer requirement is in effect, and the amount of this component is at the firm's discretion, unlike the stress capital decline component.[32]

Several commenters recommended that the Board eliminate the dividend add-on component of the stress capital buffer requirement, noting that the Board's capital buffer requirement framework includes regulatory limitations on the payments of dividend distributions.[33] Some commenters noted that the Board has the authority to restrict capital actions and concluded that the dividend add-on component is therefore not necessary. One commenter also argued that the dividend add-on component increases the complexity of the stress capital buffer requirement. One commenter argued that a firm should be permitted to dip into and reduce its stress capital buffer requirement by the amount of a dividend in order to use those pre-funded resources to distribute to shareholders. A few commenters opposed removing the dividend add-on component, arguing that such a change would weaken the stress capital buffer requirement framework by reducing capital requirements and undermining banking system resilience.[34] One commenter suggested that the Board extend the dividend add-on component to include nine quarters of planned dividends. Another commenter suggested that the Board restore the previous assumption in the Comprehensive Capital and Review exercise to include a pre-funding requirement of both planned dividends and share repurchases over a nine-quarter period.

Consistent with the proposal, the final rule maintains the dividend add-on component, which will continue to be updated on an annual basis and not be subject to averaging. The final rule updates the definition of the dividend add-on component to cover dividends issued in quarters five through eight of the planning horizon of the supervisory stress test. As part of the stress capital buffer requirement, a firm's dividend add-on component provides important benefits to the regulatory capital framework by helping to ensure that firms maintain sufficient capital to absorb losses under hypothetical stress scenarios, issue planned dividends for the four quarters that the stress capital buffer requirement is in effect and continue to lend to households and businesses under stressful conditions. The Board also chose to maintain the dividend add-on component for intermediate holding companies of foreign banking organizations, as this approach will maintain the stress capital buffer requirement framework in a consistent and comparable manner across all firms subject to the stress capital buffer requirement and reduce complexity.

4. Material Change

The Board can recalculate a firm's stress capital buffer requirement if the firm experiences a material change.[35] Under the proposal, results averaging

[30] One commenter on the enhanced transparency and public accountability proposal reiterated support for two-year averaging of stress test results in the stress capital buffer calculation but argued that averaging should only be implemented on a prospective basis after the Board adopts revised models that incorporate public comment. *See* Enhanced Transparency and Public Accountability of the Supervisory Stress Test Models and Scenarios; Modifications to the Capital Planning and Stress Capital Buffer Requirement Rule, Enhanced Prudential Standards Rule, and Regulation LL [R–1873], *https://www.federalreserve.gov/apps/proposals/FR-2025-0063-01/comments.*

[31] *See* Board, Press Release (Feb. 4, 2026), *https://www.federalreserve.gov/newsevents/pressreleases/bcreg20260204a.htm.*

[32] In addition, while a firm must provide the amount of its dividend add-on component prior to knowing its stress capital decline component, the firm can revise its dividend add-on component after receiving its preliminary stress capital buffer requirement.

[33] One commenter specifically requested eliminating the dividend add-on component for intermediate holding companies of foreign banking organizations, given their different risk profile as subsidiaries of foreign parents. The commenter asserted that they effectively do not and, often cannot, distribute capital through share repurchases, and therefore the exclusion for share repurchases from the pre-funding of capital actions is unusable.

[34] Two commenters noted if that the Board were to pursue removing the dividend add-on component, it should propose the change with a full public comment process and associated economic analysis.

[35] A firm that has its stress capital buffer requirement recalculated outside of the regular timeline is also given the opportunity to adjust its planned dividends and request reconsideration of its stress capital buffer requirement.

would not have been applied when recalculating a firm's stress capital buffer requirement due to a material change.[36] The Board would have resumed results averaging for the subsequent stress capital buffer requirement calculation if such calculation was not a recalculation due to a material change.[37]

Two commenters requested that the Board provide a quantitative definition of a material change. These commenters also requested that the deadline to resubmit capital plans be extended from 30 to 90 days following a material change. The same commenters asked that the Board eliminate the requirement for prior Federal Reserve approval for capital distributions following a material change. These commenters also recommended that the Board not suspend results averaging when determining a firm's stress capital buffer requirement after a material change, pointing to potential long delays before a transaction resulting in a material change determination is reflected in the data used in two consecutive supervisory stress tests. One commenter suggested that in the event of a material change, a firm should only require prior approval for a capital distribution if the firm falls below the payout restrictions. Another commenter recommended that the Board not require any resubmission for any acquisition subject to an application or notice requiring prior approval under the Bank Holding Company Act. One commenter asserted that eliminating the Board's authority to require capital plan submissions in response to changing market conditions would represent a major overhaul of the stress testing framework and therefore require a separate proposal with its own public comment process.

Consistent with the proposal, under the final rule, the Board will generally not use results averaging when recalculating a firm's stress capital buffer requirement because of a material change. Results averaging will resume, as applicable, for the subsequent stress capital buffer requirement calculation if such calculation is not a recalculation resulting from a material change.[38] The Board considered the comments that argued in favor of using results averaging even in the event of a material change. However, results averaging that partially includes a firm's balance sheet prior to a material change may misrepresent the firm's risk level when recalculating its stress capital buffer requirement, because a material change may significantly impact the firm's business profile, risk exposure, and balance sheet. Accordingly, the final rule maintains the risk sensitivity of the stress capital buffer requirement by not averaging when recalculating a firm's stress capital buffer requirement due to a material change.

The Board is also clarifying that, under the proposal, results averaging would not have been suspended with respect to the calculation of a firm's stress capital buffer in circumstances other than a recalculation, including when a firm has resubmitted its capital plan and the Board has not yet decided whether to recalculate its stress capital buffer requirement. Those aspects of the proposal are retained in the final rule.

5. Stress Testing Policy Statement

Under the proposal, the Board would have revised its Stress Testing Policy Statement to no longer specify that highly material model changes be phased in over a two-year period. Under the Stress Testing Policy Statement, the Board phases in highly material supervisory stress test model changes over a two-year period to mitigate sudden and unexpected changes to the supervisory stress test results.[39] Because the proposal introduced results averaging over a two-year period, material model changes would have, in most cases, been mechanically phased in to the proposed calculation of the stress capital decline component.

One commenter suggested that the Board maintain the phase-in of highly material supervisory model changes, contending that material changes to a firm's stress capital buffer from model changes do not reflect actual portfolio risk. Another commenter argued that the Board should maintain the phase-in of highly material model changes specifically for Category IV firms to reduce volatility in the stress capital buffer requirements for those firms, as these firms would generally not receive stress capital buffer requirements based on results averaging.

Some commenters provided other general input on the Stress Testing Policy Statement. Two commenters provided suggestions to modify the assumption that the size of a firm's balance sheet remains constant over the stress period, as described in the Stress Testing Policy Statement. One commenter provided additional quantitative analysis asserting that this assumption is not reflective of credit card loan balance behavior. Another commenter recommended that the Board put out the entire Stress Testing Policy Statement for public comment.[40]

Consistent with the proposal, the final rule revises the Board's Stress Testing Policy Statement to remove the phase-in of highly material supervisory stress test model changes over a two-year period. Results averaging automatically applies a phase-in of material model changes, removing many of the benefits received from a concurrent phase-in of model changes. Although the removal of the phase-in could potentially result in slightly higher volatility for firms subject to Category IV standards in certain years when a model change is incorporated,[41] the final rule eliminates

[36] For purposes of this discussion, the term ''material change'' also includes circumstances in which the Board, or the appropriate Reserve Bank with the concurrence of the Board, has directed a firm to resubmit its capital plan because its internal stress scenario(s) are not appropriate for the firm's business model and portfolios, or changes in financial markets or the macro-economic outlook that could have a material impact on a firm's risk profile and financial condition require the use of updated scenarios. 12 CFR 225.8(e)(4)(i)(B)(*3*); 12 CFR 238.170(e)(4)(i)(B)(*3*). In addition to a material change, the Board, or the appropriate Reserve Bank with the concurrence of the Board, may direct a firm to resubmit its capital plan where the capital plan is incomplete or contains material weaknesses. *See* 12 CFR 225.8(e)(4)(i)(B)(*1*); 12 CFR 238.170(e)(4)(i)(B)(*1*). In circumstances where the Board recalculates a firm's stress capital buffer requirement following such a resubmission, the proposal provided that the Board would use results averaging, because the risk profile of the firm is less likely to have changed materially over the period being averaged.

[37] In order to align with results averaging over a two-year period, the proposal would have used averaging for a firm subject to Category IV standards when subject to a recalculated stress capital buffer requirement only if the recalculation and a subsequent annual supervisory stress test that is not related to a recalculation in which the firm participates occurred within the same calendar year or in consecutive years.

[38] The Final Rule includes certain technical changes from the proposal to make clear that the Board will use averaging for a firm subject to Category IV standards when subject to a recalculated stress capital buffer requirement if the recalculation and a subsequent annual supervisory stress test in which the firm participates occur within the same calendar year or in consecutive years. *See* 12 CFR 225.8(f)(2)(i) and (ii); 12 CFR 238.170(f)(2)(i) and (ii). These changes are consistent with the way the calculation was described in the proposal. *See* 90 FR 16843 at 16849 (April 22, 2025).

[39] *See* 12 CFR part 252 Appendix B, section 2.3.

[40] The Board previously invited comment on a proposal to adopt the Stress Testing Policy Statement in 2017, and the statement was published as part of a final rule in 2019. *See* 82 FR 59528 (December 15, 2017) and 84 FR 6664 (February 28, 2019).

[41] Under the final rule, the effects of a material model change would be fully incorporated into a firm's stress capital buffer requirement if the firm receives a new stress capital buffer requirement that is not calculated using results averaging in a year when a material model change is implemented (that is, a stress capital buffer requirement that is not calculated using results averaging would incorporate the full effects of the model change because those effects would not be phased in over two supervisory stress testing cycles as they are under the current rule.)

the phase-in for all firms to reduce complexity and ensure consistent models for all firms subject to the stress test.

Additionally, as part of the separate enhanced transparency and public accountability final rule, the Board is adopting a process to seek public input on material model changes prior to their use in the stress test.[42] The threshold for a material model change is lower than the threshold for a highly material model change. Given this process, the phase-in of highly material model changes is less important because firms will have an opportunity to provide input on material model changes before they are implemented. To ensure that the stress capital buffer requirements based on 2027 stress test results are calculated only using models informed by public input, the Board determined to remove the phase-in of highly material model changes prior to the 2027 stress test.

The Board is maintaining the assumption in the Stress Testing Policy Statement that aggregate credit supply does not contract during the stress test horizon period.

6. Supervisory Stress Testing Models and Scenarios

The proposal invited comment on ways for the Board to improve the transparency and effectiveness of the supervisory stress test and its planned approach to seek comment on the supervisory stress test models and scenarios. Several commenters cited specific concerns with the global market shock component, large counterparty default component, credit and loan loss models, operational loss models, and PPNR models in the supervisory stress test.[43] Another commenter suggested an alternative methodology to calculate the collateral haircut approach for repo-style transactions under the standardized approach for risk-weighted assets and in the supervisory stress test. Another commenter said that the stress capital buffer framework in general is not sufficiently strong or stringent.

One commenter suggested that the Board expand the supervisory stress test to include additional scenarios that include more severe assumptions. The commenter also advocated that the Board include a qualitative objection process to the supervisory stress test. Another commenter recommended an earlier release of the annual supervisory stress test scenarios as well as defined parameters for all components of the annual scenarios. One commenter recommended a streamlined stress capital buffer requirement reconsideration process, including defined acceptable documentation to ensure consistent and transparent reviews. Two commenters suggested changes to stress test model overlays, including that the Board provide an explanation to firms when applying an overlay.[44] One commenter recommended giving firms an opportunity to appeal overlays, and the commenter also suggested that the Board issue for comment a rule that establishes the criteria for overlays and outlines the process by which they are applied. These comments are addressed by the enhanced transparency and public accountability final rule and associated documentation.

7. Interaction With Other Regulatory Capital Frameworks

Several commenters expressed concern about potential overlaps and incongruity between the supervisory stress testing framework and the 2023 Basel III proposal,[45] which could lead to inappropriate calibration of capital requirements. Some commenters cited concerns with the holistic calibration and potential structural overlaps attributed to the operational risk capital requirements and the market risk capital requirements between the supervisory stress testing framework and the Basel III proposal. One commenter requested that the Board commit to not applying the stress capital buffer requirement to the capital requirements framework that would be associated with the potential adoption of the Basel III proposal. Some commenters suggested removing the stress capital buffer floor of 2.5 percent. Another commenter recommended the Board introduce a post-stress leverage ratio measurement and leverage ratio buffer to the supervisory stress test framework. One commenter stated that the impact analysis of the proposal did not appropriately take into account how other outstanding proposals on regulatory capital for large firms interacted with the proposed rule on the calculation of the stress capital buffer requirement. Several commenters urged the Board to broadly revise the supervisory stress testing framework, arguing that it is conceptually inconsistent with the risk-weighted assets framework.

The Board has carefully reviewed the comments regarding interactions within its regulatory capital framework. Several rulemakings have progressed or changed since the proposal was published in April 2025, including the stress testing enhanced transparency and public accountability proposal[46] and the 2026 Basel III and standardized approach risk-based capital proposal.[47] Combined, these proposals aim to improve the risk sensitivity of requirements in a way that considers the cumulative effect of the entire capital framework. While the Board acknowledges there are interactions between minimum capital requirements, the stress capital buffer framework, and the GSIB surcharge requirement, the volatility final rule does not address these interactions, as the primary objective of the proposal is to reduce the volatility of the stress capital buffer requirement. The Board will further evaluate interactions within the regulatory capital framework in the context of rulemakings addressing stress testing, minimum capital requirements, and the GSIB surcharge requirement and will seek to mitigate any potential redundancies.

*C. Changes to the Annual Effective Date of the Stress Capital Buffer Requirement*

Under the proposal, the annual effective date of the stress capital buffer requirement would have been extended by one quarter for all firms subject to the stress capital buffer requirement. Specifically, the effective date of a firm's updated stress capital buffer requirement would have been moved to January 1 of the year immediately following the calendar year in which the capital plan was submitted, which represents an extension of one quarter from the current effective date of October 1. This revision would help to alleviate the challenges that firms can face due to large and unexpected changes in capital requirements by providing firms with additional time to comply with updated stress capital buffer requirements. The Board is

[42] The definition of ''material'' model changes in the enhanced transparency and public accountability proposal for the purpose of seeking public input is different from the Stress Testing Policy Statement's definition of ''highly material'' model changes for the purpose of the phase-in of these model changes. *See* 90 FR 51856 (Nov. 18, 2025), available at *https://www.federalregister.gov/d/2025-20211.*

[43] One commenter recommended specific changes to the modeling of non-interest expenses, including adding more granular sub-categories, such as marketing expenses, and adjusting the modeling of these specific sub-categories.

[44] Adjustments to supervisory stress test models are regularly described in the annual Federal Reserve Stress Test Results disclosure. For example, see Box 1 in Board of Governors of the Federal Reserve System, *2025 Federal Reserve Stress Test Results* (June 2025), *https://www.federalreserve.gov/publications/files/2025-dfast-results-20250627.pdf.*

[45] *See* 88 FR 64028 (Sept. 18, 2023).

[46] *See* 90 FR 51856 (Nov. 18, 2025), available at *https://www.federalregister.gov/d/2025-20211.*

[47] *See* Board, Press Release (Mar. 19, 2026), *https://www.federalreserve.gov/newsevents/pressreleases/bcreg20260319a.htm.*

addressing additional changes to the stress test and stress capital buffer requirement timelines in a separate rulemaking.

Commenters generally supported moving the annual effective date to January 1, noting that it would help firms optimize management buffers and better conduct end-of-year capital planning. One commenter asserted that moving the effective date to January 1 would create alignment with the annual GSIB surcharge requirement effective date for applicable firms, reducing the volatility and number of annual changes to regulatory capital requirements. By contrast, one commenter argued that the implementation date should remain October 1 in the year which the stress test is conducted to maximize the risk sensitivity of the stress capital buffer requirement.

Consistent with the proposal, the final rule extends the annual effective date of the stress capital buffer requirement by one quarter from October 1 to January 1. Providing an additional three months for a firm to meet an updated stress capital buffer requirement will increase a firm's ability to make any adjustments to its capital planning and, as necessary, increase retain earnings to comply with a new requirement. In combination with results averaging, extending the effective date would help to alleviate the impact of large changes in stress capital buffer requirements.

*D. Changes to the FR Y–14 Reporting Forms*

Under the proposal, the FR Y–14A/Q/M reports would have been extended for three years and modified to collect additional information on a firm's PPNR, which would improve the calculation of a firm's stress capital buffer requirement. Specifically, the proposed revisions would have collected: (1) more granular data on compensation expenses and (2) information on non-recurring expenses. The proposed revisions would have been effective for the December 31, 2025, report date.

The FR Y–14Q, Schedule G (PPNR) does not currently segment the portion of total compensation that is variable in a firm's business. To ensure the supervisory stress test more accurately reflects a firm's compensation structure, the proposal would have added two new items related to wealth management (WM) and financial advisory (FA) activities, along with compensable revenues and commissions on compensable revenues to Schedule G (items 28.F (Compensable Revenues) and 28.G (Commissions from WM or FA activities)). The proposal would also have added corresponding revisions to the FR Y–14A, Schedule A.7.a (PPNR Projections).

Currently, the FR Y–14A/Q/M reports also do not adequately isolate expenses that are known to be non-recurring, one-time events. To systematically identify non-recurring expenses related to business divestitures and the write-down of consolidated investment entities, the proposal would have revised the instructions for FR Y–14Q, Schedule G.3 (PPNR Metrics), item 47 (Non-recurring PPNR items) to better capture these expenses.

The proposed revisions also would have removed items that were no longer needed to conduct the supervisory stress test, including information on non-interest income from servicing activities, including mortgage servicing rights (MSR). Specifically, the proposal would have removed the following items from FR Y–14A, Schedule A.7.a (PPNR Projections Sub-schedule) and FR Y–14Q, Schedule G.1 (PPNR Submission Worksheet):

- Item 14.J (Servicing & Ancillary Fees);
- Item 14.K (MSR Amortization);
- Item 14.L (MSR Value Changes due to Changes in Assumptions/Model Inputs/Other Net of Hedge Performance); and
- Item 14.M (Other).

The proposal also would have revised the instructions for item 14.I (Servicing) on Schedule A.7.a and Schedule G.1 so that the instructions clearly indicate that all non-interest income related to servicing activities should be reported in item 14.I.

These revisions were proposed to strengthen the risk sensitivity of the supervisory stress test and improve the accuracy of the stress capital buffer requirement calculation. The revisions also would have reduced regulatory reporting burden.

Commenters generally supported the proposed revisions to the FR Y–14A/Q/M reports. One commenter recommended additional clarifications to the line items in the proposed revisions. Another commenter recommended that the Board release more information about how it uses data gathered via the reporting forms to allow for more informed public feedback. Other commenters suggested additional enhancements and ways to streamline the regulatory reports. One commenter recommended that the FR Y–14A/Q/M forms be consolidated into a single, standardized reporting template with a dedicated glossary with term definitions. Two commenters recommended further elimination of data elements not used for the supervisory stress test.[48] Two commenters suggested that the reports be aligned with other regulatory reporting forms where practicable, including when changes are made to reports, and that the Board should remove redundant reporting items. One commenter also suggested that the Board provide additional notice ahead of changes to forms and instructions. Another commenter suggested aligning certain items in the FR Y–14A/Q/M reports with U.S. generally accepted accounting principles. This commenter also recommended that the Board establish thresholds to determine the materiality of errors in FR Y–14A/Q/M fields and reflect in instructions that immaterial errors will not be viewed as defects in reporting. The same commenter suggested reducing information currently collected monthly on the FR Y–14M to quarterly. Several commenters made specific suggested changes to line items in the FR Y–14A/Q/M forms.

The Board has approved the extension of the FR Y–14A/Q/M reports for three years, with revisions to collect additional information on compensation expenses and non-recurring expenses. These revisions were approved as proposed, except that, in response to a comment, the Board modified a proposed FR Y–14Q instruction to refer to ''consolidated variable interest entities,'' rather than ''consolidated investment entities,'' in non-recurring PPNR items. The amended terminology is more widely used and consistent with U.S. generally accepted accounting principles and the FR Y–9C reports. These revisions are effective for the June 30, 2027, report date.

Finally, the Board is not adopting the proposed removal of items from FR Y–14Q, Schedule G.1 and FR Y–14A, Schedule A.7.a as certain of these items would be used in the Proposed PPNR Model.[49] Reducing unnecessary regulatory reporting burden remains a goal, and the Board will consider all relevant comments as it develops proposals for further changes to streamline the FR Y–14A/Q/M reports. In particular, the Board is reviewing the reports with the goal of eliminating items that are no longer necessary to conduct the supervisory stress test. However, the Board is not at this time adopting revisions to the FR Y–14A/Q/

[48] As an example, one of these commenters discussed the requirement to report information on loans and securities as of their origination date and suggested that this information is not relevant to the supervisory stress test.

[49] The model documentation is available on the Board's website at: *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2027.htm.*

M reports other than those described here.

## II. Economic Analysis

Consistent with the proposal, the final rule's changes to the Board's supervisory stress testing framework aim to reduce the volatility of capital requirements and provide more time for firms to adjust capital plans in response to updated stress capital buffer requirements. These measures would allow firms to streamline capital planning while maintaining adequate capital to withstand economic shocks. The Board evaluated the potential impacts of these changes on the affected firms and the broader economy.[50]

The economic analysis is structured into five parts. The first part, an overview of the baseline, describes the current state of supervisory stress testing practices up until the effective date of this final rule. The second part presents a discussion of the final rule. The third part presents a discussion of alternatives to the current approach. The fourth part presents estimated changes in the level and volatility of capital requirements resulting from the revised stress capital buffer calculation under the final rule and under reasonable alternatives and provides a detailed discussion of potential costs and benefits of the changes in the final rule.[51] The fifth part includes a detailed discussion of comments on the proposal related to the economic analysis.

### *A. Baseline Analysis*

The current framework prior to the final rule (discussed in detail in Section I of this **SUPPLEMENTARY INFORMATION**) serves as the baseline for the economic analysis. The Board assessed the costs and benefits of the final rule and other policy alternatives (discussed below in Section II.C of this **SUPPLEMENTARY INFORMATION**) relative to this baseline.

Under the current framework, a firm's stress capital buffer requirement is determined based on the stress capital decline and the dividend add-on components and is floored at 2.5 percent of risk-weighted assets. As noted previously, firms subject to Category I–III standards are subject to the supervisory stress test annually, while firms subject to Category IV standards are subject to the supervisory stress test on a two-year cycle, unless they choose, or are otherwise required, to be subject to the annual supervisory stress test. A firm's preliminary stress capital buffer requirement is set in June, and its final stress capital buffer requirement generally becomes part of the firm's ongoing capital requirement on October 1. As a result, firms have approximately one quarter to comply with the updated stress capital buffer requirement.

As discussed in Section I.A.i of this **SUPPLEMENTARY INFORMATION**, a firm's stress capital buffer requirement can change from year to year based on several factors. These factors include changes in the composition of a firm's risk profile, economic conditions since the previous stress test, the severely adverse scenario used in the supervisory stress test, and the supervisory models used in the supervisory stress test.

### *B. Final Rule versus Baseline*

As discussed in detail in Section I of this **SUPPLEMENTARY INFORMATION**, under the final rule, all the elements of the current framework are maintained except that (1) for a firm participating in two consecutive annual supervisory stress tests, the firm's final stress capital buffer requirement is informed by both the current and prior year's supervisory stress test results; and (2) all firms subject to the stress buffer capital requirements have until January 1, instead of October 1, to meet their new stress capital buffer requirements.

Under the final rule, for a firm participating in two consecutive annual supervisory stress tests, the firm's stress capital buffer requirement is set using the average of the stress capital decline components from the current and previous year. The stress capital buffer requirement continues to be based on the most recent stress test results for most firms subject to Category IV standards, which are generally required to participate in the supervisory stress tests every other year. Moreover, regardless of its category, a firm has two quarters to comply with changes in the stress capital buffer requirement, compared to one quarter under the current framework.

### *C. Reasonable Alternatives*

The Board has identified several alternatives to the final rule that could help reduce volatility of stress capital buffer requirements while maintaining the benefits of the stress capital buffer requirement. These alternatives differ in (1) approach to averaging stress capital buffer requirement levels and (2) timelines for compliance. The following section discusses these alternatives and explains how they differ from the baseline and the final rule.

#### Alternative 1: Current Framework With One-Quarter Delay

This alternative deviates from the baseline in that firms would have until January 1, instead of October 1, to comply with stress capital buffer requirements. It does not include results averaging. The calculation of stress capital buffer requirements and the other parts of the supervisory stress testing process otherwise remain the same as the current approach.[52]

#### Alternative 2: Current Framework With Two-Year Averaging

Under this alternative, all the elements of the current framework are maintained except the alternative applies results averaging over the current year and the previous year for firms participating in two consecutive annual supervisory stress tests. For firms that participate in the supervisory stress tests every other year, the stress capital buffer requirement would be based on the most recent stress test results. This alternative differs from the final rule in that the time to comply with a new stress capital buffer requirement is not extended by one quarter.

#### Alternative 3: Current Framework With Three-Year Averaging

Under this alternative, all elements of the current framework are maintained except the alternative applies results averaging over the previous three years. For a firm subject to annual supervisory stress tests, this means that the stress capital buffer requirement in the current year is based on the average of stress capital declines from its three most recent stress tests. For a firm subject to Category IV standards that undergoes supervisory stress tests every other year, this means that in the year that the firm is subject to the supervisory stress test, stress capital buffer requirements are based on the average of stress capital declines in the most recent supervisory stress test and the supervisory stress test that took place two years prior. In the year that the firm is not subject to the supervisory stress test, stress capital

[50] The Board is separately finalizing the enhanced transparency and public accountability proposal to increase the transparency and public accountability of the stress test. Sections V and VII of that final rule's preamble include an estimate of the impact from changes to stress test models and economic analysis of the final rule, respectively. *See* enhanced transparency and public accountability final rule, sections V and VII.

[51] For more information on the models and bank-provided data, see Board of Governors of the Federal Reserve System, *2025 Supervisory Stress Test Methodology* (June 2025), *https://www.federalreserve.gov/publications/files/2025-june-supervisory-stress-test-methodology.pdf*.

[52] Note that, under the current framework, the dividend add-on component covers dividends issued from quarters four through seven of the stress test planning horizon (four quarters in total). In alternatives with a one-quarter delay, this component would shift to cover quarters five through eight.

buffer requirements are, in effect, solely based on the results from the prior year's test because the calculation considers the average of only one number. Under this alternative, if a firm does not participate in the supervisory stress test, the stress capital decline for that year is treated as a missing observation for the purposes of computing the firm's stress capital buffer requirement. This alternative deviates from results averaging under the final rule, which applies over a two-year period. Additionally, under this alternative, stress capital buffer requirements for firms subject to Category IV standards would automatically incorporate some averaging, while under the final rule, stress capital buffer requirements for these firms would generally not incorporate results averaging.

Alternative 4: Current Framework With Asymmetric Two-Year Averaging With One-Quarter Delay

Under this alternative, all the elements of the current framework remain the same with two exceptions: (1) a firm would have until January 1, instead of October 1, to comply with its stress capital buffer requirement, and (2) for a firm participating in two consecutive annual supervisory stress tests, the firm's final stress capital buffer requirement is informed by the current year's as well as last year's supervisory stress test results. If a firm's stress capital decline component based on the current year's stress test is larger than the projected decline from the prior year's stress test, then its stress capital decline component would be based on the average of these two results. However, if the stress capital decline component from the current year's stress test is smaller than the decline in the prior year's stress test, the firm's stress capital decline component would be based on only the current year's supervisory stress test results. For firms that participate in the supervisory stress tests every other year, the stress capital decline component would be based on the most recent stress test results. This alternative deviates from the final rule, which applies the averaging of the stress capital decline component on a symmetrical basis.

Alternative 5: Current Framework With Tailored Stress Test Averaging With One-Quarter Delay

Under this alternative, all elements of the current framework are maintained except that (1) a firm would have until January 1, instead of October 1, to comply with its stress capital buffer requirement, and (2) results averaging would be applied (a) over the previous two years for firms participating in two consecutive annual supervisory stress tests; and (b) up to three years for firms that are subject to the supervisory stress test tests once every two years. For a firm participating in two consecutive annual supervisory stress tests, this means that the stress capital buffer requirement in the current year is informed by the average of the stress capital decline components from its two most recent stress tests. For a firm subject to Category IV standards that undergoes supervisory stress tests every other year, this means that in the year that a firm is subject to the supervisory stress test, its stress capital buffer requirement is informed by the average of the stress capital decline components in the most recent supervisory stress test and in the supervisory stress test that took place two years prior. In the year that the firm is not subject to the supervisory stress test, its stress capital buffer requirement is solely informed by the results from the prior year's test. This alternative deviates from results averaging in the final rule and Alternative 2, which applies over a two-year period for all firms. It also deviates from results averaging under Alternative 3, which applies over a three-year period for all firms.

*D. Analysis of Benefits and Costs*

This section provides an assessment of the benefits and costs of the final rule and alternatives relative to the current framework. The final rule and alternatives presented in the previous sections have different benefits and costs that arise from their different implications for the volatility of the stress capital buffer requirement, its average level, its sensitivity to current risks, and the timeliness of stress capital buffer requirement revisions.

1. Estimated Changes in Stress Capital Buffer Requirement Outcomes Under the Final Rule and the Alternatives

The Board recalculated stress capital buffer requirements using historical data to quantitatively describe what the stress capital buffer requirement results would have been under the final rule and each alternative. This analysis provides an understanding of how the changes in the final rule would have affected capital requirements in recent years. The results are presented in Table 1.

The analysis in Table 1 uses supervisory stress test results from 2018 to 2025.[53] This data is used to project stress capital buffer requirements under the final rule from 2020 to 2025 and compares them to the actual stress capital buffer requirements over this period. The sample does not include results from the 2026 supervisory stress test because these results were not used to inform stress capital buffer requirements.[54] The analysis sample includes all firms that received a stress capital buffer requirement in any given year, even if that firm was not subject to the supervisory stress test in that year. Results are presented as averages for each firm category and for the entire sample. The table reports average stress capital buffer requirements in percentage points, average year-over-year absolute changes in firm-specific stress capital buffer requirement levels in basis points, time to comply under each alternative in quarters, and average data-to-implementation gap in months.

The analysis presented in Table 1 differs from the analysis presented in the proposal because the analysis presented in the final rule incorporates the preliminary results for the 2025 supervisory stress test,[55] as well as the revised results for the 2024 supervisory stress test.[56]

[53] Available on Board of Governors of the Federal Reserve System's website at *http://www.federalreserve.gov/publications/dodd-frank-act-stress-test-publications.htm.* The 2018–2019 stress test results have been adjusted to reflect the stress test assumption changes finalized in the rule that established the stress capital buffer requirement.

[54] As noted above, in February 2026, the Board voted to maintain the current stress capital buffer requirements until 2027, when new requirements can be calculated based on models that take public feedback into consideration. *See* Board, Press Release (Feb. 4, 2026), *https://www.federalreserve.gov/newsevents/pressreleases/bcreg20260204a.htm.*

[55] For the stress capital decline component, the final rule's analysis uses 2025 stress test results as of June 27, 2025, when results were published. For the dividend add-on component, the analysis uses planned capital actions as of July 1, 2025. These components are considered preliminary because they could change if the Board were to reconsider results for any firms following the reconsideration request process. A firm may request reconsideration of its preliminary stress capital buffer requirement within fifteen calendar days of receipt of notice of a preliminary stress capital buffer requirement.

[56] On June 27, 2025, the Board released corrected 2024 stress test results and capital requirements stemming from modest errors in the loss projections for corporate and first-lien mortgage loans. These corrections did not change the aggregate post-stress capital decline in 2024. For a comprehensive list of revisions, *see https://www.federalreserve.gov/publications/files/2024-dfast-results-20240626.pdf.*

TABLE 1—ESTIMATED STRESS CAPITAL BUFFER REQUIREMENT OUTCOMES UNDER BASELINE, FINAL RULE, AND ALTERNATIVES

| | Average stress capital buffer requirement (percent) | Average absolute stress capital buffer requirement year-over-year change (bps) | Time to comply (quarters) | Average data-to-implementation gap (months) |
|---|---|---|---|---|
| **Baseline: Current Framework** | | | | |
| Category I | 3.61 | 46 | 1 | 9 |
| Category II–III | 4.44 | 98 | ..... | 9 |
| Category IV | 3.40 | 45 | ..... | 15 |
| Average | 3.83 | 64 | ..... | 11 |
| **Final Rule: One-quarter Delay and Two-year Averaging** | | | | |
| Category I | 3.66 | 23 | 2 | 18 |
| Category II–III | 4.34 | 73 | ..... | 18 |
| Category IV | 3.39 | 36 | ..... | 18 |
| Average | 3.80 | 47 | ..... | 18 |
| **Alternative 1: One-quarter Delay, No Results Averaging** | | | | |
| Category I | 3.61 | 47 | 2 | 12 |
| Category II–III | 4.40 | 94 | ..... | 12 |
| Category IV | 3.36 | 43 | ..... | 18 |
| Average | 3.80 | 63 | ..... | 14 |
| **Alternative 2: Two-year Averaging, No Delayed Effective Date** | | | | |
| Category I | 3.65 | 23 | 1 | 15 |
| Category II–III | 4.38 | 76 | ..... | 15 |
| Category IV | 3.43 | 38 | ..... | 15 |
| Average | 3.83 | 48 | ..... | 15 |
| **Alternative 3: Three-year Averaging, No Delayed Effective Date** | | | | |
| Category I | 3.70 | 24 | 1 | 21 |
| Category II–III | 4.24 | 51 | ..... | 21 |
| Category IV | 3.34 | 38 | ..... | 21 |
| Average | 3.75 | 39 | ..... | 21 |
| **Alternative 4: Asymmetric Two-year Averaging, One-quarter Delay** | | | | |
| Category I | 3.53 | 35 | 2 | 18 |
| Category II–III | 4.15 | 72 | ..... | 18 |
| Category IV | 3.34 | 38 | ..... | 18 |
| Average | 3.68 | 49 | ..... | 18 |
| **Alternative 5: Tailored Stress Test Averaging, No Delayed Effective Date** | | | | |
| Category I | 3.65 | 23 | 2 | 18 |
| Category II–III | 4.37 | 76 | ..... | 18 |
| Category IV | 3.35 | 39 | ..... | 22 |
| Average | 3.79 | 48 | ..... | 20 |

Under the current framework and under alternatives that do not require results averaging, a firm's stress capital buffer requirement in a given year is calculated as the common equity tier 1 ratio decline in the supervisory stress test plus the dividend add-on component for that particular year,[57] and is floored at 2.5 percent. The dividend add-on component is calculated by summing four quarters of projected common dividends and dividing that total by risk-weighted assets.

Under results averaging, a firm's stress capital buffer requirement for a given year is calculated as the average of the common equity tier 1 capital ratio declines observed in the supervisory stress tests of the current and previous years plus the dividend add-on for that particular year, with the result floored at 2.5 percent. Volatility is measured as the absolute value of the year-on-year change in the stress capital buffer requirement.

The average data-to-implementation gap is defined as the average time elapsed between the date of the financial statements used for stress capital buffer requirement calculations

[57] Firms' dividend plans impact the estimates of volatility of the stress capital buffer requirement. If changes in firms planned dividends move in opposite direction of the changes in stress test results, reliance on historical observations of the dividend add-on component could overstate volatility under results averaging.

and the effective date of those requirements. The supervisory stress test results published in June primarily use financial data as of December 31, with the resulting stress capital buffer requirement becoming effective on October 1 of the same year. This process results in a time lag of 9 months. In contrast, a two-year averaging regime would incorporate financial statements from both the previous two year-ends. This approach yields an average time lag of 15 months, calculated as the mean of 9 months (for the most recent data) and 21 months (for the older data). Further, extending the effective date by one quarter would add 3 months to the data-to-implementation gap calculation. In other words, the final rule, which involves two-year averaging and a one-quarter delay, would yield an average data-to-implementation gap of 18 months, calculated as the mean of 12 months for most recent data and 24 months for the older data.

As expected, options with averaging tend to feature less volatility in the stress capital buffer requirement, while options with delayed effective dates provide firms more time to comply. Another observation from this analysis is that the interaction of results averaging with the 2.5 percent floor can lead to a small reduction in the overall level of stress capital buffer requirements. Such a reduction can occur when the requirement for a specific firm is at the 2.5 percent floor one year and above the floor in another. This nonlinear effect impacts a firm if its stress capital buffer requirement fluctuates around the 2.5 percent floor instead of being consistently above or equal to the floor.[58]

2. Cost-Benefit Analysis of Final Rule Relative to Baseline

As shown in Table 1, the final rule reduces year-over-year changes in a firm's stress capital buffer requirement from an average of 64 basis points under the current framework to 47 basis points (a decline of about 27 percent). The final rule generally maintains the current average level of the stress capital buffer requirement. Under the final rule, the average stress capital buffer requirement is 3.80 percentage points, slightly lower than the average under the current framework (3.83). The addition of the 2025 stress capital decline components results in a larger reduction in the volatility of stress capital buffer requirements than was shown in the proposal's economic analysis.[59] Firms' estimated time to comply with the stress capital buffer requirement is one quarter more than under the current framework, and the average data-to-implementation gap increases by seven months.

Costs

The primary concern with this approach is the slower responsiveness of stress capital buffer requirements to changes in firm risk profiles and economic conditions. Averaging results over two years and incorporating a longer gap between the estimation of stress capital buffer requirements and their effective dates can result in a less timely requirement.

The final rule's results averaging has an uneven impact across firm categories. While results averaging meaningfully reduces the volatility of the stress capital buffer requirements for firms subject to annual supervisory stress tests (as shown in Table 1), it offers minimal reduction in volatility to firms subject to biennial supervisory stress tests. These firms face less volatility than firms subject to supervisory stress test on an annual basis as they are only subject to supervisory stress test every other year. However, this difference does not mean firms subject to Category IV standards do not benefit from the final rule, as these firms can choose to be subject to results averaging by participating in consecutive annual supervisory stress tests. In addition, the one-quarter extension of the stress capital buffer requirement's effective date in the final rule applies to firms of all categories.

Benefits

The final rule provides more stable capital requirements for firms. By smoothing the impact of annual fluctuations in supervisory stress test results, firms may be able to develop more consistent long-term capital strategies. This stability could potentially lead to more sustainable lending and other financial intermediation practices and reduce the effects that sudden changes in capital requirements could have on firms and the U.S. economy. The final rule would also reduce the likelihood of firms needing to take action to meet a sharp increase in in stress capital buffer requirements.

Reduced volatility in capital requirements would mitigate the likelihood of firms needing to raise external capital, reduce dividends, and/or shrink balance sheets and the provision of banking services in response to an unexpected and material increase in the stress capital buffer requirement.

In addition, the extended timeline would further enable better planning and decision-making by firms. With an additional three months, firms can more thoroughly assess options for meeting new stress capital buffer requirements, lessening the risk of a curtailment in credit provisioning or other services. Moreover, firms would have additional time to retain earnings and better prepare to manage large increases in stress capital buffer requirements before turning to raising external financing or changing their business activities. In the long run, this extended compliance period could potentially lead to lower management buffers as well. As a firm has more time to adjust and plan, it may feel less pressure to maintain large discretionary buffers to deal with stress capital buffer requirement uncertainty. The increased predictability and reduced time pressure could allow firms to operate with capital levels that more closely align with activities and risk exposures, improving capital efficiency without meaningfully affecting safety and soundness.

3. Cost-Benefit Analysis of Other Policy Alternatives

Alternative 1: Baseline With One-Quarter Delay, No Results Averaging

Alternative 1 maintains the benefits and costs associated with the additional three months to meet changes in the stress capital buffer requirement, as discussed above. However, merely postponing the implementation date does not significantly alter the volatility of the stress capital buffer requirement.[60] An advantage of this alternative relative to the final rule is, however, its simplicity. While maintaining the current risk sensitivity of the stress capital buffer requirement, this extension would benefit all firms subject to Category I–IV standards without significantly altering the current regulatory framework.

Overall, while this alternative is expected to provide positive net benefits

[58] The nonlinear effect reflects a mathematical result known as Jensen's inequality, which states that for a convex function, the function evaluated at the average of two or more values is less than or equal to the average of the function evaluated at those same values.

[59] Without 2025 data and revised 2024 data, the proposal would have reduced year-over-year changes in firms' stress capital buffer requirements from an average of 65 basis points to 54 basis points (a change of about 17 percent). *See* 90 FR 16843 (April 22, 2025). Table 1, Estimated Stress Capital Buffer Requirement Outcomes Under Baseline, Proposal and Alternatives. pg., 16853.

[60] The slight differences in average levels and year-over-year change values between Alternative 1 and the baseline are due to the shift in the dividend add-on component coverage period, as mentioned earlier. This shift results from the one-quarter delay in implementation under Alternative 1.

compared to the baseline, it offers smaller net benefits than the final rule.

Alternative 2: Baseline With Two-Year Averaging, No Delayed Effective Date

Alternative 2 maintains the benefits and costs associated with reduced volatility, as discussed above. Reducing year-over-year fluctuations in capital requirements enhances predictability and stability for firms' capital planning. However, it does not include the benefits and costs related to the added time to come into compliance with changes to the stress capital requirement. Particularly, this alternative offers minimal advantage to firms subject to biennial supervisory stress tests. The final rule, on the other hand, applies results averaging while granting an additional quarter to firms of all categories. The benefit of this approach over the final rule is more timeliness in the stress capital buffer requirement. Overall, while this alternative is expected to provide positive net benefits compared to the baseline, it offers smaller net benefits than the final rule.

Alternative 3: Three-Year Averaging, No Delayed Effective Date

As shown in Table 1, this alternative reduces year-over-year changes in a firm's stress capital buffer requirement from an average of 64 basis points under the baseline to 39 basis points (or about 39 percent), while yielding a modest decline in the aggregate level of the stress capital buffer requirement, from an average of 3.83 percentage points under the baseline to 3.75 percentage points. The time firms have to comply with the new stress capital buffer requirement does not change under this alternative relative to the baseline.

The main drawback of Alternative 3 is reduced timeliness and sensitivity to current economic conditions and firm risk profiles. This alternative leads to an even higher time gap due to averaging over a longer time horizon, as shown by an average data-to-implementation gap of 21 months. This difference may lead to a more pronounced disconnect between regulatory requirements and the risks on firms' balance sheets, potentially lowering the effectiveness of the capital adequacy framework for firms.

This approach shares similar benefits as in the final rule and Alternative 2 in that by averaging out the impact of annual fluctuations in stress test results, firms can develop more consistent, long-term capital planning strategies that potentially lead to more sustainable lending practices and reduce the effects that sudden changes in capital requirements might have on the broader economy. Another benefit relative to the final rule and Alternative 2 is that most firms subject to Category IV standards would benefit from an additional reduction in the volatility of their stress capital buffer requirements due to results averaging. In addition, the treatment of firms subject to Category IV standards would be more consistent with the approach for firms subject to Category I–III standards as all firms would receive the benefits of results averaging.

Alternative 4: Asymmetric Two-Year Averaging With One-Quarter Delay

Alternative 4 maintains the benefits and costs associated with the additional three months to meet changes in the stress capital buffer requirement, as discussed above. It also maintains some of the benefits and costs associated with reduced volatility. Table 1 in section D shows that the average year-over-year volatility decreases from 64 basis points under the baseline to 49 basis points under this alternative (a reduction of about 23 percent). This alternative lowers the average stress capital buffer requirement levels relative to historical values (a reduction from 3.83 percent under the baseline to 3.68 percent under this alternative). The latter result indicates that, relative to the baseline and the final rule, averaging only when stress capital declines in the supervisory stress tests are larger would lead to a lower stress capital buffer requirement.

Further, the results in Table 1 demonstrate that this alternative would not reduce stress capital buffer requirement volatility as much as the final rule, which saw a reduction in volatility of about 27 percent. This difference can be attributed to two offsetting factors. First, asymmetric averaging does not smooth out decreases, which contribute to volatility. Thus, this factor increases volatility relative to the final rule. However, the 2.5 percent floor becomes binding more frequently under this alternative, which tends to reduce volatility. The floor becomes binding more frequently because this alternative lowers the average level of the stress capital buffer, as explained above, making the floor more relevant.

Similar to the final rule, a cost of this alternative is slower responsiveness of stress capital buffer requirements to changes in firm risk profiles and economic conditions. Another cost of this alternative is that applying averaging only when stress capital decline components are steeper would lead to modestly lower stress capital buffer requirements, on average. This could slightly reduce the safety and soundness of covered firms.

An advantage of this method is its alignment with the asymmetric costs firms face when adjusting their capital in response to changing capital requirements. While responding to increases in capital requirements can be costly and challenging for firms, especially over short periods, firms typically find it easier and less costly to adjust capital levels downward. This alternative acknowledges this asymmetry, allowing for more rapid capital reductions when the stress capital decline component is smaller, while providing more time for firms to prepare against sudden, potentially disruptive increases in capital requirements when the stress capital decline component is larger. As a result, this alternative may offer a less expensive framework for firms to manage their capital levels.

Alternative 5: Tailored Stress Test Averaging, No Delayed Effective Date

As shown in Table 1, this alternative reduces year-over-year changes in a firm's stress capital buffer requirement from an average of 64 basis points under the baseline to 48 basis points (or about 25 percent), while yielding a modest decline in the aggregate level of the stress capital buffer requirement, from an average of 3.83 percentage points under the baseline to 3.79 percentage points.

Alternative 5 shares the general costs and benefits of alternatives involving averaging. An additional benefit relative to the final rule is that firms subject to Category IV standards, which face less volatility in the current framework as they are only subject to supervisory stress tests every other year, would benefit from a further reduction in stress capital buffer requirement volatility. Moreover, an advantage over the three-year averaging for all firms (Alternative 3) is that this method extends averaging results up to three years only to those firms subject to biennial supervisory stress tests. Consequently, it has a significantly smaller overall average gap between data collection and implementation.

The downside of this alternative relative to the final rule and alternatives that are based on two-year averaging is that for most firms subject to Category IV standards, this alternative would reduce the ability for a timely adjustment of stress capital buffer requirements in response to new risks or rapid shifts in the economic landscape.

*E. Comments Related to Economic Analysis*

The Board received several comments related to the economic analysis and the alternatives included in the proposal.

Several commenters argued in favor of one of the alternatives presented in the proposal, while others suggested new potential alternatives. As noted previously, several commenters argued that a final rule should adopt an asymmetric averaging approach while other commenters expressed opposition. The asymmetric averaging approach is similar to Alternative 4 in this economic analysis, and its benefits and costs are discussed in detail in the prior subsection.

Two commenters suggested a weighted averaging approach, which was not included as an alternative for impact analysis in the proposal. Under this alternative, a firm's stress capital buffer requirement would be based on a weighted average of its stress capital decline components from the current and previous years, with the current year weighted more than the previous year. For example, one commenter suggested a 60 percent weight for the current year and a 40 percent weight for the previous year.[61] For firms that participate in the supervisory stress test every other year, the stress capital buffer requirement would be based on the most recent supervisory stress test results. This alternative differs from the final rule by using a weighted average instead of an equal-weighted average. The suggested 60–40 weighting falls between the current practice (which assigns 100 percent weight to the current year's supervisory stress test results and 0 percent to the previous year) and the final rule (which assigns 50 percent weight to each year). Under this alternative, the current year's supervisory stress test results would have a larger impact than the prior year's results on a firm's stress capital buffer requirement, but not as large as under the current practice. Therefore, the changes in the volatility of the stress capital buffer requirement under this alternative would fall between those of the current practice and the final rule, which are discussed previously in the economic analysis.

One advantage of this alternative method relative to the final rule is its slightly higher risk sensitivity. By placing more weight on the current year and less weight on the prior year, the alternative would incorporate more current firm risks and macroeconomic conditions, as measured by the most recent supervisory stress test. A cost of this alternative would be its increased complexity, as a weighted average could further complicate the interpretation of stress capital buffer requirements, and its reduced impact on volatility.

One commenter expressed concern that results averaging could lead to lower overall capital levels by incentivizing banks to reduce management buffers, potentially increasing shareholder payouts through share buybacks and dividends. The commenter suggested that recent history shows banks tend to distribute capital to shareholders when facing lower capital requirements, rather than allocating it to more socially productive uses. It is important to clarify that the goal of the rule is to reduce volatility in stress capital buffer requirements, not to reduce their overall level. The analysis provided above demonstrates that while the final rule reduces average year-over-year changes in stress capital buffer requirements, it generally maintains the average level of stress capital buffer requirements.

Some commenters expressed concern about the depth and timeliness of the cost-benefit analysis provided in the proposed rule. These commenters suggested that the analysis offers vague statements about potential benefits and costs without providing detailed quantitative analysis or a comprehensive comparison of these factors. Commenters also noted that the proposed rule does not adequately describe how it intersects with other related requirements, proposals, and upcoming proposals, such as those concerning stress testing, Basel III implementation, the GSIB surcharge requirement, and the enhanced supplementary leverage ratio requirement. Commenters expressed concern about the potential for incorrectly calibrated stress capital buffer requirements due to the intersection with other capital requirements. Another commenter recommended that the Board consider the overall effect on bank capital levels as part of the economic analysis, rather than just the impact on stress capital buffer requirements.

The economic analysis in the final rule focuses specifically on the changes to the stress capital buffer requirement calculation method and implementation timeline. The Board's approach involves using historical data from the past five years of stress capital buffer requirements to recalculate what the levels and volatility of capital would have been if the final rule had been in place during this period. Importantly, the Board does not assume any changes in scenarios, models, banks' starting levels of capital and risk-weighted assets, or projected values to estimate these effects. This approach allows for a clear assessment of the final rule's potential impact based on historical data, while maintaining consistency with existing methodologies and assumptions. By isolating the effects of the specific modifications to the stress capital buffer requirement, the Board provides a straightforward comparison between the current framework and the framework adopted in the final rule.

Other related requirements, proposals, and upcoming potential proposals, such as those concerning supervisory stress testing, Basel III implementation, the GSIB surcharge requirement, and the enhanced supplementary leverage ratio requirement, may impact a firm's sensitivity to risk or its starting financial condition or both. Resulting changes to a firm's balance sheet or risk profile could alter supervisory stress test outcomes. The final rule and the current rule differ in how such changes in capital decline translate into the stress capital buffer requirements. Under the final rule, it would take longer for the stress capital buffer requirement to fully reflect any such change due to results averaging. Conversely, under the current rule, any change in capital decline would be fully reflected in the current year's stress capital buffer requirement.

Therefore, the interaction between this rule and other capital requirements primarily affects how the calculated stress capital decline component translates into the final stress capital buffer requirement, not how the stress capital decline component itself is calculated. This distinction suggests that the above cost-benefit analysis sufficiently and intuitively demonstrates how the impact of any change in stress capital decline component would be comparable under the final rule and current rule.

One commenter pointed out that the capital impact projections included in the proposed rule may be outdated, given that the Federal Reserve has since announced its 2025 supervisory stress test results. The commenter suggested that the Board should provide updated analyses and allow additional time for public comment based on this new information. Regarding the timeliness of the data, the Board has updated its analysis using the 2025 supervisory stress test data and revised the calculations provided in the proposal. The multi-year historical dataset helps account for variations across different economic cycles and stress scenarios.

[61] Another commenter supported the concept of a weighted averaging approach but did not specify the percentages to apply to each year's stress test results.

As described above, the Board did not include the 2026 supervisory stress test data in its analysis, because the results of the 2026 stress test did not inform stress capital buffer requirements.[62]

## III. Administrative Law Matters

### *A. Paperwork Reduction Act*

In accordance with the requirements of the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), the Board 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 Board reviewed the information collections related to the final rule under the authority delegated to the Board by OMB.

The final rule would not create any information collections subject to the PRA; however, the Board revised the FR Y–14 reports to improve supervisory stress test modeling and the calculation of stress capital buffer requirements by enhancing the collection of information used to assess a firm's risk profile. Specifically, the revisions implement various changes that would isolate non-recurring expenses and increase the granularity of data on compensation expenses. The Board received 7 public comments on the PRA for the FR Y–14, which are discussed in detail above. The Board has adopted the revisions with amendments from the proposal. Specifically, the Board amended the FR Y–14Q instructions from the proposal to clarify the definition of one line item in response to a comment and is not adopting the proposed removal of certain FR Y–14 items.

Proposal Under OMB Delegated Authority To Extend for Three Years, With Revision, the Following Information Collection

*Collection title:* Capital Assessments and Stress Testing Reports.

*Collection identifier:* FR Y–14A/Q/M.

*OMB control number:* 7100–0341.

*General description of collection:* This family of information collections is composed of the following three reports:

- The annual FR Y–14A collects quantitative projections of balance sheet, income, losses, and capital across a range of macroeconomic scenarios and qualitative information on methodologies used to develop internal projections of capital across scenarios.[63]
- The quarterly FR Y–14Q collects granular data on various asset classes, including loans, securities, trading assets, and PPNR for the reporting period.
- The monthly FR Y–14M is comprised of three retail portfolio- and loan-level schedules, and one detailed address-matching schedule to supplement two of the portfolio- and loan-level schedules.

The data collected through the FR Y–14A/Q/M reports (FR Y–14 reports) provide the Board with the information needed to help ensure that large firms have strong, firm-wide risk measurement and management processes supporting their internal assessments of capital adequacy and that their capital resources are sufficient, given their business focus, activities, and resulting risk exposures. The data within the reports are used in connection with setting firms' stress capital buffer requirements. The data are also used to support other Board supervisory efforts aimed at enhancing the continued viability of large firms, including continuous monitoring of firms' planning and management of liquidity and funding resources, as well as regular assessments of credit risk, market risk, and operational risk, and associated risk management practices. Information gathered in this collection is also used in the supervision and regulation of respondent financial institutions. Respondent firms are currently required to complete and submit up to 17 filings each year: one annual FR Y–14A filing, four quarterly FR Y–14Q filings, and 12 monthly FR Y–14M filings.[64] Compliance with the information collection is mandatory.

*Current Actions:* The final rule modifies the FR Y–14A/Q/M reports in order to collect additional information on a firm's pre-provision net revenue, which will improve the calculation of the firm's stress capital buffer requirement. Specifically, the revisions collect (1) more granular data on compensation expenses, and (2) information on non- recurring expenses. All revisions are effective for the June 30, 2027, report date.

Compensation Expenses

Total compensation expense is composed of salaries, variable pay, and employee benefits. The compensation structure for certain business lines, including financial advisors in a firm's wealth management business, is generally determined as a ratio of compensable revenue, which is a portion of total revenue attributable to the financial advisor. As a result, the key driver of compensation change is the amount of compensable revenue generated. During a period of economic stress, this form of variable pay may decline quickly. This differs from fixed compensation expenses, such as salaries, which tend to be more stable during periods of stress because a firm may take time to assess the severity of the downturn before determining if reductions are appropriate.

FR Y–14Q, Schedule G (PPNR) does not currently segment the portion of total compensation that is variable in a firm's business. Therefore, the supervisory stress test may not adequately consider the role of variable compensation or the correlation between compensation and compensable revenue. To ensure that the supervisory stress test results reflect this compensation structure, the Board is adding two new items to Schedule G (items 28.F (Compensable Revenues) and 28.G (Commissions from WM or FA activities)) to capture data on compensable revenues and commissions on the compensable revenues. For consistency between the FR Y–14Q and the FR Y–14A, the Board also made corresponding revisions to FR Y–14A, Schedule A.7.a (PPNR Projections).

Non-Recurring Expenses

Non-recurring expenses are extraordinary or one-time expenses that are not expected to occur in the future. These expenses are distinct from recurring expenses which occur on a regular basis. The FR Y–14 reports do not currently adequately isolate expenses that are known to be due to one-time events.

As non-recurring expenses are not expected to repeat in the future, it may be appropriate to mitigate the influence of these expenses when calculating a firm's stress capital buffer requirement. To systematically identify non-recurring expenses related to business divestitures and the write-down of consolidated investment entities, the Board is revising the instructions for FR Y–14Q, Schedule G.3 (PPNR Metrics), item 47 (Non-recurring PPNR items) to better capture these expenses. Capturing data on these non-recurring expenses would strengthen the risk sensitivity of the supervisory stress test since the Board would have a more comprehensive

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[62] *See* Board, Press Release (Feb. 4, 2026), *https://www.federalreserve.gov/newsevents/pressreleases/bcreg20260204a.htm.*

[63] In certain circumstances, a firm may be required to re-submit its capital plan. See 12 CFR 225.8(e)(4); 12 CFR 238.170(e)(4). Firms that must re-submit their capital plan generally also must provide a revised FR Y–14A in connection with their resubmission.

[64] Holding companies that do not meet the materiality thresholds described in the instructions for the FR Y–14M are not required to file that report. This results in some holding companies submitting less than 17 filings each year.

picture of a firm's expenses and net income.

Non-Interest Income From Servicing Activities

The Board also proposed to remove several items that capture information related to non-interest income from servicing activities. Specifically, the Board proposed to remove the following items from FR Y–14A, Schedule A.7.a (PPNR Projections Sub-schedule) and FR Y–14Q, Schedule G.1 (PPNR Submission Worksheet):

- Item 14.J (Servicing & Ancillary Fees);
- Item 14.K (MSR Amortization);
- Item 14.L (MSR Value Changes due to Changes in Assumptions/Model Inputs/Other Net of Hedge Performance); and
- Item 14.M (Other).

However, since the proposal, these items have been incorporated into the PPNR model proposed to be used in the 2027 stress test. Therefore, the Board is not adopting the proposed revision to remove these items from Schedule G.1 and Schedule A.7.a as they continue to be necessary to conduct the supervisory stress test.

*Frequency:* Annually, quarterly, and monthly.

*Respondents:* Holding companies with $100 billion or more in total consolidated assets, as based on (1) the average of the firm's total consolidated assets in the four most recent quarters as reported quarterly on the firm's Consolidated Financial Statements for Holding Companies (FR Y–9C; OMB No. 7100–0128) or (2) the average of the firm's total consolidated assets in the most recent consecutive quarters as reported quarterly on the firm's FR Y–9Cs, if the firm has not filed an FR Y–9C for each of the most recent four quarters.

*Total estimated number of respondents:* 35.

*Total estimated change in burden:* 0.

*Total estimated annual burden hours:* 760,428.[65]

*B. Regulatory Flexibility Act*

The Regulatory Flexibility Act (RFA) generally requires that, in connection with a final rulemaking, an agency prepare and make available for public comment a final regulatory flexibility analysis describing the impact of the final rule on small entities.[66] However, a final regulatory flexibility analysis is not required if the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Under regulations issued by the U.S. Small Business Administration (SBA), a small entity includes a depository institution, bank holding company, or savings and loan holding company with total assets of $850 million or less.[67] For the reasons described below and under section 605(b) of the RFA, the Board certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

In connection with the proposed rule, the Board stated that it did not believe the proposed rule would have a significant economic impact on a substantial number of small entities. Nevertheless, the Board published and invited comment on an initial regulatory flexibility analysis of the proposed rule. No comments were received on the initial regulatory flexibility analysis.

The Board is finalizing amendments to Regulations Y,[68] LL,[69] and YY [70] that would affect the regulatory requirements that apply to bank holding companies, U.S. intermediate holding companies of foreign banking organizations, and savings and loan holding companies, each with at least $100 billion in total consolidated assets, as well as certain nonbank financial companies supervised by the Board and any other bank holding company or covered savings and loan holding company domiciled in the United States that is made subject to the capital plan rule [71] by order of the Board.[72] The reasons and justification for, and economic impacts of, the final rule are described above in more detail in this **SUPPLEMENTARY INFORMATION**.

The Board has considered whether to conduct a final regulatory flexibility analysis in connection with this final rule. However, the assets of entities subject to this final rule substantially exceed the $850 million asset threshold under which a banking organization is considered a ''small entity'' under SBA regulations. Because the final rule is not likely to apply to any entity with assets of $850 million or less, it is not expected to apply to any small entity for purposes of the RFA. The Board does not believe that the final rule duplicates, overlaps, or conflicts with any other Federal rules. In light of the foregoing, the Board certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

*C. Plain Language*

Section 722(a) of the Gram-Leach-Bliley Act (12 U.S.C. 4809(a)) requires the Board to use plain language in its proposed and final rulemakings. In the proposal, the Board invited but did not receive comments on its use of plain language. In the final rule, the Board uses plain language.

**List of Subjects**

*12 CFR Part 225*

Administrative practice and procedure, Banks, banking, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Securities.

*12 CFR Part 238*

Administrative practice and procedure, Banks, banking, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Securities.

*12 CFR Part 252*

Administrative practice and procedure, Banks, Banking, Capital planning, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Securities, Stress testing.

**Authority and Issuance**

For the reasons stated in the preamble, the Board of Governors of the Federal Reserve System amends 12 CFR chapter II as follows:

## PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL (REGULATION Y)

■ 1. The authority citation for part 225 continues to read as follows:

**Authority:** 12 U.S.C. 1817(j)(13), 1818, 1828(o), 1831i, 1831p–1, 1843(c)(8), 1844(b), 1972(1), 3106, 3108, 3310, 3331–3351, 3906, 3907, and 3909; 15 U.S.C. 1681s, 1681w, 6801, and 6805.

### Subpart A—General Provisions

■ 2. In § 225.8:

[65] On May 20, 2026, the Board adopted revisions to the FR Y–14 reports (*see* 91 FR 29485), which impacted estimated FR Y–14 burden hours. As a result, this burden estimate differs from the proposal to reflect the new baseline estimate of FR Y–14 burden hours.

[66] 5 U.S.C. 601 *et. seq.*

[67] *See* 13 CFR 121.201. Consistent with the SBA's General Principles of Affiliation, the Board includes the assets of all domestic and foreign affiliates toward the applicable size threshold when determining whether to classify a particular entity as a small entity. *See* 13 CFR 121.103. As of December 31, 2025, there were approximately 2,395 small bank holding companies, approximately 116 small savings and loan holding companies, and approximately 441 small state member banks.

[68] 12 CFR part 225.

[69] 12 CFR part 238.

[70] 12 CFR part 252.

[71] 12 CFR 225.8; 12 CFR 238.170.

[72] There currently are no entities with less than $100 billion in total consolidated assets subject to the capital plan rule.

■ a. Redesignate paragraphs (d)(20) through (21) as (d)(21) through (22), respectively;
■ b. Add new paragraph (d)(20);
■ c. Revise paragraph (f);
■ d. In paragraph (h)(2)(ii), remove the text ''fourth through seventh'', wherever it appears and add, in its place the text ''fifth through eighth'';
■ e. Revise paragraph (h)(4)(ii)(A);
■ f. Revise paragraph (i)(1) and (i)(3)(i); and
■ g. Remove the text ''fourth'', and add, in its place the text ''fifth'' in paragraph (k)(2).

The revisions and addition read as follows:

**§ 225.8 Capital planning and stress capital buffer requirement.**

* * * * *

(d) * * *

(20) *Stress capital decline* means the ratio of a bank holding company's common equity tier 1 capital to risk-weighted assets, as calculated under 12 CFR part 217, subpart D, as of the final quarter of the previous capital plan cycle, unless otherwise determined by the Board, minus the lowest projected ratio of the bank holding company's common equity tier 1 capital to risk-weighted assets, as calculated under 12 CFR part 217, subpart D, in any quarter of the planning horizon under a supervisory stress test.

* * * * *

(f) *Calculation of the stress capital buffer requirement*—(1) *General.* (i) The Board will determine the stress capital buffer requirement that applies under 12 CFR 217.11 pursuant to this paragraph (f). For each bank holding company that is not a Category IV bank holding company, the Board will calculate the bank holding company's stress capital buffer requirement annually. For each Category IV bank holding company, the Board will calculate the bank holding company's stress capital buffer requirement biennially, occurring in each calendar year ending in an even number, and will adjust the bank holding company's stress capital buffer requirement biennially, occurring in each calendar year ending in an odd number. Notwithstanding the previous sentence, the Board will calculate the stress capital buffer requirement of a Category IV bank holding company in a year ending in an odd number with respect to which that company makes an election pursuant to 12 CFR 252.44(d)(2)(ii). The stress capital buffer requirement calculations described in this paragraph will be conducted using paragraphs (f)(2)(i) or (f)(2)(ii) of this section, as appropriate. The stress capital buffer requirement adjustment described in this paragraph will be conducted using paragraph (f)(4) of this section.

(ii) Unless otherwise determined by the Board, a stress capital buffer requirement that is recalculated pursuant to paragraph (f)(3) of this section will be calculated pursuant to the methodology in paragraph (f)(2)(ii) of this section, except that a stress capital buffer requirement that is recalculated following the resubmission of a capital plan pursuant to paragraph (e)(4)(i)(B)(1) of this section will be calculated pursuant to the methodology in paragraph (f)(2)(i) of this section.

(2) *Stress capital buffer requirement calculation.* (i) For a bank holding company that was subject to the annual supervisory stress test in the previous calendar year or that was provided with a final stress capital buffer requirement that was recalculated pursuant to paragraph (f)(3) of this section in the previous calendar year or earlier in the current calendar year, a bank holding company's stress capital buffer requirement is equal to the greater of:

(A) The following calculation:

(*1*) The average of the stress capital decline of the current capital plan cycle and either the stress capital decline of the capital plan cycle for the previous calendar year or, if the bank holding company's currently effective stress capital buffer requirement was recalculated pursuant to paragraph (f)(3) of this section, the stress capital decline associated with that stress capital buffer requirement; plus

(*2*) The ratio of:

(*i*) The sum of the bank holding company's planned common stock dividends (expressed as a dollar amount) for each of the fifth through eighth quarters of the current planning horizon; to

(*ii*) The risk-weighted assets of the bank holding company in the quarter in which the bank holding company had its lowest projected ratio of common equity tier 1 capital to risk-weighted assets, as calculated under 12 CFR part 217, subpart D, in any quarter of the planning horizon under a supervisory stress test conducted in the current capital plan cycle; and

(B) 2.5 percent.

(ii) For a bank holding company to which paragraph (f)(2)(i) of this section does not apply, a bank holding company's stress capital buffer requirement is equal to the greater of:

(A) The following calculation:

(*1*) The stress capital decline of the current capital plan cycle; plus

(*2*) The ratio of:

(*i*) The sum of the bank holding company's planned common stock dividends (expressed as a dollar amount) for each of the fifth through eighth quarters of the current planning horizon; to

(*ii*) The risk-weighted assets of the bank holding company in the quarter in which the bank holding company had its lowest projected ratio of common equity tier 1 capital to risk-weighted assets, as calculated under 12 CFR part 217, subpart D, in any quarter of the planning horizon under a supervisory stress test conducted in the current capital plan cycle; and

(B) 2.5 percent.

(3) *Recalculation of stress capital buffer requirement.* If a bank holding company resubmits its capital plan pursuant to paragraph (e)(4) of this section, the Board may recalculate the bank holding company's stress capital buffer requirement. The Board will provide notice of whether the bank holding company's stress capital buffer requirement will be recalculated within 75 calendar days after the date on which the capital plan is resubmitted, unless the Board provides notice to the company that it is extending the time period.

(4) *Adjustment of stress capital buffer requirement.* In each calendar year in which the Board does not calculate a Category IV bank holding company's stress capital buffer requirement pursuant to paragraph (f)(1) of this section, the Board will adjust the Category IV bank holding company's stress capital buffer requirement to be equal to the result of the calculation set forth in paragraph (f)(2) of this section, using the same values that were used to calculate the stress capital buffer requirement most recently provided to the bank holding company, except that the value used in paragraph (f)(2)(i)(A)(*2*)(*i*) or paragraph (f)(2)(ii)(A)(*2*)(*i*) of this section, as applicable, will be equal to the bank holding company's planned common stock dividends (expressed as a dollar amount) for each of the fifth through eighth quarters of the planning horizon as set forth in the capital plan submitted by the bank holding company in the calendar year in which the Board adjusts the bank holding company's stress capital buffer requirement.

(5) *Transition period for stress capital buffer requirement calculation.* Notwithstanding paragraph (f)(2)(i) of this section, for all bank holding companies, the calculation of the stress capital buffer requirement occurring in calendar year 2027 will be conducted using paragraph (f)(2)(ii) of this section.

* * * * *

(h) * * *

(4) * * *

(ii) * * *

(A) Be effective on January 1 of the year immediately following the calendar year in which a capital plan was submitted pursuant to paragraph (e)(1)(ii) of this section; and

* * * * *

(i) * * *

(1) *General.* To request reconsideration of a stress capital buffer requirement, provided under paragraph (h) of this section, (specifically, the stress capital decline of the current capital plan cycle) a bank holding company must submit a written request for reconsideration.

* * * * *

(3) * * *

(i) A request for reconsideration must include a detailed explanation of why reconsideration should be granted (that is, why the stress capital decline of the current capital plan cycle should be reconsidered). With respect to any information that was not previously provided to the Federal Reserve in the bank holding company's capital plan, the request should include an explanation of why the information should be considered.

* * * * *

## PART 238—SAVINGS AND LOAN HOLDING COMPANIES (REGULATION LL)

■ 3. The authority citation for part 238 continues to read as follows:

**Authority:** 5 U.S.C. 552, 559; 12 U.S.C. 1462, 1462a, 1463, 1464, 1467, 1467a, 1468, 5365; 1813, 1817, 1829e, 1831i, and 1972; 15 U.S.C. 78*l*.

## Subpart S—Capital Planning and Stress Capital Buffer Requirement

■ 4. In § 238.170:

■ a. Redesignate paragraph (d)(18) as (d)(19);

■ b. Add new paragraph (d)(18);

■ c. Revise paragraph (f);

■ d. In paragraph (h)(2)(ii), remove the text ''fourth through seventh'', wherever it appears and add, in its place the text ''fifth through eighth'';

■ e. Revise paragraph (h)(4)(ii)(A);

■ f. Revise paragraph (i)(1) and (i)(3)(i); and

■ g. Remove the text ''fourth'', and add, in its place the text ''fifth'', in paragraph (k)(2).

The revisions and addition read as follows:

### § 238.170 Capital planning and stress capital buffer requirement.

* * * * *

(d) * * *

(18) *Stress capital decline* means the ratio of a covered savings and loan holding company's common equity tier 1 capital to risk-weighted assets, as calculated under 12 CFR part 217, subpart D, as of the final quarter of the previous capital plan cycle, unless otherwise determined by the Board, minus the lowest projected ratio of the covered savings and loan holding company's common equity tier 1 capital to risk-weighted assets, as calculated under 12 CFR part 217, subpart D, in any quarter of the planning horizon under a supervisory stress test.

* * * * *

(f) *Calculation of the stress capital buffer requirement*—(1) *General.* (i) The Board will determine the stress capital buffer requirement that applies under 12 CFR 217.11 pursuant to paragraph (f) of this section. For each covered savings and loan holding company that is not a Category IV savings and loan holding company, the Board will calculate the covered savings and loan holding company's stress capital buffer requirement annually. For each Category IV savings and loan holding company, the Board will calculate the covered savings and loan holding company's stress capital buffer requirement biennially, occurring in each calendar year ending in an even number, and will adjust the covered savings and loan holding company's stress capital buffer requirement biennially, occurring in each calendar year ending in an odd number. Notwithstanding the previous sentence, the Board will calculate the stress capital buffer requirement of a Category IV savings and loan holding company in a year ending in an odd number with respect to which that company makes an election pursuant to 12 CFR 238.132(c)(2)(ii). The stress capital buffer requirement calculations described in this paragraph will be conducted using paragraphs (f)(2)(i) or (f)(2)(ii) of this section, as appropriate. The stress capital buffer requirement adjustment described in this paragraph will be conducted using paragraph (f)(4) of this section.

(ii) Unless otherwise determined by the Board, a stress capital buffer requirement that is recalculated pursuant to paragraph (f)(3) of this section will be calculated pursuant to the methodology in paragraph (f)(2)(ii) of this section, except that a stress capital buffer requirement that is recalculated following the resubmission of a capital plan pursuant to paragraph (e)(4)(i)(B)(1) of this section will be calculated pursuant to the methodology in paragraph (f)(2)(i) of this section.

(2) *Stress capital buffer requirement calculation.* (i) For a covered savings and loan holding company that was subject to the annual supervisory stress test in the previous calendar year or that was provided with a final stress capital buffer requirement that was recalculated pursuant to paragraph (f)(3) of this section in the previous calendar year or earlier in the current calendar year, a covered savings and loan holding company's stress capital buffer requirement is equal to the greater of:

(A) The following calculation:

(*1*) The average of the stress capital decline of the current capital plan cycle and either the stress capital decline of the capital plan cycle for the previous calendar year or, if the savings and loan holding company's currently effective stress capital buffer requirement was recalculated pursuant to paragraph (f)(3) of this section, the stress capital decline associated with that stress capital buffer requirement; plus

(*2*) The ratio of:

(*i*) The sum of the covered savings and loan holding company's planned common stock dividends (expressed as a dollar amount) for each of the fifth through eighth quarters of the current planning horizon; to

(*ii*) The risk-weighted assets of the covered savings and loan holding company in the quarter in which the covered savings and loan holding company had its lowest projected ratio of common equity tier 1 capital to risk-weighted assets, as calculated under 12 CFR part 217, subpart D, in any quarter of the planning horizon under a supervisory stress test conducted in the current capital plan cycle; and

(B) 2.5 percent.

(ii) For a covered savings and loan holding company to which paragraph (f)(2)(i) of this section does not apply, a covered savings and loan holding company's stress capital buffer requirement is equal to the greater of:

(A) The following calculation:

(*1*) The stress capital decline of the current capital plan cycle; plus

(*2*) The ratio of:

(*i*) The sum of the covered savings and loan holding company's planned common stock dividends (expressed as a dollar amount) for each of the fifth through eighth quarters of the current planning horizon; to

(*ii*) The risk-weighted assets of the covered savings and loan holding company in the quarter in which the covered savings and loan holding company had its lowest projected ratio of common equity tier 1 capital to risk-weighted assets, as calculated under 12 CFR part 217, subpart D, in any quarter of the planning horizon under a

supervisory stress test conducted in the current capital plan cycle; and

(B) 2.5 percent.

(3) *Recalculation of stress capital buffer requirement.* If a covered savings and loan holding company resubmits its capital plan pursuant to paragraph (e)(4) of this section, the Board may recalculate the covered savings and loan holding company's stress capital buffer requirement. The Board will provide notice of whether the covered savings and loan holding company's stress capital buffer requirement will be recalculated within 75 calendar days after the date on which the capital plan is resubmitted, unless the Board provides notice to the company that it is extending the time period.

(4) *Adjustment of stress capital buffer requirement.* In each calendar year in which the Board does not calculate a Category IV savings and loan holding company's stress capital buffer requirement pursuant to paragraph (f)(1) of this section, the Board will adjust the Category IV savings and loan holding company's stress capital buffer requirement to be equal to the result of the calculation set forth in paragraph (f)(2) of this section, using the same values that were used to calculate the stress capital buffer requirement most recently provided to the covered savings and loan holding company, except that the value used in paragraph (f)(2)(i)(A)(2)(*i*) or paragraph (f)(2)(ii)(A)(2)(*i*) of this section, as applicable, will be equal to the covered savings and loan holding company's planned common stock dividends (expressed as a dollar amount) for each of the fifth through eighth quarters of the planning horizon as set forth in the capital plan submitted by the covered savings and loan holding company in the calendar year in which the Board adjusts the covered savings and loan holding company's stress capital buffer requirement.

(5) *Transition period for stress capital buffer requirement calculation.* Notwithstanding paragraph (f)(2)(i) of this section, for all covered savings and loan holding companies, the calculation of the stress capital buffer requirement occurring in calendar year 2027 will be conducted using paragraph (f)(2)(ii) of this section.

* * * * *

(h) * * *

(4) * * *

(ii) * * *

(A) Be effective on January 1 of the year immediately following the calendar year in which a capital plan was submitted pursuant to paragraph (e)(1)(ii) of this section; and

* * * * *

(i) * * *

(1) *General.* To request reconsideration of a stress capital buffer requirement, provided under paragraph (h) of this section, (specifically, the stress capital decline of the current capital plan cycle) a covered savings and loan holding company must submit a written request for reconsideration.

* * * * *

(3) * * *

(i) A request for reconsideration must include a detailed explanation of why reconsideration should be granted (that is, why the stress capital decline of the current capital plan cycle should be reconsidered). With respect to any information that was not previously provided to the Federal Reserve in the covered savings and loan holding company's capital plan, the request should include an explanation of why the information should be considered.

* * * * *

## PART 252—ENHANCED PRUDENTIAL STANDARDS (REGULATION YY)

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

**Authority:** 12 U.S.C. 321–338a, 481–486, 1467a, 1818, 1828, 1831n, 1831o, 1831p–1, 1831w, 1835, 1844(b), 1844(c), 3101 *et seq.,* 3101 note, 3904, 3906–3909, 4808, 5361, 5362, 5365, 5366, 5367, 5368, 5371.

### Appendix B to Part 252—Stress Testing Policy Statement

■ 6. Amend appendix B to part 252 by removing and reserving section 2.3.

By order of the Board of Governors of the Federal Reserve System.

**Michele Taylor Fennell,**

*Associate Secretary of the Board.*

[FR Doc. 2026–20246 Filed 10–1–26; 8:45 am]

**BILLING CODE 6210–01–P**

## SECURITIES AND EXCHANGE COMMISSION

### 17 CFR Part 200

**[Release No. 34–106537]**

### Commission Quorum Requirement

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Final rule.

**SUMMARY:** The Securities and Exchange Commission (''Commission'') is amending its rules concerning the circumstances under which a quorum of the Commission is present. The amendments are designed to promote flexibility and finality of agency rulemaking.

**DATES:** This rule is effective on October 2, 2026.

**FOR FURTHER INFORMATION CONTACT:** Natalie E. Shioji, Senior Special Counsel, Office of the General Counsel, at (202) 551–5100.

**SUPPLEMENTARY INFORMATION:**

### I. Discussion

The Commission is modifying 17 CFR 200.41, which establishes the Commission's quorum requirement. Three commissioners will continue to constitute a quorum of the Commission, with two important exceptions. First, consistent with the current rule, if the number of commissioners in office is two or one, that number is sufficient for a quorum. Second, if the number of commissioners in office minus the number disqualified from consideration with respect to a matter is two or one, then that number of commissioners constitutes a quorum for purposes of that matter.

The Securities Exchange Act of 1934 (''Exchange Act''), unlike many statutes that establish Federal agencies, does not establish a quorum requirement for the Commission. The Commission historically had a general practice that three members constituted a quorum, and in 1995, the Commission adopted a rule formally establishing that practice as a quorum requirement.[1] That rule provided that if the number of Commissioners in office is less than three, then a quorum would consist of the number of Commissioners in office, and it further provided that on any matter of business as to which the number of Commissioners in office, minus the number of Commissioners who were disqualified from consideration of that matter, is two, then two Commissioners would constitute a quorum.[2] The Commission stated, however, that it did not believe that it was necessary at that time to provide that one Commissioner may constitute a quorum when disqualifications resulted in only one Commissioner being available to deal with a particular matter.[3]

The Commission has reconsidered its approach to quorum. In prior years, the Commission has occasionally been in the position of having fewer than three members and believes it prudent to adapt its quorum rule to further accommodate that contingency. Moreover, the Commission has found that situations often arise in which one

[1] *See* 17 CFR 200.41.

[2] *Id.*

[3] *See Establishment of Commission Quorum Requirement,* Release No. 34–35548 (Mar. 30, 1995) [60 FR 17201 (Apr. 5, 1995)].

or more Commissioners have disqualified themselves or are otherwise disqualified from participating in a matter.[4] When such situations arise, it is important that the Commission be able to continue to conduct business. Accordingly, the Commission is amending the quorum rule to specify that, in a situation in which only one Commissioner is able to participate in a matter because all other Commissioners currently in office are disqualified from participating in that matter, the remaining member would constitute a quorum for that particular matter.

### II. Other Matters

The Commission finds, in accordance with the Administrative Procedure Act (the ''APA''), that these amendments relate solely to agency management and organization and do not constitute a substantive rule.[5] Accordingly, the APA's provisions regarding notice of proposed rulemaking and opportunity for public comment are not applicable. These amendments do not substantially affect the rights or obligations of non-agency parties and pertain to the management of internal Commission operations. The changes are effective on October 2, 2026. For the same reasons, the provisions of the Small Business Regulatory Enforcement Fairness Act are not applicable.[6] Additionally, the provisions of the Regulatory Flexibility Act,[7] which apply only when notice and comment are required by the APA or other law, are not applicable.[8] These amendments do not contain any collection of information requirements within the meaning of the Paperwork Reduction Act of 1995.[9] Further, because these amendments impose no new burdens on private parties, the Commission does not believe that the amendments will have any impact on competition for purposes of section 23(a)(2) of the Exchange Act.[10]

### Statutory Authority

The amendments are adopted pursuant to statutory authority granted to the Commission, including sections 4(a) and 23(a) of the Exchange Act, 15 U.S.C. 78d(a) and 78w(a).

[4] *See* 17 CFR 200.60.

[5] *See* 5 U.S.C. 553.

[6] *See* 5 U.S.C. 804(3)(C) (the term ''rule'' does not include ''any rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties'').

[7] 5 U.S.C. 601 *et seq.*

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

[9] *See* 44 U.S.C. 3501 *et seq.*; 5 CFR 1320.3.

[10] 15 U.S.C. 78w(a)(2).

### List of Subjects in 17 CFR Part 200

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

### Text of Rule Amendments

For the reasons set out in the preamble, the Commission is amending title 17, chapter II, part 200 of the Code of Federal Regulations as follows:

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

■ 1. The authority citation for part 200 continues to read in part as follows:

**Authority:** 5 U.S.C. 552b; 15 U.S.C. 78d and 78w.

■ 2. Revise § 200.41 to read as follows:

**§ 200.41 Quorum of the Commission.**

A quorum of the Commission shall consist of three members; provided, however, that if the number of Commissioners in office is less than three, a quorum shall consist of the number of members in office; and provided further that on any matter of business as to which the number of members in office, minus the number of members who either have disqualified themselves from consideration of such matter pursuant to § 200.60 or are otherwise disqualified from such consideration, is two or one, that number of members shall constitute a quorum for purposes of such matter.

By the Commission.

Dated: September 30, 2026.

**Vanessa A. Countryman,**

*Secretary.*

[FR Doc. 2026–20262 Filed 10–1–26; 8:45 am]

**BILLING CODE 8011–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Part 1

**[TD 10057]**

**RIN 1545–BS17**

## Federal Scholarship Tax Credit

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Temporary regulations.

**SUMMARY:** This document contains temporary regulations that address the new nonrefundable Federal tax credit for qualified contributions to scholarship granting organizations made in 2027 and later taxable years to fund qualified elementary and secondary education scholarships. The temporary regulations implement certain requirements and procedures for States that make elections to participate in this Federal tax credit and organizations that have been certified as scholarship granting organizations by one or more participating States. The temporary regulations affect such States and organizations, and individuals who make qualified contributions to scholarship granting organizations.

**DATES:**

*Effective date:* These temporary regulations are effective on December 1, 2026.

*Applicability date:* For dates of applicability, *see* §§ 1.25F–1T(b), 1.25F–4T(f), and 1.25F–5T(f).

**FOR FURTHER INFORMATION CONTACT:** Concerning these temporary regulations, Constance Chien, (202) 317–7009, or Andrew Fahmy, (202) 317–6487 (not toll-free numbers).

**SUPPLEMENTARY INFORMATION:**

### Authority

This document amends 26 CFR part 1 (Income Tax Regulations) by adding temporary regulations that address certain aspects of the application of the credit available for qualified contributions under section 25F of the Internal Revenue Code (Code),[1] as added by section 70411 of Public Law 119–21, 139 Stat. 72 (July 4, 2025), commonly known as the One, Big, Beautiful Bill Act (OBBBA).

The temporary regulations are issued under section 25F(h), which expressly delegates authority to the Secretary of the Treasury or the Secretary's delegate (Secretary) to issue such regulations or other guidance as the Secretary determines necessary to carry out the purposes of section 25F, including regulations or other guidance (1) providing for enforcement of the requirements under section 25F(d) and (g), and (2) with respect to recordkeeping or information reporting for purposes of administering the requirements of section 25F. The temporary regulations also are issued under the express delegation of authority in section 7805(a) of the Code, which authorizes the Secretary to prescribe all needful rules and regulations for the enforcement of the Code, including all rules and regulations as may be necessary by reason of any alteration of law in relation to internal revenue.

[1] Unless otherwise indicated, all section references are to the Internal Revenue Code or the Treasury Regulations issued thereunder.

**Background**

As added by section 70411(a) of the OBBBA, the nonrefundable income tax credit under section 25F (section 25F credit) is allowed to an individual who is a citizen or resident of the United States (within the meaning of section 7701(a)(9)) who makes qualified contributions to a ''scholarship granting organization'' (SGO). Pursuant to section 70411(c)(1) of the OBBBA, the provisions of section 25F apply to taxable years ending after December 31, 2026. Additionally, for taxable years ending after December 31, 2026, section 139K, as added by section 70411(b) of the OBBBA, excludes from the gross income of individuals or their dependents any amounts received after December 31, 2026, pursuant to SGO-provided scholarships for qualified elementary or secondary education expenses of eligible students. *See* section 70411(c)(2) of the OBBBA.

A notice of proposed rulemaking (REG–117199–25) containing a comprehensive set of proposed regulations under section 25F (proposed regulations) is published in the Proposed Rules section of this issue of the **Federal Register** and provides detailed information regarding the provisions of section 25F and the proposed regulations, including requirements for an organization to qualify as an SGO, for a contribution to qualify as a ''qualified contribution'' eligible for a section 25F credit, and for a State to qualify as a ''covered State'' that participates under section 25F.

The temporary regulations contained in this Treasury decision provide reporting and recordkeeping requirements for SGOs and requirements for elections that States must make to participate under section 25F. The proposed regulations satisfy the requirement of section 7805(e)(1) for proposed regulations to be published concurrently with the publication of temporary regulations. The text of the proposed regulations is identical to the text of the temporary regulations at §§ 1.25F–1T, 1.25F–4T(b) and (c), and 1.25F–5T (except that the temporary regulations cross-reference other provisions of the temporary regulations and do not refer to any provision of the proposed regulations). Interested persons are directed to the **ADDRESSES** and COMMENTS and PUBLIC HEARING sections of the preamble to REG–117199–25 for information on submitting public comments or requesting to testify at, or attend, the public hearing for the proposed regulations.

**Explanation of Provisions**

*I. Definitions*

Section 1.25F–1T provides definitions of terms generally applicable for purposes of applying the temporary regulations, including certain defined terms explained in this part of the Explanation of Provisions to provide additional context.

1. Located in the State

Section 25F(g)(1)(A) states that an electing State must provide a list of the SGOs that meet the requirements described in section 25F(c)(5) and are located in the State. In responding to a request for feedback in Notice 2025–70, 2025–50 I.R.B. 773, many stakeholders suggested that ''located in the State'' should mean registered to do business in the State and in compliance with otherwise applicable State laws for nonprofit organizations. Some of these stakeholders stated that requiring a physical headquarters or in-State staff would be unnecessary, inconsistent with existing State tax credit programs, and would significantly hinder effective multistate SGOs that are well-positioned to deliver scholarships at scale.

Other stakeholders stated that an SGO should be required to have a physical presence in the State if required by State law, arguing that ''located in the State'' straightforwardly means headquartered in the State, rather than simply being authorized or registered to solicit donations there. These stakeholders stated that the phrase ''located in the State'' appears in more than 90 sections of the U.S. Code and that none could be read to mean ''authorized to operate.'' Many of these stakeholders expressed the concern that allowing large multistate SGOs to be located in a State where they did not have a physical presence might limit a State's ability to implement its educational policies.

Section 1.25F–1T(a)(10) provides that an organization is ''located in a State'' if the organization is authorized to do business in the State and is in compliance with the generally applicable State laws and requirements for charitable organizations in the State, including provisions for transparency, accountability, and fraud prevention.[2] The Treasury Department and the IRS have determined that this definition is consistent with the legislative purpose of section 25F to increase access to scholarship funds.

[2] However, § 1.25F–5T(e)(2) prohibits covered States from imposing requirements on SGOs that are more restrictive than the requirements in section 25F(c)(5).

2.Qualified Contribution

Section 1.25F–1T(a)(12) provides that a ''qualified contribution'' is a charitable cash contribution made by an individual to an SGO to the extent it is designated as such by the donor at the time of contribution. If the SGO provides any goods or services as consideration for any part of the contribution, then the value of those goods and services must be subtracted from the amount of the charitable contribution to arrive at the amount of the qualified contribution.

For this purpose, the term ''cash'' means physical currency, check, money order, electronic transfer (including, for example, by credit or debit card), after-tax payroll deduction, or other similar method, in each case all in U.S. dollars, but does not include any digital assets.

Under this definition, a donor is required to designate to the recipient SGO, at the time of making the contribution, that the contribution is intended to be a qualified contribution, which requires the SGO to deposit the contribution into the SGO's section 25F segregated account as part of the SGO's compliance with sections 25F(c)(3) and 25F(c)(5)(B). If the SGO is a multistate SGO, the donor would be able to direct the recipient SGO to allocate the qualified contribution to the multistate SGO's section 25F segregated account for any one or more of the covered States on whose State SGO list the SGO appears. Once a qualified contribution has been deposited into an SGO's section 25F segregated account, the SGO must use the funds in accordance with the operational requirements in section 25F(d) to maintain its status as an SGO.

3. Scholarship Granting Organization

Section 1.25F–1T(a)(16) provides that a ''scholarship granting organization'' or ''SGO'' is an organization defined in section 25F(c)(5). Accordingly, donations made to an organization that generates State tax credits may or may not give rise to a section 25F credit, depending on whether the organization separately satisfies the Federal tax law requirements to be an SGO for purposes of the section 25F credit. For example, a contribution to an organization that qualifies for State tax credits but is not included on the State SGO list of one or more covered States in which the SGO is located, does not give rise to the section 25F credit.

Notice 2025–70 recognized that organizations may fundraise and award scholarships in more than one State and distinguished an organization that is located in only one State (single-State organization) from one that is located in

more than one State (multistate organization). The temporary regulations preserve this distinction in § 1.25F–1T(a)(20), defining a ''single-State SGO'' as an organization included on the State SGO list of only one covered State, and § 1.25F–1T(a)(11), defining a ''multistate SGO'' as an SGO that is included on the State SGO list of more than one covered State.

Although § 1.25F–5T(e)(2) clarifies that a State may not narrow the required elements of an SGO as described in section 25F(c)(5), any particular SGO may narrow its own focus and adopt more stringent requirements than those applicable under section 25F. For example, an SGO may choose to limit its scholarships for qualified elementary and secondary education expenses to specific subject matter areas such as science or foreign languages, or to students whose household income is less than 80 percent of the area median gross income, provided that the SGO meets the statutory and regulatory requirements for SGOs. The Treasury Department and the IRS assume that SGOs will publicize their particular missions, the scope of their scholarships for eligible students, and their successes in achieving better student outcomes, in order to attract more qualified contributions from taxpayers supportive of their mission.

*II. Reporting and Recordkeeping Requirements for SGOs*

A. Overview

Pursuant to the authority granted by section 25F(h)(2), § 1.25F–4T provides rules requiring electronic registration and contribution reporting by SGOs. Section 1.25F–4T(b) describes the mandatory registration process for organizations through the IRS SGO portal. Section 1.25F–4T(c) provides the requirements for an organization's acknowledgement, recordkeeping and reporting for the receipt of amounts designated as qualified contributions.

B. Mandatory Registration Through IRS SGO Portal

In determining how to enforce and administer the requirements of section 25F, the Treasury Department and the IRS considered paper or electronic communications and determined that an IRS SGO portal provides the most efficient way to interact with SGOs in a timely manner. Section 1.25F–4T(b) requires an organization to register electronically through the IRS SGO portal, which allows each organization to obtain instructions for creating a unique donor number, based on a uniform format to be used by all SGOs, and report qualified contribution information to the IRS. The organization also uses the IRS SGO portal to periodically authorize disclosure of the organization's name and identifying information on the IRS SGO list for a calendar year, available on *https://www.irs.gov.* An organization must authorize such disclosure if it wants the IRS to publish such information on the IRS SGO list.

Because an organization will not be able to generate the unique donor number to provide to a donor until the organization registers in the IRS SGO portal, and because a donor will need that unique donor number to substantiate a qualified contribution, § 1.25F–4T(b)(2) requires an organization to complete the registration process with the IRS as soon as possible and preferably before the organization appears on any State SGO list.

Section 1.25F–4T(b)(3) describes the information required to register, specifically: the organization's name, IRS employer identification number (EIN), address, telephone number, and year of formation; the name of a person whom the IRS may contact if there is an issue with the organization's registration; the organization's taxable year; and any other information the IRS deems necessary for purposes of administering the requirements of section 25F as provided in guidance. Section 1.25F–4T(b)(4) provides that the IRS will review the information provided to verify that all the required information has been submitted and will provide instructions to the organization for creating a unique donor number in a uniform format to be used by all SGOs, for each donor who has designated at least one payment to the organization as a qualified contribution to the SGO during the calendar year.

C. Donor Acknowledgement and Reporting of Qualified Contributions Received by SGOs

Notice 2025–70 asked what information SGOs should be required to provide to their donors, including whether SGOs should be required to provide the donor with written substantiation in order for the donor to take the section 25F credit. Many stakeholders recommended that SGOs provide a standardized donor acknowledgement form to taxpayers that would include the donor's name and address, the name of the SGO and its EIN, and the amount of the qualified contribution. Other stakeholders suggested that SGOs should not be responsible for reporting the particulars of a donation, other than informing donors that the donation could be eligible for the section 25F credit.

Section 1.25F–4T(c)(1) requires the organization to transmit a timely written acknowledgement to each donor with respect to qualified contributions made by such donor during the calendar year. Section 1.25F–4T(c)(1)(i) requires the timely written acknowledgement to include: the organization's EIN; the total amount of contributions made by the donor to the organization during the calendar year that the donor designated as qualified contributions; the unique donor number provided to the donor; a statement as to whether the organization provided any goods or services in consideration for any qualified contributions made by the donor; and a description and good faith estimate of the value of any such goods or services. Section 1.25F–4T(c)(1)(ii) requires organizations to provide the timely written acknowledgement to the donor no later than January 31 of the calendar year following the calendar year in which the donor made a qualified contribution. The timely written acknowledgement may be provided in writing or in any other form acceptable to the donor, including by electronic delivery if the donor consents to receiving the statement electronically and has not withdrawn the consent before the statement is furnished.

Section 1.25F–4T(c)(2) requires organizations to report information about qualified contributions to the IRS. Section 1.25F–4T(c)(2)(i) requires the following information to be reported with respect to each unique donor number assigned by the organization: the donor's name and address; the aggregate amount of qualified contributions made by the donor to the organization during the calendar year; and any other information the IRS deems necessary for purposes of administering the requirements of section 25F, as may be described in further guidance. Section 1.25F–4T(c)(2)(ii) requires organizations to report this information no later than February 28 of the year following the calendar year in which such qualified contributions were made. Unless otherwise provided in guidance, the reporting is required to be done through the IRS SGO portal in accordance with the instructions provided therein.

*III. State Election, State SGO List and Certification of SGOs*

A. Overview

Section 1.25F–5T provides rules for a State election and a State's identification and certification of organizations located in the State that

are SGOs. Section 1.25F–5T(b) describes rules for the State to register in the IRS State section 25F portal, which, except for the first year for which the State makes an election, may be used for the submission of the State election (including advance election), State SGO list, any changes to the State SGO list, annual certifications, and any other information required in accordance with guidance. Section 1.25F–5T(c) describes the requirements for a State election. Section 1.25F–5T(d) provides rules regarding the State SGO list, including information and certifications a State is required to provide for each organization included on the State SGO list and procedures a State is required to use in determining whether an organization is an SGO. Section 1.25F–5T(e) addresses State administrative requirements for SGOs.

B. IRS State Section 25F Portal

Notice 2025–70 stated that the Treasury Department and the IRS anticipated that the forthcoming proposed regulations under section 25F would require the State to electronically submit the State election, the State SGO list, and certification to the IRS. Commenters supported an electronic process for States to submit State SGO lists, as they considered electronic submissions to be more efficient and timelier than paper submissions. Thus, § 1.25F–5T(b) requires a State that chooses to participate under section 25F to register for and use the IRS State section 25F portal in accordance with the instructions therein.

Section 1.25F–5T(b)(2)(i) provides that the Governor of the State or such other individual, agency, or entity as is designated under State law to make elections with respect to Federal tax benefits on behalf of the State may authorize up to two designated officials to register for and use the IRS State section 25F portal. Section 1.25F–5T(b)(2)(ii) requires each designated official to be an elected official, the Director of Taxation, or an appointed official of the State. Section 1.25F–5T(b)(3) requires States to obtain or be assigned a special-purpose EIN for purposes of registering. The IRS will inform States how to obtain this EIN, and States will not be required to use a Form SS–4, Application for Employer Identification Number, for these purposes. Section 1.25F–5T(b)(4) requires that the following information be provided to register: the special-purpose EIN; contact information, including the name, official title, telephone number, and email address of the State's designated officials; and any other information the IRS deems necessary for purposes of administering the requirements of section 25F as may be described in future guidance.

At the conclusion of the registration process, a State will be able to electronically transmit through the IRS State section 25F portal its State election (including advance election), State SGO list, any changes to the State SGO list, annual certifications, and any other information required in future guidance.

To mitigate the risk of any State's implementation issues for the first year for which the IRS State section 25F portal will be operational, the IRS is considering the creation of alternative temporary procedures that would be outlined in future guidance to help ensure that all States that wish to participate under section 25F are reasonably able to complete their registration for the IRS State section 25F portal or otherwise submit the State election and State SGO list.

C. State Election

1. In General

Section 1.25F–5T(c) provides the procedure for making a State election. Section 1.25F–5T(c)(1) provides that, except as provided in § 1.25F–5T(c)(3), the State election may be made either as an advance election that is perfected through the submission of the State SGO list or as an election made with such submission.

Several stakeholders recommended restricting a State's ability to ''opt out'' after having made an election. Many stakeholders stated that States should not be able to opt out on a year-to-year basis, as families and students will rely on these scholarships for multiple years. However, in response to that feedback and to clarify the application of section 25F(g), § 1.25F–5T(c)(1) confirms that an election to participate under section 25F is made only for a single calendar year, and that all of the requirements in § 1.25F–5T(c) must be satisfied for each year for which an election is made. The advance election procedure in § 1.25F–5T(c)(3), discussed in part III.C.2. of this Explanation of Provisions, enables a State to opt in for an upcoming calendar year by making an advance election and then later, in effect, opt out by failing to perfect the election in accordance with § 1.25F–5T(c)(3)(ii). The Treasury Department and the IRS do not interpret section 25F(g) as allowing for any revocation once a State has completed its State election for the year, including an advance election that has been perfected.

As described in section 25F(g)(1)(B), § 1.25F–5T(c)(2) specifies that an election must be made by the Governor of the State or by such other individual, agency, or entity as is designated under State law to make such elections on behalf of the State with respect to Federal tax benefits.

2. Advance Election Procedure

Notice 2025–70 stated that the Treasury Department and the IRS read section 25F(g) to provide that an election by a State to participate under section 25F may be made prior to or contemporaneously with the submission of the State's list of all organizations located in the State that satisfy the definition of an SGO. On December 12, 2025, the Treasury Department and the IRS issued Rev. Proc. 2026–6, *Advance Election to Participate Under Section 25F for 2027,* to allow States, including the District of Columbia, to make an Advance Election to participate in a new tax credit for calendar year 2027.

Section 1.25F–5T(c)(3) provides guidance for States on how to submit an election in advance of the submission of the State SGO list, including guidance for States that have submitted an advance election for 2027 on Form 15714, *Advance Election to Participate Under Section 25F for 2027.* A State's failure to timely perfect its advance election by providing its State SGO list for a calendar year by the specified date in § 1.25F–5T(c)(3)(ii) would result in a failure to meet the requirements of section 25F(g), effectively preventing any organization in the State from qualifying as an SGO for the calendar year for which the advance election was not perfected.

Section 1.25F–5T(c)(3)(iii) provides that the IRS will maintain and publish on *https://www.irs.gov* a list of States that have made an advance election.

3. Timing of State Elections Under § 1.25F–5T(c)(3)(i) and (c)(4)

Section 1.25F–5T(c)(3)(i) identifies the time period during which an advance election may be made and § 1.25F–5T(c)(4) identifies the time period during which a State election may be made with the submission of the State SGO list.

Notice 2025–70 stated that the Treasury Department and the IRS anticipated that the forthcoming proposed regulations under section 25F would require each State electing to participate under section 25F for the 2027 calendar year to submit to the IRS, by a specified date before January 1, 2027, the State's list of organizations located in that State meeting the requirements of section 25F(c)(5) for the 2027 calendar year along with the State's certification under section

25F(g)(2), and that those forthcoming proposed regulations would include a similar requirement for submission of an annual list and certification from each electing State for subsequent years.

Section 1.25F–5T(c)(3)(i)(A) provides that, except as otherwise provided in the transition rule in § 1.25F–5T(c)(3)(i)(B), a State may submit an advance election through the IRS State section 25F portal on or after January 2 and on or before September 30 of the calendar year immediately preceding the calendar year for which the election is being made. The IRS will acknowledge or otherwise confirm receipt of a State's advance election.

Section 1.25F–5T(c)(3)(i)(B) provides a transition rule for the first calendar year for which the State makes an election. Section 1.25F–5T(c)(3)(i)(B)(*1*) provides that, for calendar year 2027, a State must submit an advance election on Form 15714 on or before January 1, 2027. Section 1.25F–5T(c)(3)(i)(B)(*2*) provides that, for future years, a State making its first election to participate under section 25F must submit an advance election as provided in future guidance. Consistent with these transition rules, § 1.25F–5T(c)(4) provides that, for the first year in which the State is electing to participate under section 25F, it cannot make its election with the submission of the State SGO list.

During the last three months of the immediately preceding calendar year or on January 1 of the year for which the election is being made, a State may make its election to participate under section 25F either as part of submitting its State SGO list for that year with the required information and certifications, or by perfecting its advance election made under § 1.25F–5T(c)(3)(i)(A) by providing its State SGO list for that year with the required information and certifications.

Several stakeholders requested clarification that the deadline for an election to participate for the 2027 calendar year should be after January 1, 2027, consistent with section 25F(g)(1)(A). For calendar year 2027 only, a State must submit its advance election on or before January 1, 2027, however, the State may perfect its advance election by submitting its State SGO list on or before February 15, 2027.

Some stakeholders recommended clarifying that the election deadline for calendar years after 2027 should be no later than 11:59 p.m. on January 1 of the calendar year, to accommodate an election made by a Governor who is newly inaugurated. The Treasury Department and the IRS agree and clarify that, for these purposes, ''on or before January 1 of that year'' means up to 11:59 p.m. on January 1.

4. Certifications and Other Required Information for State Elections

Section 1.25F–5T(c)(5) requires that the person with authority to make the State election, or a designated official, certify that the individual, agency, or entity making the State election has the authority to make the State election on behalf of the State, and the person authorizing any individuals as designated officials under § 1.25F–5T(b)(2) has the authority to do so.

In addition, § 1.25F–5T(c)(5) requires the person with authority to make the State election or a designated official to:

(1) Provide the enacted statutory or regulatory provisions that are binding on the State and establish the authority of an individual to make the State election on behalf of the State, if the individual making the election is not the Governor of the State (or the Mayor of the District of Columbia);

(2) Provide the required information and certifications for each SGO on the State SGO list;

(3) Certify that the State SGO list includes every organization located in the State that is seeking inclusion on the State SGO list, that meets the definition of an SGO, and is operating in a manner that satisfies the operational requirements in section 25F(d) and the applicable State requirements;

(4) Provide the certification of State policies and procedures required for its State SGO list in § 1.25F–5T(d)(6);

(5) Describe any tax credit (including relevant State statutes, regulations, and other authoritative guidance) available under State law for contributions made to SGOs during the calendar year for which the State is electing to participate under section 25F; and

(6) Provide any other information and certifications described in future guidance.

D. State SGO Lists

1. Overview

Section 3.03 of Notice 2025–70 stated that the Treasury Department and the IRS interpret section 25F(g) as requiring each covered State to verify that each organization on the State's list satisfies all the requirements of section 25F(c)(5). Section 3.04 of Notice 2025–70 further stated that the Treasury Department and the IRS anticipate that States will be required to have implemented, and to comply with, various procedures to verify that the required information submitted by the covered State is accurate and complete. Section 3.04 of Notice 2025–70 requested comments on what types of uniform policies, procedures, recordkeeping, or other requirements would be reasonable to ensure States can reliably verify that each organization meets the requirements of section 25F(c)(5), and, for States with similar programs, how those States determine whether organizations are meeting applicable requirements.

Many stakeholders favored self-attestation by SGOs that they met the requirements of section 25F(c)(5) so as to avoid the need for any State-level review process, stating that requiring States to verify compliance is overly burdensome and could discourage participation. Several stakeholders expressed concern that providing States with significant discretion over organizations seeking certification as an SGO would permit State officials to discriminate against organizations based on factors other than compliance with the requirements of section 25F. Some stakeholders requested explicit limits on State authority to prevent intrusion into SGO operations, as well as an appeals process for any organizations excluded from a State's list based on the State's administration of SGO requirements.

Section 1.25F–5T(d) provides guidance on State SGO lists. Section 1.25F–5T(d)(2) and (3) describe the information and certifications required as part of the State's election or advance election for a calendar year. Section 1.25F–5T(d)(4) provides a transition rule for an organization that has not yet been required to provide information and certifications. Section 1.25F–5T(d)(5) provides a procedure that applies when an organization's application for recognition of tax-exempt status is pending with the IRS. Section 1.25F–5T(d)(6) requires a State to make a certification regarding its policies and procedures. Section 1.25F–5T(d)(7) provides rules for changes to a State SGO list, and § 1.25F–5T(d)(8) provides rules for the removal of an SGO from the IRS SGO list. Section 1.25F–5T(d)(9) provides for the publication of the names of covered States and their State SGO lists on *https://www.irs.gov.*

2. Information the State Is Required To Provide About Each SGO on Its State SGO List

Section 1.25F–5T(d)(2) sets forth the information that a State must provide annually with respect to each organization named on the State SGO list, including the name, the EIN, address, and telephone number of the organization; whether the organization has received recognition as a public charity under section 501(c)(3) (section

501(c)(3) public charity), or has a pending application for such recognition; and any other information the IRS deems necessary for purposes of administering the requirements of section 25F as may be described in future guidance.

3. Certifications the State Is Required To Provide About Each SGO on Its State SGO List

Except as provided by the transition rule described in part III.D.3. of this Explanation of Provisions, § 1.25F–5T(d)(3) requires the State to certify that, with respect to each organization included on the State SGO list, the organization is located in the State and the organization prevents the co-mingling of qualified contributions with other amounts by maintaining a segregated section 25F account exclusively for qualified contributions, depositing all qualified contributions into its section 25F segregated account, and maintaining a complete set of books and records for its section 25F segregated account. The State also must certify that the organization satisfies each of the operational requirements in section 25F(d) and that the State has determined whether the SGO is a single-State or multistate SGO, reviewed the annual financial and programmatic audit report the organization is required to provide to the State, reviewed annual certifications and other information the organization is required to provide to the IRS and investigated any failure by the SGO to provide the required certifications and other information and has become reasonably satisfied that the SGO has corrected the failure, if possible, or has put in place procedures to prevent future failures. Finally, a State must certify that the organization satisfies any other requirements the IRS deems necessary for purposes of administering section 25F as may be described in future guidance.

The Treasury Department and the IRS request comments on the certifications States are required to make in accordance with § 1.25F–5T(d)(3), including any other certifications that should be required for a multistate SGO. Comments are also requested on whether any certification is disproportionately burdensome compared to the benefits to tax administration.

4. Transition Rule for an Organization That Has Not Yet Been Required To Provide Information and Certifications to the IRS

In recognition of the fact that much of the required reporting is of data derived from operations in the prior fiscal year, § 1.25F–5T(d)(4) provides a transition rule for recently formed entities and other organizations without such historical data that have not yet been required to report on their operations as an SGO. This transition rule allows the State to rely on the organization's governing documents or bylaws, written policies and procedures, and other documentation the organization provides to the State as part of its request to be included on its State SGO list, reducing the burden on the State for this type of SGO.

However, for each year for which such an organization is included on the State SGO list during this transition period, § 1.25F–5T(d)(4) requires the State to determine that the organization's provisions, policies, and procedures expressly require the organization to satisfy the operational requirements in section 25F(d), and that the documentation and information available to the State evidences the organization's ability and intent to satisfy such operational requirements. Section 1.25F–5T(d)(4) also requires the organization to concurrently provide the State with a copy of any information and certifications required to be provided to the IRS before the end of the transition period.

5. Procedure for When an Organization's Application for Recognition of Tax-Exempt Status Is Pending With the IRS

Section 1.25F–5T(d)(5) allows a State to include on its State SGO list those organizations whose applications for recognition of tax-exempt status are pending with the IRS, but only if the State includes on its State SGO list all organizations seeking inclusion on that list whose application for recognition of tax-exempt status is pending with the IRS, the State has complied with the requirements of § 1.25F–5T(d)(4) for each organization, and the State makes the required certifications regarding the organization's tax-exempt status. The required certifications include that the organization has applied for tax-exempt status as a section 501(c)(3) public charity, the organization's tax-exempt status, if granted, will be effective retroactively to a date that is on or before January 1 of the year for which the State SGO list applies, and the State SGO list indicates that such organization's tax-exempt status is pending IRS recognition. Whether tax-exempt status will be effective retroactively to a date on or before that January 1 of the year for which the State SGO list applies is determined by the date of the formation of the organization, the date of its application for recognition of tax-exempt status, and whether any material changes to the organization's activities were required for it to qualify for exemption. *See* section 6.09 of Rev. Proc. 2026–5, 2026–1 I.R.B. 258 (updated annually).

As provided in § 1.25F–5T(d)(9)(ii), which is discussed in part III.D.8 of this Explanation of Provisions, the IRS will add each of these organizations to the IRS SGO list upon determining that the organization qualifies for tax-exempt status as a section 501(c)(3) public charity, if the organization consents to being included on the IRS SGO list.

6. Certification of State Policies and Procedures

Section 1.25F–5T(d)(6) requires a State to certify that its policies and procedures, including its procedures for assessing and responding to audit results, enable the State to make its own determination that each organization on the State SGO list is located in the State, is in compliance with section 25F(c)(5)(A) and (B) and is operating in a manner that satisfies the operational requirements in section 25F(d) and the applicable State requirements. Section 1.25F–5T(d)(6) also requires that a State certify that its policies and procedures provide for the prompt removal of an organization from the State SGO list, and notification to the IRS through the IRS State section 25F portal of such removal, upon a determination that an organization is not an SGO or does not meet the applicable State requirements. A State must certify that its policies and procedures require any publicly available lists of SGOs maintained by the State to be identical to the most recently submitted State SGO list and include the IRS SGO list's URL (Uniform Resource Locator). Finally, § 1.25F–5T(d)(6) requires that the State certify that its policies and procedures ensure that the State's procedures before and after the removal of an organization from the State SGO list are fairly administered and afford due process in accordance with applicable Federal and State laws.

7. Changes to State SGO List

Section 1.25F–5T(d)(7)(i) and (ii) provide guidance regarding the time period during which a State may replace or supplement its State SGO list for a calendar year. A State may replace or supplement its State SGO list for a calendar year at any time before the deadline for perfecting or completing an election for that year by submitting the change in the IRS State section 25F portal in accordance with future guidance. A State will not be able to make any additions to the State SGO list for a calendar year after that deadline;

instead, any additions a State seeks to make after such deadline may be included as part of the State's submission of its State SGO list for the following calendar year.

Section 1.25F–5T(d)(7)(iii) provides that a State may remove an SGO from its State SGO list at any time during the calendar year to which that list applies. If an SGO requests to be removed from a State SGO list, the State is required to comply.

Many stakeholders requested guidance regarding the State's discretion in removing an SGO from the State SGO list. Stakeholders expressed concern that States could remove SGOs arbitrarily or for political reasons and sought rules to ensure transparency and uniformity regarding the removal process. In response, § 1.25F–5T(d)(7)(iii) provides that a State may remove an organization from its State SGO list if the State determines, through a procedure providing due process to the organization, that the organization is not located in the State, does not satisfy the requirements for an SGO in section 25F(c)(5)(A) or (B), or is not operating in a manner that satisfies the operational requirements in section 25F(d) and the applicable State requirements. In each event, the State must indicate the removal and its effective date on its State SGO list and promptly notify the IRS so the IRS can remove the SGO from the IRS SGO list for the current year. The organization will be removed from the relevant part of the IRS SGO list for the current year to ensure that any contributions to the organization after the date of its removal from the State or IRS SGO list are not treated as qualified contributions.

8. Removal of a Non-Compliant Organization From the IRS SGO List

Section 1.25F–5T(d)(8) provides the list of circumstances under which an organization may be removed from the IRS SGO list. Under § 1.25F–5T(d)(8)(i), the IRS will remove an organization from the IRS SGO list following its determination that the organization is not a section 501(c)(3) public charity or automatic revocation of the organization's tax-exempt status by function of section 6033(j). Section 1.25F–5T(d)(8)(ii) further provides that the IRS may remove an organization following its determination that the organization has failed to comply with a requirement of section 25F (other than the tax-exempt status requirement in section 25F(c)(5)(A)), or has failed to comply with the applicable reporting and recordkeeping requirements, including a failure to report qualified contributions in accordance with § 1.25F–4T(c). This IRS determination of non-compliance with the requirements of section 25F is a Federal tax controversy under section 7803(e)(3) and § 301.7803–2, which provides the organization an opportunity to seek review by the IRS Independent Office of Appeals in the time and manner prescribed in applicable forms, instructions, or other administrative guidance. Under § 1.25F–5T(d)(8)(iii)(A), the IRS will remove an organization from the part of the IRS SGO list for a particular covered State upon notification that it has been removed from the State SGO list of that covered State.

Finally, § 1.25F–5T(d)(8)(iii)(B) provides that, if a multistate SGO that is removed from a State SGO list under § 1.25F–5T(d)(8)(iii)(A) continues to satisfy the operational requirements in section 25F(d) and one or more other covered States' applicable requirements as described in § 1.25F–5T(e)(1), the SGO will remain on the IRS SGO list with respect to such other covered States, subject to any further discretionary examination of the SGO by such other covered States or the IRS.

9. Publication of Covered States and State SGO Lists

Section 1.25F–5T(d)(9)(i) provides that the IRS will maintain and publish the IRS SGO list on *https://www.irs.gov.* For those SGOs that have authorized the disclosure of their information on the IRS SGO list, the IRS SGO list will contain each SGO included on a State SGO list for each of the covered States for the calendar year and reflect each removal from a State SGO list and the date of the removal. If an SGO is removed from the IRS SGO list, its name and identifying information will be displayed in strike-through text, along with the date of the organization's removal from the list, to provide taxpayers with the information they may need in determining if their contribution is being made, or was made, to a valid SGO and thus is a qualified contribution eligible for the section 25F credit.

Section 1.25F–5T(d)(9)(ii) provides for updating the IRS SGO list to include an organization whose tax-exempt status was pending when the State SGO list was submitted. Upon determining that the organization qualifies for tax-exempt status and that the effective date of such tax-exempt status is on or before January 1 of the calendar year for which the State SGO list applies, the IRS will add the organization to the IRS SGO list for that year as soon as the organization gives permission to be included on that list.

The publication of an IRS SGO list is consistent with feedback requesting that the IRS publish information to facilitate taxpayers' ability to determine which tax-exempt organizations are eligible to receive qualified contributions.

E. State Administrative Requirements

Stakeholders submitted a broad range of comments regarding the level of discretion the State should have in reviewing and certifying SGOs. Concerns were raised that States might seek to prioritize particular types of schools or students, or otherwise implement State education policies in a manner inconsistent with section 25F.

Section 1.25F–5T(e) provides guidance on State administrative requirements. Section 1.25F–5T(e)(1) provides that a State must require that SGOs meet all generally applicable State requirements for charitable organizations, including any State requirements that any organization must satisfy to be authorized to do business in the State and to solicit charitable contributions in the State. Additionally, States are required to impose certain application, documentation and financial reporting requirements that are reasonably tailored to support the State's determination that the organization satisfies the operational requirements in section 25F(d), and to facilitate the prevention and detection of fraud or abuse, including the misuse of scholarship funds such as through the duplication of scholarship awards to the same student for the same qualified elementary or secondary education expense.

Section 1.25F–5T(e)(2) prohibits a State from requiring SGOs to operate in a manner that is more restrictive than the requirements set forth in section 25F(c)(5), such as by limiting the type of school that scholarship recipients may attend or the types of qualified elementary or secondary education expenses for which scholarship funds may be used. This prohibition is responsive to stakeholder feedback expressing concern that permitting States to impose additional requirements on SGOs or to exercise discretion to exclude an otherwise qualifying organization from the State SGO list could lead to arbitrary determinations and improper discrimination.

Section 1.25F–5T(e)(3) provides that the procedures a State implements in accordance with § 1.25F–5T(e) are subject to Federal review. Upon discovering a pattern of irregularities or noncompliance, the IRS, in its discretion, may require a State to modify its procedures to ensure that its

determinations regarding an organization's location in the State, and its satisfaction of the operational requirements in section 25F(d) are being administered in accordance with the applicable statutory, regulatory, and appropriate State-level requirements.

Nothing in section 25F or these temporary regulations would alter States' obligations to comply with all other applicable Federal and State law, for example, the requirements under the Individuals with Disabilities Education Act, 20 U.S.C. 1400 *et. seq.*

*IV. Applicability Date*

These temporary regulations under §§ 1.25F–1T, 4T, and 5T apply on or after September 1, 2026, so that the Treasury Department and the IRS have procedural rules in place with which to develop the necessary implementation processes. *See* section 7805(b)(2). The temporary regulations expire on October 1, 2029.

**Special Analyses**

*I. Good Cause*

The Administrative Procedure Act (5 U.S.C. Subchapter II) provides that advance notice and the opportunity for public comment are not required with respect to a rulemaking when an ''agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.''

The Treasury Department and the IRS find that good cause exists for making these temporary regulations immediately effective without notice and comment, including because failure to do so would be impracticable, contrary to the public interest, and against the intent of Congress.

Congress intended for the section 25F credit to be available for taxpayers making contributions beginning in taxable year 2027. Beginning on January 1, 2027, individual taxpayers will be able to make contributions to any eligible SGOs that have been certified by the States on whose SGO list they appear. The States' election to participate and certification of SGOs are critical prerequisites to implementing the section 25F credit. As Congress expressly required in section 25F(g), States that voluntarily elect to participate under section 25F are required to annually submit a list of SGOs located in the State that meet the requirements described in section 25F(c)(5).

Additionally, to facilitate the proper administration of the section 25F credit, SGOs must be required and able to track contributions received that are designated as qualified contributions that may give rise to credits to individual taxpayers as of January 1, 2027.

In order for the section 25F credit to operate as intended by Congress, taxpayers require certainty that a State has certified that an SGO satisfies the statutory requirements of section 25F prior to donating funds to organizations beginning on January 1, 2027. It is therefore important to immediately put into effect the necessary State certification procedures and recordkeeping requirements for SGOs.

The process of State certification of SGOs requires the State to ensure that each organization seeking to appear on its list of SGOs has met the criteria found in section 25F(c)(5). This certification process requires SGOs to submit certain documentation to support their assertion that they meet the statutory requirements. The State can only then review the submissions and, upon the State's certification that an organization meets the criteria set forth in section 25F(c)(5), include the organization on its list of SGOs for the following calendar year.

In addition, it is critical for SGOs to understand the necessary recordkeeping requirements for contributions to ensure that all section 25F credits claimed by taxpayers for a given taxable year correspond to verifiable qualified contributions. These requirements help maintain the integrity of the section 25F credit by preventing duplication and improper or excessive credits being claimed.

The Treasury Department and the IRS find that failure to make these temporary regulations effective prior to notice and comment would be contrary to the public interest. Without these temporary regulations, the IRS would be unable to ensure that States are able to adequately review applicant SGOs, complete their elections to participate under section 25F (or to perfect advance elections), and certify the SGOs that meet the statutory requirements before January 1, 2027. These temporary regulations must be issued promptly to allow enough time for organizations to submit the required documentation to States participating under section 25F, and for States to determine whether each organization meets all of the statutory requirements for inclusion on the State SGO list.

Additionally, the SGO reporting requirements must be made effective through these temporary regulations so that each SGO may obtain instructions for creating unique donor numbers that will be used to validate qualified contributions to the SGO. Taxpayers may begin making qualified contributions on January 1, 2027. The first step in an SGO creating standardized unique donor numbers is an electronic registration process that is completed through the IRS SGO portal before January 1, 2027. Registration will allow SGOs to obtain instructions for creating unique donor numbers for donors in a uniform format to be used by all SGOs and to authorize disclosure of their identifying information, allowing the IRS to include SGOs that have provided such authorization on the IRS SGO list. Accordingly, these requirements must be implemented before the time qualified contributions begin to be made on January 1, 2027.

The public interest is served by the certainty that these temporary regulations will provide to taxpayers, SGOs, and States. The Treasury Department and the IRS expect that many new SGOs will be created, and these temporary regulations will provide those organizations certainty in their formation and operations and will reduce the costs of uncertainty that would result if final regulations are not issued prior to taxpayers making contributions that they expect will be eligible for the section 25F credit.

The Treasury Department and the IRS also find that good cause exists for making these temporary regulations immediately effective because it would be impracticable to comply with the notice and comment process in time to achieve the previously described results intended by Congress. The section 25F credit involves novel issues, including federalism aspects, that interact with established tax law in complicated ways. This credit requires the creation of new IRS portals to interface both with SGOs and States, significant actions by States in identifying and certifying SGOs and ongoing administration with respect to SGOs, and IRS publication of the IRS SGO list, each of which must be developed before January 1, 2027. In addition, the IRS must establish systems to facilitate matching of reported qualified contributions against individual income tax returns. Each of these features presents unique tax administration challenges. In order to facilitate implementation of the section 25F credit, rules addressing the submission of State elections, SGO lists, and certifications and SGO registration and recordkeeping of contributions must be implemented by January 1, 2027.

The Treasury Department and the IRS understand the need to carefully consider all public comments and

provide robust responses to all relevant comments. The limited time available between the publication of proposed regulations and the effective date of the section 25F credit, at which point State lists of SGOs must be certified and submitted and contributions may begin to be made, is insufficient to receive, review, and meaningfully respond to public comments. Since the enactment of the OBBBA, and especially since the release of Notice 2025–70, the Treasury Department and the IRS have been actively engaged with stakeholders and have been responsive to feedback, some of which has been incorporated in these temporary regulations. Furthermore, there would not be sufficient time after the receipt of public comments on proposed regulations to make any necessary changes to the applicable procedures or to the State and SGO portals in time for the January 1, 2027, effective date of the section 25F credit.

Comments are being solicited in the notice of proposed rulemaking (REG–117199–25) published in the Proposed Rules section of this issue of the **Federal Register**. Any comments will be considered before final regulations are issued.

*II. Regulatory Planning and Review—Economic Analysis*

Executive Orders 12866 and 13563 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

These temporary regulations, and the notice of proposed rulemaking (REG–117199–25) published elsewhere in this issue of the **Federal Register**, have been designated by the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) as subject to review under Executive Order 12866 pursuant to the Memorandum of Agreement (July 4, 2025) between the Treasury Department and OMB regarding review of tax regulations. OIRA has determined that these temporary regulations and the corresponding proposed rulemaking are economically significant and subject to review under section 3(f) of Executive Order 12866 and section 1(c) of the Memorandum of Agreement. Accordingly, these temporary regulations, and the proposed regulations contained in the notice of proposed rulemaking (REG–117199–25) published in the Proposed Rules section of this issue of the **Federal Register**, have been reviewed by OMB. Please refer to part I of the Special Analyses section of the notice of proposed rulemaking for the Regulatory Planning and Review discussion.

Executive Order 14192, titled ''Unleashing Prosperity Through Deregulation,'' was issued on January 31, 2025. Section 3(a) of E.O. 14192 requires an agency, unless prohibited by law, to identify at least 10 existing regulations to be repealed when the agency issues a new regulation. In furtherance of this requirement, section 3(c) of E.O. 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 E.O. 12866) that would impose total costs greater than zero is considered an E.O. 14192 regulatory action. This final rule is considered an E.O. 14192 regulatory action. Details on the estimated costs of this final rule can be found in the rule's economic analysis.

*III. Paperwork Reduction Act*

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA) generally requires that a Federal agency obtain the approval of the OMB before collecting information from the public, whether that collection of information is mandatory, voluntary, or required to obtain or retain a benefit. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any Internal Revenue law. Generally, tax returns and tax return information are confidential, as required by section 6103.

The collections of information in these temporary regulations include reporting, third-party disclosure, and recordkeeping requirements for States and SGOs. Therefore, the likely respondents are State governments and tax-exempt organizations. The collection requirements are necessary to administer the section 25F credit for contributions to SGOs. The collections of information generally would be used by the States to be able to identify and certify SGOs in the State; by SGOs to provide information to donors on their qualified contributions to enable them to qualify for the credit; by SGOs to report information on those contributions to the IRS; and by the IRS to administer the credit to ensure that only qualified contributions give rise to the tax credit.

A. Collection Requirements Applicable to States

The collections of information applicable to States can be grouped into three categories: (1) registering through the IRS State section 25F portal; (2) electing to participate under section 25F, and (3) submitting the State SGO list, required certifications about the SGOs, and the State's policies for certifying SGOs.

1. State Registration

Section 1.25F–5T provides rules under section 25F(g) for a State's election to participate under section 25F and the State's identification and certification of organizations located in the State that are SGOs. Section 1.25F–5T(b) describes the IRS State section 25F portal used for the submission of State elections and State SGO lists.

Section 1.25F–5T(b)(1) requires a State that chooses to make an election to participate under section 25F to obtain a special-purpose EIN under the procedures in § 1.25F–5T(b)(3) and complete a registration process under the procedures in § 1.25F–5T(b)(4) on *https://www.irs.gov* to electronically transmit information through the IRS State section 25F portal.

A State will use the IRS State section 25F portal to submit the State election and State SGO list and required certifications and information. To complete its registration, § 1.25F–5T(b)(4) requires a State to provide the special-purpose EIN, contact information for the State, and any other information the IRS deems necessary for purposes of administering the requirements of section 25F. The State registration and the requirement to obtain a special-purpose EIN will be approved by OMB under control number 1545–2335, pursuant to the emergency procedures in 5 CFR 1320.13, and its associated burden will be reflected in Tables 1 and 2 of this section.

2. State Election To Participate

Section 1.25F–5T(c) provides rules for State elections. As part of providing an election and the State SGO list, the State must provide certain certifications and other required information as described in § 1.25F–5T(c)(5), which includes the information and certifications required by § 1.25F–5T(d)(2) through (5) for each organization on the State SGO list and

a certification that the State SGO list includes every organization located in the State that is described in section 25F(c)(5)(A) and (B), is seeking inclusion on the State SGO list, and is operating in a manner that satisfies the operational requirements in section 25F(d) and the applicable State requirements described in § 1.25F–5T(e)(1). The State election will be approved by OMB under control number 1545–2335 pursuant to the emergency procedures in 5 CFR 1320.13 and its associated burden will be reflected in Tables 1 and 2 of this section.

3. State Submission of State SGO List and Required Certification

The collection of information in § 1.25F–5T includes recordkeeping requirements related to the section 25F credit. A State will use these records to submit its State SGO list and the required certifications and other information. These recordkeeping requirements are considered general tax records under § 1.6001–1(e). For PRA purposes, general tax records and their associated burdens are already approved by OMB under control number 1545–0047 for tax-exempt organizations and governmental entities.

Section 1.25F–5T(d)(1) requires a State to provide its State SGO list and include the information and certifications required under § 1.25F–5T(d)(2) and (3) as part of its State election. Section 1.25F–5T(d)(6) requires a State to provide a certification regarding its policies and procedures for determining whether an organization is an SGO. Section 1.25F–5T(d)(7)(iii)(B) provides rules for a State's removal of an SGO from the State SGO list. Section 1.25F–5T(e) provides general guidance regarding the policies and procedures States adopt for SGOs and Federal review of such policies and procedures. The submission of the State SGO list and required certification will be approved by OMB under control number 1545–2335 pursuant to the emergency procedures in 5 CFR 1320.13 and its associated burden will be reflected in Tables 1 and 2 of this section.

B. Collection Requirements Applicable to SGOs

The collections of information in these temporary regulations applicable to SGOs can be grouped into two categories: (1) registering through the IRS SGO portal and (2) providing the donor with a written acknowledgement of the qualified contribution as well as reporting information related to those contributions to the IRS.

1. SGO Registration

SGOs will need to report information related to qualified contributions made by the donor to the SGO during the calendar year through the IRS SGO portal, described in § 1.25F–1T(a)(8), in accordance with the instructions provided therein. As such, SGOs will need to register through the IRS SGO portal and provide the information required to complete the registration process.

Section 1.25F–4T(b) provides rules regarding the mandatory registration through the IRS SGO portal that an organization must complete. An organization needs to complete the registration process electronically through the IRS SGO portal and in accordance with the instructions provided therein, providing the information in § 1.25F–4T(b)(3). This includes the organization's general information, a point of contact, the organization's tax year, and any other information required in guidance. As part of the registration process, SGOs may authorize the IRS to disclose their information for inclusion on the IRS SGO list, as described in § 1.25F–4T(b)(1). The SGO registration will be approved by OMB under control number 1545–2335 pursuant to the emergency procedures in 5 CFR 1320.13, and its associated burden will be reflected in Tables 1 and 2 of this section.

2. Collections of Information by SGOs Related to Contributions

Section 1.25F–4T(c) provides rules on the reporting, recordkeeping, and third-party disclosure requirements of qualified contributions made by the donor to the SGO during the calendar year.

The collections of information in § 1.25F–4T(c) include recordkeeping requirements related to the section 25F credit. An SGO will use these records to enable it to provide the donor with a timely written acknowledgement of a contribution and to report to the IRS the necessary information about qualified contributions made by the donor to the SGO during the calendar year. These recordkeeping requirements are considered general tax records under § 1.6001–1(e). For PRA purposes, general tax records and their associated burdens are already approved by OMB under control number 1545–0047 for tax-exempt organizations.

Section 1.25F–4T(c)(1)(i) provides that an SGO must provide a timely written acknowledgement to each donor with respect to qualified contributions made by the donor to the SGO during the calendar year. The timely written acknowledgement must include the total amount of contributions made by the donor, the unique donor number the SGO created for the donor (pursuant to § 1.25F–4T(b)(4)), and a statement as to whether or not the SGO provided any goods or services in consideration, in whole or in part, for any qualified contributions made by the donor and if so, a description and good faith estimate of the value of any goods or services. The SGO can provide timely written acknowledgement in writing, or in any other form acceptable to the donor, including by electronic delivery. The timely written acknowledgement must be provided no later than January 31 of the calendar year following the calendar year in which a donor made a qualified contribution to the SGO. The timely written acknowledgement will be approved by OMB under control number 1545–2335 pursuant to the emergency procedures in 5 CFR 1320.13, and its associated burden will be reflected in Tables 1 and 2 of this section.

Section 1.25F–4T(c)(2) requires an SGO to annually report to the IRS, no later than February 28 of the year following the year in which qualified contributions were made, information with respect to each unique donor number assigned by the SGO, including the donor's name and address, the aggregate amount of qualified contributions made by the donor to the SGO during the calendar year, and any other information the IRS deems necessary for purposes of administering the requirements of section 25F as may be described in future guidance. The SGO will need to report the information to the IRS through the IRS SGO portal in accordance with the instructions provided therein. This information is necessary to allow the IRS to validate donor information collected by SGOs against filed tax returns claiming the section 25F credit. Availability of this information through the portal may facilitate earlier identification and resolution of discrepancies between filed returns and SGO data, allowing for timelier resolution of any disparities and limiting duplication, fraud, or abuse in the operation of the credit. This annual reporting will be approved by OMB under control number 1545–2335 pursuant to the emergency procedures in 5 CFR 1320.13, and its associated

burden will be reflected in Tables 1 and 2 of this section.

TABLE 1—AFFECTED ENTITIES

| Entity type | Number of entities |
|---|---|
| States and District of Columbia | 51. |
| Scholarship Granting Organizations (SGOs) | 600 to 700. |
| Individual Contributors | 11 million. |

TABLE 2—ESTIMATED BURDEN

| Collection | Estimated number of respondents | Estimated frequency of responses | Estimated total responses | Estimated burden per response | Estimated total annual burden hours |
|---|---|---|---|---|---|
| **STATE COLLECTIONS** | | | | | |
| Registration *§ 1.25F–5T(b)* | 51 | Once (1) | 51 | 1 hour 2 minutes (1.03 hours). | 53 hours. |
| Election *§ 1.25F–5T(c)(1)–(4)* | 51 | Annually (1) | 51 | 17 minutes (0.29 hours) | 15 hours. |
| State compiling and submitting the SGO list § *1.25F–5T(d) certifications and information regarding SGOs on State SGO list required by § 1.25F–5(d)(2) and (3).* | 51 | Annually [3] (13) | 650 | 10 hours | 6,500 hours. |
| State certifications—*certifications and information required by § 1.25F–5T(c)(5) & (d)(6) (policies and procedures).* | 51 | Annually (1) | 51 | 1 hour 43 minutes (1.71 hours). | 87 hours. |
| State removal of SGO (reporting changes as needed or required) § 1.25F–5T(d)(7)(iii). | 8 | On Occasion [4] (7) | 56 | 30 minutes | 28 hours. |
| **SGO COLLECTIONS** | | | | | |
| Registration*§ 1.25F–4T(b)* | 650 | Once (1) | 650 | 1 hour 20 minutes (1.33 hours). | 865 hours. |
| Contribution Related Collection—Drafting Template for Acknowledgement and unique ID generation process *§ 1.25F–4T(c)(1).* | 650 | Once (1) | 650 | 2 hours [5] | 1,300 hours. |
| Contribution Related Collection—SGO giving contributors a written acknowledgement [6] *§ 1.25F–4T(c)(1).* | 650 | Annually [7] (16,923) | 11,000,000 | 15 minutes | 2,750,000 hours. |
| Contribution Related Collection (Annual Report to IRS of Contributor Information) *§ 1.25F–4T(c)(2).* | 650 | Annually (16,923) | 11,000,000 | 30 minutes | 5,500,000 hours. |

*IV. Regulatory Flexibility Act*

For applicability of the Regulatory Flexibility Act, please refer to the notice of proposed rulemaking (REG–117199–25) published in the Proposed Rules section of this issue of the **Federal Register**.

[3] States will consider, approve, submit and certify to multiple SGOs (650). (650 total SGOs divided by 51 States = approximately 13 SGOs per State).

[4] As States submit new SGO lists every year, the list for the next year can show changes from the prior year. If, however, an SGO needs to be removed from the State SGO list during the current year, the State must report that removal to the IRS. The IRS anticipates that few States will be required, or choose, to report changes throughout the year. Therefore, the IRS estimates only 15% of the States (8) will do this for approximately 1% of the total SGO population (7).

[5] The IRS anticipates that SGOs already have procedures in place to generate acknowledgements to donors for other purposes, but the IRS anticipates SGOs will need some time to create a process for generating and tracking the unique donor number and including that number in the acknowledgement. IRS anticipates this will be a one-time startup burden on SGOs.

[6] The IRS anticipates that most acknowledgements will be issued electronically to contributors and less than 1% may be issued as a paper version. The burden to issue the acknowledgement could take less than 1 minute to send electronically and up to 30 minutes to issue a paper version. Therefore, the IRS estimates it could take 15 minutes to issue an acknowledgement.

[7] SGOs will give information to multiple contributors each year (11 million total contributors divided by 650 SGOs = approximately 16,923 contributors per SGO per year).

*V. Section 7805(f)*

Pursuant to section 7805(f) of the Code, these temporary regulations will be submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on their impact on small business.

*VI. Unfunded Mandates Reform Act*

Section 202 (2 U.S.C. 1532(a)) of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. The Treasury Department and the IRS have concluded that these temporary regulations, and the notice of proposed rulemaking (REG–117199–25) published in the Proposed Rules section of this issue of the **Federal Register**, do not include any Federal mandate that may result in expenditures by State, local, or Tribal governments, or by the private sector, in excess of that threshold.

A ''Federal intergovernmental mandate'' is defined in 2 U.S.C. 658(5)(A), in part, as any provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or Tribal governments, except for a duty arising from participation in a voluntary Federal program. Among other things, ''federal tax policies that preempt specific state and local tax policies, and administrative rules issued by federal agencies cannot be avoided, [therefore] they are enforceable duties and are covered under UMRA.'' Adam G. Levin, *Unfunded Mandates Reform Act: History, Impact, and Issues* (CRS Report No: R40957) (2021) *https://www.congress.gov/crs-product/R40957.*

Section 1.25F–5T provides rules for the State's submission of its election to participate under section 25F and the State SGO list; rules regarding the information and certifications a State is required to provide for each organization included on the State SGO list; requirements that States must use in determining whether organizations meet the requirements of section 25F(c)(5); procedures for notifying the IRS of any determination by the State that an organization on the State SGO list is being removed from such list for not satisfying each of the requirements of section 25F(c)(5); and procedures regarding State requirements for SGOs.

These rules do not create a Federal intergovernmental mandate as defined in Title 2 of the United States Code. First, the rules do not impose an ''enforceable duty'' on the States. These rules do not preempt any State tax policies. Rather, for States that provide a State tax credit for donations to scholarship granting entities, these rules act in concert with State laws in this area and do not replace them. Second, even if these rules imposed an ''enforceable duty,'' that duty arises from a State's voluntary participation in a Federal tax credit. Section 25F(g)(1)(A) provides that a State voluntarily elects to participate under section 25F. If a State does not want to participate, it is not required to do so.

A ''Federal private sector mandate'' is defined in 2 U.S.C. 658(7)(A), in part, as any provision in legislation, statute, or regulation that would impose an enforceable duty upon the private sector, except for a duty arising from participation in a voluntary Federal program. 2 U.S.C. 658(9) provides that the term ''private sector'' means ''all persons or entities in the United States, including individuals, partnerships, associations, corporations, and educational and nonprofit institutions, but shall not include State, local, or tribal governments.''

Section 1.25F–4T(b) provides rules for the mandatory registration process through the IRS SGO portal that each SGO must complete. Section 1.25F–4T(c) provides the requirements for acknowledgement, recordkeeping, and reporting of qualified contributions received by the SGO.

These rules do not create a Federal private sector mandate as defined in title 2, United States Code. First, the rules do not impose an ''enforceable duty'' on any member of the private sector. These rules do not include direct statutory orders, a total or partial preemption, or administrative rules issued by Federal agencies that cannot be avoided. Instead, they fall squarely in the exception for a duty arising from voluntary participation in a Federal tax credit. Tax-exempt organizations are not required to be SGOs, but to the extent that an organization wants to be an SGO, the organization would then be subject to the rules in these regulations. Likewise, an individual taxpayer is not required to claim a credit under section 25F, but to the extent that a taxpayer wants to claim a credit, the taxpayer would need to follow the rules provided in the proposed regulations.

If these rules were to create a Federal mandate, based on OIRA's determination that these temporary regulations and the corresponding proposed rulemaking are economically significant and subject to review under section 3(f) of Executive Order 12866, the UMRA would require the Treasury Department and the IRS to assess anticipated costs and benefits and take certain other actions before issuing a final rule. For a discussion of such an assessment and analysis, see the discussion of the Regulatory Flexibility Act and E.O. 12866 in the Special Analyses section of the notice of proposed rulemaking (REG–117199–25) published in the Proposed Rules section of this issue of the **Federal Register**.

*VII. Executive Order 13132: Federalism*

Executive order 13132 (Federalism) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on State and local governments, and is not required by statute, or preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. The Treasury Department and the IRS conclude that these temporary regulations do not have federalism implications, do not impose substantial direct compliance costs on State and local governments, and do not preempt State law within the meaning of the Executive order.

Section 1(a) of Executive Order 13132 provides that, for purposes of the order, ''Policies that have federalism implications'' refers to regulations, legislative comments or proposed legislation, and other policy statements or actions that 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.'' As such, Executive Order 13132 prohibits an agency from publishing a rule if the rule either imposes substantial, direct compliance costs on State and local governments, and is not required by statute, or preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. The Tenth Amendment to the United States Constitution provides that ''[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.'' Section 1.25F–5T of these temporary regulations makes States responsible for ensuring SGOs on their SGO list have complied with the requirements of section 25F, but only if a State ''voluntarily elects to participate under'' section 25F. These temporary regulations do not violate the Executive Order or the Tenth

Amendment because States will only need to comply with the guidance if they voluntarily elect to participate under section 25F.

The temporary regulations would not coerce State governments into administering Federal law in violation of the Executive Order or the Tenth Amendment because States do not lose any funding or face any other negative consequences if they decline to participate under section 25F. A State that does not want to ensure that organizations have complied with reporting requirements can decline to submit an annual list of SGOs under section 25F(g)(1)(A). If a State does not submit a list of SGOs, it does not need to comply with any guidance related to section 25F.

In addition, section 25F and these temporary regulations would not insulate the Federal or State governments from political accountability, which indicates that the section and guidance would be permissible under the Tenth Amendment. If residents want their State to submit a list of SGOs (and to take on the resulting administrative responsibilities), they can lobby their State government to do so. The same is true for residents who do not want their State to participate under the section. Thus, rather than invading the domain of State authority, section 25F enables States to determine whether to implement a Federal policy. Any State that does not want to participate in section 25F can decline to submit a list of SGOs, which would prevent taxpayers from claiming credits based on contributions to organizations within the State that would otherwise be SGOs.

Further, these temporary regulations do not impose substantial direct compliance costs on State and local governments. While States will incur some costs in complying with the requirements of these temporary regulations, those costs will not be substantial. See the discussion of the Regulatory Flexibility Act and Executive Order 12866 elsewhere in this Special Analyses section.

*VIII. Congressional Review Act*

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as a major rule as defined by 5 U.S.C. 804(2).

**Drafting Information**

The principal authors of these regulations are Nicole Cammarota of the Office of Division Counsel (Litigation & Advisory), Constance Chien of the Office of Associate Chief Counsel (Income Tax & Accounting), and Andrew Fahmy of the Office of Associate Chief Counsel (Corporate). However, other personnel from the Treasury Department and the IRS participated in their development.

**List of Subjects in 26 CFR Part 1**

Income taxes, Reporting and recordkeeping requirements.

**Adoption of Amendments to the Regulations**

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

## PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding the following entries for §§ 1.25F–1T, 1.25F–4T, and 1.25F–5T in numerical order to read in part as follows:

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

* * * * *

Section 1.25F–1T also issued under 26 U.S.C. 25F(h).

Section 1.25F–4T also issued under 26 U.S.C. 25F(h).

Section 1.25F–5T also issued under 26 U.S.C. 25F(h).

* * * * *

■ **Par. 2.** Section 1.25F–1T is added to read as follows:

**§ 1.25F–1T Definitions (temporary).**

(a) *In general.* The definitions of terms in this paragraph (a) apply for purposes of section 25F and the section 25F regulations (that is, this section and §§ 1.25F–4T and 1.25F–5T).

(1) *Advance election.* The term *advance election* means a State's submission described in § 1.25F–5T(c)(3).

(2) *Covered State.* The term *covered State* means a State that makes a State election, in accordance with § 1.25F–5T(c), to participate under section 25F for a particular calendar year.

(3)–(5) [Reserved]

(6) *Guidance.* The term *guidance* means guidance published in the **Federal Register** or Internal Revenue Bulletin (*see* §§ 601.601(d)(2) and 601.602 of this chapter) or, as appropriate, in forms, instructions, and publications available on *https://www.irs.gov* and through the IRS SGO portal or IRS State section 25F portal, as applicable.

(7) *IRS SGO list.* The term *IRS SGO list* means the aggregated list of SGOs included on one or more State SGO lists that the IRS maintains and publishes on *https://www.irs.gov* in accordance with § 1.25F–5T(d)(9).

(8) *IRS SGO portal.* The term *IRS SGO portal* consists of the module(s) on *https://www.irs.gov* that an SGO is required by § 1.25F–4T(b) to use, in accordance with the instructions provided therein, to electronically obtain instructions for creating a unique donor number in a uniform format to be used by all SGOs, authorize disclosure of its name and identifying information on the IRS SGO list, and report specified information.

(9) *IRS State section 25F portal.* The term *IRS State section 25F portal* consists of the module(s) on *https://www.irs.gov* that a State is required by § 1.25F–5T(b) to use, in accordance with guidance, to electronically transmit its State election (or advance election), State SGO list, any changes to the State SGO list, annual certifications, and any other information required in guidance.

(10) *Located in a State.* An organization is *located in a State* if the organization is authorized to do business in the State and is in compliance with the generally applicable State laws and requirements for charitable organizations in the State, including provisions for transparency, accountability, and fraud prevention. *But see* § 1.25F–5T(e)(2) (prohibiting covered States from imposing requirements on SGOs that are more restrictive than the requirements in section 25F(c)(5)).

(11) *Multistate SGO.* The term *multistate SGO* means an SGO that is included on the State SGO list of more than one covered State.

(12) *Qualified contribution*—(i) *In general.* The term *qualified contribution* means a charitable contribution of cash made by an individual to an SGO to the extent that the donor designates to the recipient SGO, at the time of making the contribution, that the contribution is intended to be a qualified contribution for purposes of section 25F. Such designation, once made, is irrevocable.

(ii) *Goods or services received as consideration for the contribution.* If the SGO provides any goods or services as consideration for any part of the contribution, then the value of those goods and services must be subtracted from the amount of the charitable contribution to arrive at the amount of the qualified contribution.

(iii) *Cash.* For purposes of paragraph (a)(12)(i) of this section, the term *cash*—

(A) Means physical currency, check, money order, electronic transfer, after-tax payroll deduction, or other similar method, in each case all in U.S. dollars, and

(B) Does not mean any digital asset.

(13)–(15) [Reserved]

(16) *Scholarship granting organization (SGO).* The term *SGO* is defined in section 25F(c)(5).

(17) [Reserved]

(18) *Section 25F segregated account.* The term *section 25F segregated account* means the separate account exclusively for qualified contributions and the earnings therefrom that the SGO must maintain pursuant to section 25F(c)(5)(B).

(19) [Reserved]

(20) *Single-State SGO.* The term *single-State SGO* means an organization included on the State SGO list of only one covered State.

(21) *State.* References to *State* include each of the 50 States and the District of Columbia.

(22) [Reserved]

(23) *State election.* The term *State election* means a State election to participate under section 25F for a particular calendar year that is made in accordance with the procedures set forth in § 1.25F–5T(b) and (c).

(24) *State SGO list.* The term *State SGO list* means the list of all SGOs located in the State that the covered State submits to the IRS for a particular calendar year in accordance with § 1.25F–5T(d) (and that may be changed during such calendar year in accordance with § 1.25F–5T(d)(7)).

(25) *Timely written acknowledgement.* The term *timely written acknowledgement* means the written acknowledgement an SGO must provide to donors with respect to qualified contributions made during the calendar year in accordance with § 1.25F–4T(c)(1).

(26) [Reserved]

(b) *Applicability date*—(1) *In general.* This section applies on or after September 1, 2026. The applicability of this section expires on or before October 1, 2029.

(2) [Reserved]

■ **Par. 3.** Sections 1.25F–4T and 1.25F–5T are added to read as follows:

**§ 1.25F–4T Reporting and recordkeeping requirements for SGOs (temporary).**

(a) [Reserved]

(b) *Mandatory registration through IRS SGO portal*—(1) *In general.* Except to the extent otherwise provided in guidance, an organization that plans to solicit qualified contributions must electronically register through the IRS SGO portal in accordance with the instructions provided therein. Registration through the IRS SGO portal will allow the organization to obtain instructions for creating a unique donor number in a uniform format to be used by all SGOs, authorize disclosure of its name and identifying information on the IRS SGO list, and report qualified contribution information. An organization must authorize disclosure in accordance with section 6103(c) of its name and identifying information on the IRS SGO list for a calendar year if the organization wants the IRS to publish such information on the IRS SGO list for that year.

(2) *Time for registration through IRS SGO portal.* An organization must register with the IRS as soon as possible and preferably before the organization appears on any State SGO list. Until the organization has registered in the IRS SGO portal, the organization will not be able to comply with the acknowledgement and reporting requirements in paragraph (c) of this section, and that compliance is a necessary part of substantiating that a donor's qualified contribution is eligible for the credit allowed under section 25F.

(3) *Information required to complete registration.* An organization must provide the following information to the IRS to register in the IRS SGO portal:

(i) The organization's name, IRS employer identification number (EIN), address, telephone number, and year of formation;

(ii) The name of a person whom the IRS may contact if there is an issue with the registration, and who either possesses legal authority to bind the organization or provides a properly executed power of attorney on Form 2848, *Power of Attorney and Declaration of Representative;*

(iii) The organization's taxable year; and

(iv) Any other information the IRS deems necessary for purposes of administering the requirements of section 25F as provided in guidance.

(4) *Donor number.* The IRS will review the registration submission to verify that all the required information has been submitted and will provide the organization with instructions for creating a unique donor number for each donor who has designated at least one payment to the organization as a qualified contribution to the SGO during the calendar year.

(c) *Acknowledgement and reporting of qualified contributions received by SGOs*—(1) *Reporting to donor*—(i) *In general.* An organization must provide a timely written acknowledgement to each donor that includes the following information:

(A) The organization's EIN;

(B) The total amount of contributions made by the donor to the organization during the calendar year that the donor designated as qualified contributions;

(C) The unique donor number the organization created for the donor in accordance with paragraph (b)(4) of this section;

(D) A statement as to whether or not the organization provided any goods or services in consideration, in whole or in part, for any qualified contributions made by the donor to the SGO during the calendar year; and

(E) A description and good faith estimate of the value of any goods or services described in paragraph (c)(1)(i)(D) of this section, if any.

(ii) *Time and manner of providing timely written acknowledgement.* An organization must provide the timely written acknowledgement no later than January 31 of the calendar year following the calendar year in which a donor made a qualified contribution to the organization. The timely written acknowledgement can be provided in writing or in any other form acceptable to the donor, including by electronic delivery if the donor consents to receive the statement electronically and does not withdraw the consent before the statement is furnished.

(2) *Reporting qualified contributions to the IRS*—(i) *In general.* An organization must annually report to the IRS the following information with respect to each unique donor number assigned by the organization as set forth in paragraph (b)(4) of this section:

(A) The donor's name;

(B) The donor's address;

(C) The aggregate amount of qualified contributions made by the donor to the organization during the calendar year; and

(D) Any other information the IRS deems necessary for purposes of administering the requirements of section 25F as may be described in future guidance.

(ii) *Time and manner of reporting.* An organization must report the information described in paragraph (c)(2)(i) of this section no later than February 28 of the year following the year in which such qualified contributions were made. Unless otherwise provided in guidance, the reporting must be done through the IRS SGO portal in accordance with the instructions provided therein.

(d) and (e) [Reserved]

(f) *Applicability date*—(1) *In general.* This section applies on or after September 1, 2026. The applicability of this section expires on or before October 1, 2029.

(2) [Reserved]

**§ 1.25F–5T State election, State SGO list, and certification of SGOs (temporary).**

(a) *Overview.* This section provides rules under section 25F(g) for a State election and participation under section 25F. Paragraph (b) of this section describes the IRS State section 25F

portal used for the submission of State elections and State SGO lists and the reporting of any changes to State SGO lists and other required information. Paragraph (c) of this section provides rules for the State election, including an advance election, and the provision of the State SGO list. Paragraph (d) of this section provides rules regarding State SGO lists. Paragraph (e) of this section provides general guidance regarding Federal review of the policies and procedures States adopt for SGOs.

(b) *IRS State section 25F portal*—(1) *In general.* A State that chooses to participate under section 25F must register in the IRS State section 25F portal in accordance with the instructions therein. Registration requires obtaining or being assigned a special-purpose employer identification number (EIN) in accordance with paragraph (b)(3) of this section and then providing the information required by paragraph (b)(4) of this section. At the conclusion of the registration process, a State will be able to electronically transmit through the IRS State section 25F portal its State election (including an advance election), State SGO list, any changes to the State SGO list, annual certifications, and any other information required by future guidance.

(2) *Delegation*—(i) *In general.* The Governor of the State or such other individual, agency, or entity as is designated under State law to make elections with respect to Federal tax benefits on behalf of the State may authorize up to two designated officials, as described in paragraph (b)(2)(ii) of this section, to register for and use the IRS State section 25F portal. The State must provide any information and documentation necessary, in accordance with future guidance, to establish an individual's authority to use the IRS State section 25F portal on behalf of the State.

(ii) *Designated officials.* A designated official for purposes of the delegation described in paragraph (b)(2)(i) of this section must be one of the following individuals:

(A) An elected official;

(B) The Director of Taxation; or

(C) An appointed official.

(3) *Special purpose EIN.* Before a State may begin the registration process for the IRS State section 25F portal, the State must obtain or be assigned a special-purpose EIN, to be used only for purposes of section 25F, in accordance with applicable IRS guidance. The State may not obtain its own special-purpose EIN using the general guidance for obtaining an EIN set forth in § 301.6109–1(d)(2)(i) of this chapter. The special-purpose EIN cannot be used for any other purpose under the Code.

(4) *Information required to complete registration.* A State must provide the following information to complete the registration process for the IRS State section 25F portal:

(i) The State's special-purpose EIN obtained or assigned in accordance with paragraph (b)(3) of this section;

(ii) Contact information, including the name, official title, telephone number, and email address of each of the State's designated officials (if any) authorized as provided in paragraph (b)(2) of this section; and

(iii) Any other information the IRS deems necessary for purposes of administering the requirements of section 25F as may be described in future guidance.

(c) *State election*—(1) *In general.* Except as provided in paragraph (c)(3)(i)(B) of this section (providing a special rule for the first year a State makes an election), a State election may be made either as an advance election that is perfected, as described in paragraph (c)(3) of this section, or as an election made as part of the submission of the State SGO list, as described in paragraph (c)(4) of this section. The State election is made only for a single calendar year, and all the requirements in this paragraph (c) must be satisfied for each year for which an election is made.

(2) *Authority to make a State's election.* A State election, including an advance election, must be made either by the Governor of the State (or the Mayor of the District of Columbia) or by such other individual, agency, or entity as is designated under State law to make such elections with respect to Federal tax benefits on behalf of the State.

(3) *Advance election*—(i) *Submission of advance election*—(A) *In general.* Except as provided in the transition rule in paragraph (c)(3)(i)(B) of this section (or as otherwise provided in guidance), a State may submit an advance election through the IRS State section 25F portal on or after January 2 and on or before September 30 of the calendar year immediately preceding the calendar year for which the election is being made. The IRS will acknowledge or otherwise confirm receipt of a State's advance election.

*(B)* Transition rule for the first calendar year for which the State makes an election—*(1)* Calendar year 2027. *For calendar year 2027 only, a State must submit an advance election on Form 15714,* Advance Election to Participate Under Section 25F for 2027, *on or before January 1, 2027. The IRS will acknowledge or otherwise confirm receipt of a State's advance election.*

(2) *Future years.* For calendar years after 2027, a State making its first election to participate under section 25F must submit an advance election as provided in future guidance.

(ii) *Perfection of advance election*—(A) *In general.* If a State has submitted an advance election in accordance with paragraph (c)(3)(i) of this section, the State must perfect its election by providing its State SGO list for a calendar year, with the information and certifications required in paragraph (c)(5) of this section, on or before January 1 of that year, but not earlier than October 1 of the immediately preceding calendar year.

(B) *Transition rule for the first calendar year for which section 25F applies.* For calendar year 2027 only, a State may provide its State SGO list on or before February 15, 2027.

(C) *Failure to perfect.* Because a State that makes an advance election is required by section 25F(g) to provide its State SGO list as part of its State election, a failure to perfect its advance election within the time period set forth in this paragraph (c)(3)(ii) would result in a failure to meet the requirements of section 25F(g). Accordingly, no organization in that State would qualify as an SGO for the calendar year for which the advance election was not perfected.

(iii) *IRS advance election list.* The IRS will maintain and publish on *https://www.irs.gov* a list of States that have made an advance election.

(4) *Election with submission of the State SGO list.* Except for the first year for which the State makes its election (see paragraph (c)(3)(i)(B) of this section), a State may make its State election for a calendar year when the State submits its State SGO list for that year by providing its State election and State SGO list for that calendar year, with the information and certifications required in paragraph (c)(5) of this section, on or before January 1 of that year, but not earlier than October 1 of the immediately preceding calendar year.

(5) *Certifications and other required information.* As part of providing a State election and the State SGO list under this paragraph (c), the person with authority to make the State election, as described in paragraph (c)(2) of this section, or a designated official, as described in paragraph (b)(2) of this section, must, in accordance with future guidance:

(i) Certify that the individual, agency, or entity making the State election has

the authority to make the State election on behalf of the State;

(ii) Certify that the person authorizing any individuals as designated officials under paragraph (b)(2) of this section has the authority to do so;

(iii) Provide the enacted statutory or regulatory provisions that are binding on the State and establish the authority of an individual to make the election on behalf of the State, if the individual making the election is not the Governor of the State (or the Mayor of the District of Columbia);

(iv) Provide the information and certifications required by paragraphs (d)(2) and (3) of this section for each SGO on the State SGO list;

(v) Certify that the State SGO list includes every organization located in the State that is described in section 25F(c)(5)(A) and (B), is seeking inclusion on the State SGO list, and is operating in a manner that satisfies the operational requirements in section 25F(d) and the applicable State requirements described in paragraph (e)(1) of this section;

(vi) Provide the certification of State procedures as required by paragraph (d)(6) of this section;

(vii) Describe any tax credit (including relevant State statutes, regulations, and other authoritative guidance) available under State law for contributions made to SGOs during the calendar year for which the State is electing to participate under section 25F; and

(viii) Provide any other information and certifications described in future guidance.

(d) *State SGO lists*—(1) *In general.* Except to the extent otherwise provided in future guidance, a State must provide its State SGO list and include the information and certifications required under paragraphs (d)(2) and (3) of this section as part of its State election. Paragraph (d)(4) of this section provides a transition rule for an organization that has not yet been required to provide information and certifications to the IRS. Paragraph (d)(5) of this section provides a procedure that applies when an organization's application for recognition of tax-exempt status is pending with the IRS. Paragraph (d)(6) of this section requires a State to provide a certification regarding its policies and procedures for determining whether an organization is included on the State SGO list. Paragraph (d)(7) of this section provides rules for changes to a State SGO list, and paragraph (d)(8) of this section provides rules for the removal of an SGO from the IRS SGO list. Paragraph (d)(9) of this section provides for the publication of the names of covered States and their State SGO lists on *https://www.irs.gov.*

(2) *Required SGO information.* For each organization named on the State SGO list, a State must provide:

(i) The name, EIN, address, and telephone number of the organization;

(ii) The Federal tax-exempt status of the organization, meaning that the organization either is currently described in section 501(c)(3), exempt from tax under section 501(a), and not a private foundation as defined in section 509(a), or, if paragraph (d)(5) of this section applies, that the organization's application for recognition of tax-exempt status is pending with the IRS; and

(iii) Any other information the IRS deems necessary for purposes of administering the requirements of section 25F as may be described in future guidance.

(3) *Required SGO certifications.* Except as provided for the transition rule in paragraph (d)(4) of this section, for each organization named on the State SGO list, the State must certify that:

(i) The organization is located in the State;

(ii) The organization prevents the co-mingling of qualified contributions with other amounts by maintaining a section 25F segregated account, which must contain only qualified contributions and the earnings therefrom, depositing all qualified contributions into its section 25F segregated account and maintaining a complete set of books and records for its section 25F segregated account;

(iii) The organization meets all the operational requirements described in section 25F(d);

(iv) As part of the State's determination that an organization is or will be an SGO, the State has:

(A) Determined whether the organization is or will be a single-State SGO or a multistate SGO;

(B) Reviewed the annual financial and programmatic audit report the organization is required to provide to the State in accordance with guidance;

(C) Reviewed the annual certifications and other information the organization is required to provide to the IRS; and

(D) Investigated any failure by the SGO to provide the required certifications and other information, and, with respect to any such failure, has become reasonably satisfied that the SGO has corrected the failure, if possible, or has put in place procedures to prevent future failures in a manner that satisfies the State that the SGO will satisfy the requirements to be an SGO located in the State; and

(v) The organization satisfies any other requirements the IRS deems necessary for purposes of administering section 25F as may be described in future guidance.

(4) *Transition rule for an organization that has not yet been required to provide information and certifications to the IRS.* Until an organization first provides information establishing its satisfaction of the operational requirements of section 25F(d) in accordance with guidance, a State may rely, in determining whether the organization may be treated as an SGO, on the organization's governing documents or bylaws, written policies and procedures, and other documentation the organization provides to the State as part of its submission requesting inclusion on the State SGO list. However, for each year during this transition period for which the organization is listed as an SGO on the State SGO list, the State must:

(i) Determine that the SGO satisfies all requirements of section 25F(c)(5)(A) and (B);

(ii) Determine that the SGO's provisions, policies, and procedures expressly require (beyond a general requirement to comply with applicable law) the SGO to satisfy the operational requirements for an SGO in section 25F(d);

(iii) Determine that the documentation and information available to the State evidences the SGO's ability and intent to satisfy the operational requirements in section 25F(d); and

(iv) Require the SGO to concurrently provide the State with a copy of any information and certifications required to be provided to the IRS before the end of the transition period in accordance with guidance.

(5) *Procedure that applies when an organization's application for recognition of tax-exempt status is pending with the IRS.* A State SGO list may include organizations whose applications for recognition of tax-exempt status are pending with the IRS as of the date of submission of the State SGO list if the State includes on its State SGO list all organizations seeking inclusion on the State SGO list whose application for recognition of tax-exempt status is then pending with the IRS, provides the information and certifications required under paragraphs (d)(2) and (3) of this section for each such organization, and certifies, for each such organization, that:

(i) The organization has applied for, but has not yet received, IRS recognition of its status as an organization described in section 501(c)(3);

(ii) The organization's tax-exempt status, if granted, will be effective retroactively to a date that is on or before January 1 of the year for which the State SGO list applies;

(iii) The State SGO list indicates that such organization's tax-exempt status is pending IRS recognition; and

(iv) The State has complied with the requirements of paragraph (d)(4) of this section for each such organization.

(6) *Certification of State policies and procedures.* A State must certify that its policies and procedures, including its procedures for assessing and responding to audit results:

(i) Enable the State to make its own determination that each organization on the State SGO list is located in the State, is in compliance with the requirements of section 25F(c)(5)(A) and (B), and is operating in a manner that satisfies the operational requirements in section 25F(d) and the applicable State requirements described in paragraph (e)(1) of this section;

(ii) Provide for the prompt removal of an organization from the State SGO list, and notification to the IRS through the IRS State section 25F portal, upon a determination that the organization does not satisfy each of the required criteria referenced in paragraph (d)(6)(i) of this section;

(iii) Require that any publicly available list of SGOs maintained by the State is identical to the most recently submitted State SGO list and includes the IRS SGO list's URL (Uniform Resource Locator); and

(iv) Ensure that the State's procedures before and after the removal of an organization from the State SGO list are fairly administered and afford due process in accordance with applicable Federal and State laws.

(7) *Changes to State SGO list*—(i) *Changes before the deadline for the elected calendar year.* A State may replace or supplement its State SGO list for a calendar year at any time before the deadline for perfecting or completing an election for that year by submitting the change in the IRS State section 25F portal in accordance with future guidance.

(ii) *Additions to State SGO list after the deadline for the elected calendar year.* Except to the extent provided otherwise in guidance, a State may not make any additions to the State SGO list for a calendar year after the deadline provided in paragraph (c)(3)(ii) or (c)(4) of this section, as applicable. Any additions a State seeks to make after that deadline may be included as part of the State's submission of its State SGO list for the following calendar year.

(iii) *Removal from State SGO list*—(A) *Removal request from SGO.* If an SGO requests to be removed from a State SGO list, a State must comply, indicate the removal and its effective date on that list, and promptly notify the IRS of that removal through the IRS State section 25F portal so the IRS can remove the SGO from the IRS SGO list for the current year.

(B) *State removal procedures.* A State may remove an SGO from its State SGO list if the State determines, through a procedure providing due process to the organization, that the SGO is not located in the State, or that the SGO does not satisfy the requirements for an SGO in section 25F(c)(5) or (d) or the applicable State requirements described in paragraph (e)(1) of this section. The State must promptly notify the IRS of the removal and its effective date through the IRS State section 25F portal.

(8) *Removal of a non-compliant organization from the IRS SGO list.* An organization may be removed from the IRS SGO list, and will be shown on that list as having been removed as of the date the IRS removes the organization from that list, in the following circumstances:

(i) *Removal following change in tax-exempt status.* The IRS will remove an organization from the IRS SGO list if:

(A) The organization is not described in section 501(c)(3) and exempt from tax under section 501(a); or

(B) The organization is a private foundation.

(ii) *IRS determination of non-compliance with applicable requirements.* The IRS may remove an organization from the IRS SGO list following a determination that the organization has failed to comply with a requirement of section 25F (other than the tax-exempt status requirement in section 25F(c)(5)(A)) or has failed to comply with the applicable reporting, recordkeeping, or audit requirements, including a failure to report qualified contributions in accordance with § 1.25F–4T(c). Such an IRS determination is a Federal tax controversy under section 7803(e)(3), which gives the SGO an opportunity to seek review of the determination by the IRS Independent Office of Appeals in the time and manner prescribed in applicable forms, instructions, or other administrative guidance.

(iii) *Removal following State SGO status determination*—(A) *In general.* If a State removes an SGO from its State SGO list in accordance with paragraph (d)(7)(iii) of this section, the IRS will remove an SGO from the relevant part of the IRS SGO list.

(B) *Multistate SGO.* If a State removes a multistate SGO from its State SGO list under paragraph (d)(7)(iii) of this section, but the SGO continues to satisfy all applicable requirements for an SGO in a different covered State on whose State SGO list it appears, as well as the applicable requirements as described in paragraph (e)(1) of this section in such other State(s), the SGO will remain on the IRS SGO list with respect to such other covered State(s), subject to any further discretionary examination of the SGO by such other covered States or the IRS.

(9) *Publication of covered States and State SGO lists*—(i) *In general.* The IRS will maintain and publish the IRS SGO list on *https://www.irs.gov*. For those SGOs that have authorized the disclosure of their information on the IRS SGO list, the IRS SGO list will contain each SGO included on a State SGO list for each of the covered States for the calendar year and reflect each removal from a State SGO list and the date of the removal.

(ii) *Addition of organizations with pending tax-exempt status to IRS SGO list.* Upon determining that an organization described in paragraph (d)(5) of this section qualifies for tax-exempt status and that the effective date of such tax-exempt status is on or before January 1 of the calendar year for which the State SGO list applies, the IRS will add the organization to the IRS SGO list for that year if, and as soon as, the organization authorizes publication of its information to be included on that list.

(e) *State administrative requirements*—(1) *In general.* Except as provided in paragraph (e)(2) of this section, a State must:

(i) Require that organizations meet all generally applicable State requirements for charitable organizations, including any State requirements that any organization must satisfy to be authorized to do business in the State and to solicit charitable contributions in the State; and

(ii) Require SGOs to comply with application, documentation, and financial reporting requirements that are reasonably tailored to:

(A) Support the State's certifications under paragraph (d)(3) of this section; and

(B) Facilitate the prevention and detection of fraud or abuse, including the misuse of scholarship funds, such as through the duplication of scholarship awards to the same student for the same qualified elementary or secondary education expense.

(2) *Prohibition on additional State requirements or discretionary*

*exclusions.* A State may not require SGOs to operate in a manner that is more restrictive than the requirements set forth in section 25F(c)(5), such as by limiting the type of school that scholarship recipients may attend or the types of qualified elementary or secondary education expenses for which scholarship funds may be used. Accordingly, the State requirements provided in paragraph (e)(1)(ii) of this section must be reasonably related to determining whether an organization is located in the State, meets the requirements of section 25F(c)(5) and the operational requirements in section 25F(d), and satisfies the generally applicable State requirements for charitable organizations in the State for accountability and fraud prevention.

(3) *Federal review.* The procedures a State implements in accordance with this paragraph (e) are subject to Federal review. Upon discovering a pattern of irregularities or noncompliance, the IRS, in its discretion, may require a State to modify its procedures to ensure that its determinations regarding an organization's satisfaction of the requirements in section 25F(c)(5) and (d) are being administered in accordance with the applicable statutory, regulatory, and appropriate State requirements.

(f) *Applicability date.* This section applies on or after September 1, 2026. The applicability of this section expires on or before October 1, 2029.

**Frank J. Bisignano,**

*Chief Executive Officer.*

Approved: September 10, 2026.

**Kevin Salinger,**

*Acting Assistant Secretary of the Treasury (Tax Policy).*

[FR Doc. 2026–20264 Filed 10–1–26; 8:45 am]

**BILLING CODE 4831–GV–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 100

**[Docket No. USCG–2026–0999]**

## Special Local Regulations; Southern California Annual Marine Events for the San Diego Captain of the Port Zone, San Diego Sharkfest Swim, San Diego Bay, San Diego, CA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notification of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce special local regulations for the San Diego Sharkfest Swim on October 18, 2026, to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Southwest Coast Guard District identifies the regulated area for this event in the San Diego Bay. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

**DATES:** The regulation in 33 CFR 100.1101, Table 1 to § 100.1101, Item No. 7, will be enforced from 9 a.m. until 10 a.m. on October 18, 2026.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notification of enforcement, call or email Lieutenant Skye Eastman, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone (619) 278–7656, email *D11MarineEventsSD@uscg.mil.*

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce special local regulations in 33 CFR 100.1101 for the San Diego Sharkfest Swim regulated area from 9 a.m. to 10 a.m. on October 18, 2026. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for Southern California Annual Marine Events for the San Diego Captain of the Port Zone, § 100.1101, specifies the location of the regulated area for the San Diego Sharkfest Swim which encompasses portions of San Diego Bay. During the enforcement periods, as reflected in § 100.100(c), if you are the operator of a vessel in the regulated area you must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and Marine Safety Information Broadcasting.

**R.C. Tucker,**

*Captain, U.S. Coast Guard, Captain of the Port San Deigo.*

[FR Doc. 2026–20225 Filed 10–1–26; 8:45 am]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 100

**[Docket No. USCG–2026–1220]**

## Special Local Regulations; Marine Events Within the USCG East District—Philadelphia, PA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notification of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce special local regulations for the Philadelphia Cup Regatta on October 3, 2026, to provide for the safety of life on navigable waterways during the event. Our regulation for marine events within the USCG East District identifies the regulated area for this event in Philadelphia, PA. During the enforcement period, the operator of any vessel in the regulate area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

**DATES:** The regulations in 33 CFR 100.501 will be enforced for the special local regulations listed in Table 1 to Paragraph (i)(1) of § 100.501 for the Philadelphia Cup Regatta from 9 a.m. through 5 p.m. on October 3, 2026.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notification of enforcement, call or email Petty Officer Dominick J. Dobridge, Waterways Management Division, Sector Delaware Bay, U.S. Coast Guard; telephone (206) 815–6688, option 3; email *SecDelBayWWM@uscg.mil.*

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce the special local regulation in Table 1 to Paragraph (i)(1) in 33 CFR 100.501, for the regulated area of the Philadelphia Cup Regatta from 9 a.m. to 5 p.m. on October 3, 2026. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the USCG East District, § 100.501, specifies the location of the regulated area for the ''Philadelphia Cup Regatta'' which encompasses portions of the Delaware River, in Philadelphia, PA. During the enforcement period, as reflected in § 100.501(d)(2), a vessel operator may request permission to enter and transit through a regulated area by contacting the Event PATCOM or official patrol vessel on VHF–FM channel 16. When authorized to transit through the regulated area, the vessel

must proceed at the minimum speed necessary to maintain a safe course that minimizes wake near the event area.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and Broadcast Notice to Mariners.

**R. Rivera,**

*Captain, U. S. Coast Guard, Captain of the Port, Sector Delaware Bay.*

[FR Doc. 2026–20223 Filed 10–1–26; 8:45 am]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 100

**[Docket No. USCG–2026–1228]**

### Special Local Regulations; Marine Events Within the USCG East District—Ocean City, NJ

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notification of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce special local regulations for the Ocean City Chase Race on October 3, 2026, to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the USCG East District identifies the regulated area for this event in Ocean City, NJ. During the enforcement period, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

**DATES:** The regulations in 33 CFR 100.501 will be enforced for the special local regulations listed in Table 1 to Paragraph (i)(1) of § 100.501 for the Ocean City Chase Race from 7:00 a.m. through 2:00 p.m. on October 3, 2026.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notification of enforcement, call or email Petty Officer Dominick J. Dobridge, Waterways Management Division, Sector Delaware Bay, U.S. Coast Guard; telephone (206) 815–6688, option 3; email *SecDelBayWWM@uscg.mil.*

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce the special local regulation in Table 1 to Paragraph (i)(1) in 33 CFR 100.501, for the regulated area of the Ocean City Chase Race from 7:00 a.m. to 2:00 p.m. on October 3, 2026. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the USCG East District, § 100.501, specifies the location of the regulated area for the ''Ocean City Chase Race'' which encompasses portions of the New Jersey Intracoastal Waterway, in Ocean City, NJ. During the enforcement period, as reflected in § 100.501(d)(2), a vessel operator may request permission to enter and transit through a regulated area by contacting the Event PATCOM or official patrol vessel on VHF–FM channel 16. When authorized to transit through the regulated area, the vessel must proceed at the minimum speed necessary to maintain a safe course that minimizes wake near the event area.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and Broadcast Notice to Mariners.

**R. Rivera,**

*Captain, U.S. Coast Guard, Captain of the Port, Sector Delaware Bay.*

[FR Doc. 2026–20224 Filed 10–1–26; 8:45 am]

**BILLING CODE 9110–04–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[EPA–HQ–OPP–2025–0090; FRL–13583–01–OCSPP]**

### Phosphatidylcholine in Pesticide Formulations; Exemption From the Requirement for a Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of phosphatidylcholine (CAS Reg. No. 97281–47–5) when used as an inert ingredient (adjuvant/carrier) in pesticide contraceptive formulations applied to cervid, porcine, raccoon, and bovine. Compliance Services International on behalf of SpayVac-for-Wildlife, Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of phosphatidylcholine, when used in accordance with the terms of that exemption.

**DATES:** This regulation is effective October 2, 2026. Objections and requests for hearings must be received on or before December 1, 2026 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of this document).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2025–0090, is available online at *https://www.regulations.gov.* Additional information about dockets generally, along with instructions for visiting the docket in person, is available at *https://www.epa.gov/dockets.*

**FOR FURTHER INFORMATION CONTACT:** Charles Smith, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: *RDFRNotices@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

#### I. Executive Summary

*A. Does this action apply to me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive but rather provides a guide to help readers determine whether this document applies to them.

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. What is EPA's authority for taking this action?*

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(c)(2)(A)(i) allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' FFDCA section 408(c)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all

other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .'' Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider, among other things, ''available information concerning the cumulative effects of a particular pesticide's residues'' and ''other substances that have a common mechanism of toxicity.''

*C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify the docket ID number EPA–HQ–OPP–2025–0090 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before December 1, 2026.

EPA's Administrative Law Judges Division (ALJD), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. *See* ''Order Urging Electronic Filing and Service,'' dated December 3, 2025, which can be found at *https://www.epa.gov/system/files/documents/2025-12/2025-12-03-order-urging-electronic-filing-and-service.pdf.* Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the ALJD electronically, a person should utilize the ALJD e-filing system at *https://yosemite.epa.gov/oa/eab/eab-alj_upload.nsf.*

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute. If you wish to include CBI in your request, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

## II. Petitioned-for Exemption

In the **Federal Register** of December 15, 2025 (90 FR 57944, FRL–12474–08–OCSPP), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11877) by Compliance Services International (7501 Bridgeport Way West Lakewood, WA 98499) on behalf of SpayVac-for-Wildlife, Inc. (1202 Ann Street Madison, WI 53713). The petition requested that 40 CFR 180.930 be amended by establishing an exemption from the requirement of a tolerance for residues of phosphatidylcholine (CAS Reg. No. 97281–47–5) when used as an inert ingredient (adjuvant/carrier) in pesticide formulations applied in equine, cervid, bovine, porcine, pinniped, elephant, raccoon, feral dog, and feral cat contraceptive formulations. That document referenced a summary of the petition prepared by Compliance Services International on behalf of SpayVac-for-Wildlife, Inc., the petitioner, which is available in the docket. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing the tolerance exemption for the use of phosphatidylcholine as an inert ingredient in pesticide contraceptive formulations applied to cervid, porcine, raccoon, and bovine. Under section 408(d)(4) of the FFDCA, EPA is authorized to establish a tolerance or exemption that varies from what is sought by the petitioner. The reasons for the variation here is that the following animals for which a tolerance exemption was requested cannot be sold in interstate commerce as food for human consumption: elephants, feral dogs and cats, pinnipeds, and equine animals. Because EPA is authorized only to establish tolerances or exemptions for residues of pesticides in or on food intended to enter interstate commerce, EPA is not establishing the exemption for any residues of this inert ingredient in those animals. Additional information regarding this limitation can be found in the Agency's risk assessment which can be found at *https://www.regulations.govin the document* ''*IN–11877; Phosphatidylcholine. Human Health Risk Assessment and Ecological Effects Assessment to Support Inert Ingredient Approval for use in Pesticide Formulations*'' *in docket ID number* EPA–HQ–OPP–2025–0090.

## III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

*IV. Aggregate Risk Assessment and Determination of Safety*

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no harm to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to

ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

FFDCA section 408(c)(2)(A)(i) allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' FFDCA section 408(c)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . . '' Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider, among other things, ''available information concerning the cumulative effects of a particular pesticide's residues'' and ''other substances that have a common mechanism of toxicity.''

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for phosphatidylcholine including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with phosphatidylcholine follows.

*A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by phosphatidylcholine as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The toxicological database of phosphatidylcholine is supported by data regarding hydrogenated phosphatidylcholine, phosphatidylserine, lecithin, soybean lecithins and hydrogenated lecithins. Phosphatidylcholine is derived from soybean lecithin and is a glyceride of fatty acids linked to a phosphoric acid or phosphoric ester. It is a member of the lecithin group associated with soya lecithin and egg yolk lecithin. EPA has determined that it is appropriate to bridge hydrogenated phosphatidylcholine, phosphatidylserine, lecithin, soybean lecithins and hydrogenated lecithins data to assess phosphatidylcholine due to similarities in structure, physical and chemical properties.

Phosphatidylcholine is expected to be of low toxicity. No adverse effects are observed in chronic oral toxicity studies in rats or dogs at 1,000 milligrams/kilogram body weight/day (mg/kg/day), the limit dose. There is no evidence of susceptibility in the available developmental toxicity studies in rats, mice, and rabbits. Concern for carcinogenicity is low based on the lack of effects in the available chronic toxicity study in the dog and negative results in mutagenicity and genotoxicity studies.

No evidence of neurotoxicity or immunotoxicity was observed in the available studies.

*B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level, generally referred to as a population-adjusted dose or a reference dose, and a safe margin of exposure. For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program.*

The hazard profile of phosphatidylcholine is adequately defined. Overall, phosphatidylcholine is expected to be of low acute, subchronic, chronic, and developmental toxicity. No systemic toxicity is observed up to 1,000 mg/kg/day. Since signs of toxicity were not observed, no toxicological endpoints of concern or PODs were identified. Therefore, a qualitative risk assessment for phosphatidylcholine can be performed.

*C. Exposure Assessment*

1. Dietary Exposure From Food and Feed Uses

In evaluating dietary exposure to phosphatidylcholine, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from phosphatidylcholine in food as follows.

Dietary exposure (food) to phosphatidylcholine may occur following ingestion of foods with residues from their use in accordance with this exemption. Dietary exposure via drinking water is not expected based on the proposed use pattern of phosphatidylcholine. Since a toxicological endpoint for risk assessment was not identified, a quantitative dietary exposure assessment was not conducted.

2. From Non-Dietary Exposure

The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Phosphatidylcholine may be present in non-pesticide products such as cosmetics, nutritional compounds and pharmaceuticals. However, a quantitative residential exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

3. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Based on the lack of toxicity in the available database, EPA has not found phosphatidylcholine to share a common mechanism of toxicity with any other substances, and phosphatidylcholine does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance exemption, therefore, EPA has assumed that phosphatidylcholine does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

*D. Additional Safety Factor for the Protection of Infants and Children*

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act safety factor. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

Based on an assessment of phosphatidylcholine, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children. Because there are no threshold effects associated with phosphatidylcholine, EPA conducted a qualitative assessment. As part of that assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

*E. Aggregate Risks and Determination of Safety*

Because no toxicological endpoints of concern were identified, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to phosphatidylcholine residues.

*F. Analytical Enforcement Methodology*

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

*G. Conclusions*

Therefore, an exemption from the requirement of a tolerance in 40 CFR 180.930 is established for residues of phosphatidylcholine (CAS Reg. No. 97281–47–5) when used as an inert ingredient (adjuvant/carrier) in pesticide contraceptive formulations applied to cervid, porcine, raccoon, and bovine.

**V. Statutory and Executive Order Reviews**

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

*A. Executive Order 12866: Regulatory Planning and Review*

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866.

*B. Executive Order 14192: Unleashing Prosperity Through Deregulation*

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance under FFDCA section 408 are exempted from review under Executive Order 12866.

*C. Paperwork Reduction Act (PRA)*

This action does not impose an information collection burden under the PRA 44 U.S.C. 3501 *et seq.,* because it does not contain any information collection activities.

*D. Regulatory Flexibility Act (RFA)*

This action is not subject to the RFA, 5 U.S.C. 601 *et seq.* The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. This rule is not subject to the APA but is subject to FFDCA section 408(d), which does not require notice and comment rulemaking to take this action in response to a petition.

*E. Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of $100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local, or Tribal governments or the private sector.

*F. Executive Order 13132: Federalism*

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

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

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

However, EPA's 2026 *Policy on Children's Health* applies to this action. This rule finalizes tolerance actions under the FFDCA, which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that

no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . .'' (FFDCA 408(b)(2)(C)). The Agency's consideration is documented in the pesticide-specific review documents, located in the applicable docket at *https://www.regulations.gov.*

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

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

*J. National Technology Transfer Advancement Act (NTTAA)*

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

*K. Congressional Review Act (CRA)*

This action is subject to the CRA, 5 U.S.C. 801 *et seq.,* and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 29, 2026.

**Charles Smith,**

*Director, Registration Division, Office of Pesticide Programs.*

For the reasons stated in the preamble, the EPA amends 40 CFR chapter I as follows:

## PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.930, amend Table 1 to § 180.930 by adding, in alphabetical order, an entry for ''phosphatidylcholine'' to read as follows:

**§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.**

* * * * *

TABLE 1 TO § 180.930

| Inert ingredients | Limits | Uses |
|---|---|---|
| * * | * * * * * | * |
| Phosphatidylcholine (CAS Reg. No. 97281–47–5). | In contraceptive formulations applied to cervid, porcine, raccoon, and bovine. | Adjuvant/Carrier. |
| * * | * * * * * | * |

[FR Doc. 2026–20219 Filed 10–1–26; 8:45 am]

BILLING CODE 6560–50–P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 660

**[Docket No. 260929–0005; RTID 0648–XF629]**

## Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Annual Specifications; 2026–2027 Annual Specifications and Management Measures for Pacific Sardine

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

**ACTION:** Final rule.

**SUMMARY:** NMFS is implementing annual harvest specifications and management measures for the northern subpopulation of Pacific sardine (hereafter, Pacific sardine), for the fishing year from July 1, 2026, through June 30, 2027. This rule prohibits most directed commercial fishing for Pacific sardine off the coasts of Washington, Oregon, and California. Pacific sardine harvest is allowed for use only as live bait, in minor directed fisheries, as incidental catch in other fisheries, or as authorized under exempted fishing permits (EFPs). The incidental harvest of Pacific sardine will be limited to 20 percent by weight of all fish per trip when caught with other stocks managed under the Coastal Pelagic Species (CPS) Fishery Management Plan (FMP), or up to 2 metric tons (mt) per trip when caught with non-CPS stocks. The harvest specifications for 2026–2027 include an overfishing limit (OFL) of 4,645 mt, an acceptable biological catch (ABC) of 3,613 mt, an annual catch limit (ACL) of 2,200 mt, and an annual catch target (ACT) of 2,100 mt. This final rule is intended to conserve, manage, and rebuild the Pacific sardine stock off the coasts of Washington, Oregon, and California.

**DATES:** Effective October 2, 2026.

**FOR FURTHER INFORMATION CONTACT:** Katie Davis, West Coast Region, NMFS, (323) 372–2126, *Katie.Davis@noaa.gov.*

**SUPPLEMENTARY INFORMATION:** NMFS manages the Pacific sardine fishery in the U.S. exclusive economic zone off the Pacific coast (*i.e.,* off the U.S. west coast states of California, Oregon, and Washington) in accordance with the CPS FMP. The CPS FMP and its implementing regulations require NMFS to set annual reference points and management measures for the Pacific sardine fishery based on the annual specification framework and control rules in the FMP. These control rules include the harvest guideline (HG) control rule, which, in conjunction with the OFL and ABC control rules in the FMP, are used to set required reference points, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (MSA) (16 U.S.C. 1801 *et seq.*). The ACL for Pacific sardine is set according to the framework established in the Pacific sardine rebuilding plan, approved on May 29, 2025, as Amendment 23 to the CPS FMP (90 FR 23461, June 3, 2025). Additionally, the CPS FMP requires additional management measures intended to restrict harvest for the Pacific sardine fishery (*e.g.,* incidental catch restrictions).

NMFS publishes annual specifications in the **Federal Register** to establish these annual reference points (*e.g.,* the OFL, ABC, and ACL) and management measures for each Pacific sardine fishing year. NMFS published proposed specifications and management measures on June 29, 2026 (91 FR 39054). The proposed rule for this action included additional background on the specifications and details of how they were derived and the basis for which the Pacific Fishery Management Council (Council) recommended them to NMFS for potential approval. Those details are not repeated here. For additional information on this action, please refer to the proposed rule. This final rule adopts, without changes, the annual reference points and management measures as proposed for the 2026–2027 fishing year.

*Final Reference Points and Management Measures*

Based on the 2025 stock assessment for Pacific sardine, the associated estimated age 1+ biomass of 30,158 mt, the control rule formulas in the FMP, and the Pacific sardine rebuilding plan (90 FR 23461, June 3, 2025), NMFS is implementing, as proposed, an OFL of 4,645 mt, an ABC of 3,613 mt, an ACL of 2,200 mt, and an ACT of 2,100 mt.

The CPS FMP includes a prohibition of the primary directed fishery when the biomass is at or below 150,000 mt. The Pacific sardine primary directed fishery is therefore closed, and Pacific sardine catch during the 2026–2027 fishing season is prohibited unless it is harvested as part of the live bait or minor directed fisheries, as incidental catch in other fisheries, or as part of EFP activities.

The 2026–2027 fishing year specifications can be found in table 1, and management measures are listed after table 1.

TABLE 1—HARVEST SPECIFICATIONS FOR THE 2026–2027 SARDINE FISHING YEAR, IN METRIC TONS (MT)

| Biomass estimate | OFL | ABC | HG | ACL | ACT |
|---|---|---|---|---|---|
| 30,158 | 4,645 | 3,613 | 0 | 2,200 | 2,100 |

The following are the additional management measures and in-season accountability measures for the 2026–2027 Pacific sardine fishing year:

(1) An incidental per-landing limit of 20 percent (by weight) of Pacific sardine applies to other CPS primary directed fisheries (*e.g.,* Pacific mackerel);

(2) If the ACT of 2,100 mt is attained, then a per-trip limit of 1 mt of Pacific sardine applies to all CPS fisheries (*i.e.,* management measure (1) described above will no longer apply); and

(3) An incidental per-landing allowance of 2 mt of Pacific sardine applies to non-CPS fisheries until the ACL is reached.

In addition to the management measures and in-season accountability measures listed above, Pacific sardine catch in the minor directed fishery remains limited to 1 mt per trip per day, and 1 trip per day by any vessel, per regulations at 50 CFR 660.511(d)(2).

All sources of catch, including any EFP set-asides, the live bait fishery, and other minimal sources of harvest, such as incidental catch in CPS and non-CPS fisheries and minor directed fishing, will be accounted for against the ACT and ACL. Any Pacific sardine harvested between July 1, 2026, and the effective date of this final rule will count toward the 2026–2027 ACT and ACL.

At the April 2026 Council meeting, the Council recommended apportioning 520 mt of the ACL for an EFP proposal to support stock assessments for Pacific sardine. NMFS published a notice of receipt of application in the **Federal Register** and requested public comment. After these specifications are effective, NMFS will determine whether it will issue the EFP.

The NMFS West Coast Regional Administrator will publish a notice in the **Federal Register** to announce when catch reaches the incidental limits, as well as any changes to allowable incidental catch percentages or trip limits. Additionally, to ensure that the regulated community is informed of any closure, NMFS will make announcements through other means available, including emails to fishermen, processors, and state fishery management agencies.

**Comments and Responses**

On June 29, 2026, NMFS published a proposed rule for this action and solicited public comments through July 14, 2026 (91 FR 39054). NMFS received two public comment letters, one from the California Wetfish Producers Association (CWPA) and one from a private citizen. After considering the public comments, NMFS made no changes from the proposed rule.

*Comment 1:* CWPA expressed support for the annual specifications and management measures for the northern subpopulation of Pacific sardine off the west coast. However, despite its support, CWPA also expressed their belief that these specifications reflect excessive precautions and fail to consider the recent trend of assessment projections falling below the estimates of surveys and strongly urged NOAA to continue its support to revise sardine management to a single stock.

*Response:* CWPA's support for the approval of these annual specifications is noted and NMFS acknowledges CWPA's concern that they also reflect excessive precaution. The annual specifications being implemented by this action are based on the framework and control rules in the CPS FMP, as well as the current definition of Pacific sardine in the CPS FMP. Currently, the annual stock assessments are considered the best scientific information available for management of the northern subpopulation of Pacific sardine. The stock assessments utilize a variety of data to produce the annual estimate of biomass, and the survey estimates are one important component. From year to year, the estimates directly from the survey can be both higher and lower than the estimates from the stock assessments. The survey estimates on their own have not been reviewed for direct use in management. NMFS intends to continue to support the efforts of the Council in their development of a proposal to revise the Pacific sardine stock definition within the CPS FMP.

*Comment 2:* The private citizen expressed personal beliefs about fishing (*e.g.,* ''do not torture and/or kill the fish anymore'') that were not directly responsive to this action.

*Response:* This comment is not within the scope of this action.

**Classification**

Pursuant to section 304(b)(1)(A) of the MSA, the NMFS Assistant Administrator has determined that this final rule is consistent with the CPS FMP, other provisions of the MSA, and other applicable law.

This final rule is exempt from review under Executive Order 12866. This final rule is not an Executive Order 14192 regulatory action because it is a routine fishing action.

NMFS finds good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in the date of effectiveness of these final harvest specifications for the 2026–2027 Pacific sardine fishing season. In accordance with the FMP, this rule was recommended by the Council at its meeting in April 2026. The contents of this rule are based on the best scientific information available on the population status of Pacific sardine, which became available at that April 2026 meeting. Making these final specifications effective immediately is necessary for the conservation and management of the Pacific sardine resource because last year's restrictions on harvest ended on June 30, 2026. The FMP requires a prohibition on primary directed fishing for Pacific sardine for the 2026–2027 fishing year because the sardine biomass has dropped below the CUTOFF. The purpose of the CUTOFF in the FMP, and for prohibiting a primary directed fishery when the biomass drops below this level, is to protect the stock when biomass is low and provide a buffer of spawning stock that is protected from fishing and can contribute to rebuilding the stock. Without effective specifications, there is no prohibition on primary directed fishing, no regulations on catch, and a significant amount of sardine could theoretically be caught in a short period.

Delaying the effective date of this rule is contrary to the public interest because it would jeopardize the sustainability of the Pacific sardine stock and affected minor fisheries. Furthermore, most affected fishermen have already been operating under a prohibition of the primary directed fishery for years, are aware that the Council recommended that primary directed commercial fishing be prohibited again for the 2026–2027 fishing year, and are fully prepared to comply with the prohibition. Further delay in the effective date creates unnecessary confusion in the Pacific sardine industry around current specifications and management measures.

The Senior Lead Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities for the purposes of the Regulatory Flexibility Act. The factual basis for the certification was published in the proposed rule (91 FR 39054, June 29, 2026) and is not repeated here. As a result, a final regulatory flexibility analysis was not required and none was prepared.

A Tribal summary impact statement under paragraphs (5)(b)(2)(B) and (5)(c)(2) of Executive Order 13175 was not required for this final rule because this action does not impose substantial direct compliance costs on Indian Tribal Governments and this action does not preempt Tribal law. A Tribal summary impact statement has therefore not been prepared.

This action does not contain a collection-of-information requirement for purposes of the Paperwork Reduction Act. There are no relevant Federal rules that may duplicate, overlap, or conflict with the proposed action.

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

Dated: September 29, 2026.

**Samuel D. Rauch III,**

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

[FR Doc. 2026–20234 Filed 10–1–26; 8:45 am]

**BILLING CODE 3510–22–P**

# Proposed Rules

Federal Register
Vol. 91, No. 190
Friday, October 2, 2026

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 71

**[Docket No. FAA–2026–8948; Airspace Docket No. 26–ASO–16]**

**RIN 2120–AA66**

## Amendment of Class D and E Airspace, Revocation of Class E Airspace; Montgomery, AL

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This action proposes to amend Class D airspace for Maxwell Air Force Base (AFB), Montgomery, AL, by making administrative updates. It also proposes to amend Class E airspace from 700 feet by expanding it by 0.5 NM from a 7-mile to a 7.5-mile radius around Maxwell AFB to contain IFR departures, along with making administrative changes. Finally, it proposes to revoke Class E airspace from the surface around Maxwell AFB, as the airport no longer meets the qualifications for Class E surface area airspace. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

**DATES:** Comments must be received on or before November 16, 2026.

**ADDRESSES:** Send comments identified by FAA Docket No. FAA–2026–8948 and Airspace Docket No. 26–ASO–16 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *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 W58–213, West Building 5th Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W58–213 of the West Building, 5th Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

*Docket:* Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W58–213 of the West Building, 5th Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FAA Order JO 7400.11M, Airspace Designations and Reporting Points, and subsequent amendments, can be viewed online at *www.faa.gov/air_traffic/publications/.* You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267–8783.

**FOR FURTHER INFORMATION CONTACT:** Rachel Cruz, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; telephone: (404) 305–5571.

**SUPPLEMENTARY INFORMATION:**

### Authority for This Rulemaking

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

### Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

*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 *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

### Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA, 30337.

**Incorporation by Reference**

Class D and Class E airspace designations are published in paragraphs 5000, 6002, and 6005 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 proposes to amend the current version of that order, FAA Order JO 7400.11M, Airspace Designations and Reporting Points, dated July 30, 2026, and effective September 15, 2026. These amendments would be published subsequently in the next update to FAA Order JO 7400.11. FAA Order JO 7400.11M, 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 Proposal**

This action proposes to amend 14 CFR part 71 by updating geographic coordinates for Maxwell AFB in the Class D airspace legal description. It would also update the header for the Maxwell AFB legal description to list the city and state instead of the airport name to comply with FAA guidance.

This action also proposes to amend the Class E airspace extending upward from 700 feet above the surface at Montgomery, AL, by increasing the radius of the airspace surrounding Maxwell AFB from a 7-mile radius to a 7.5-mile radius. The additional airspace is needed to contain IFR departures from Maxwell AFB as they transition to the adjacent Class E airspace extending upward from 1,200 feet above the surface. Additionally, this action proposes to update the reference to Montgomery Regional Airport—Dannelly Field, AL, to Montgomery Regional Airport (Dannelly Field), AL; update the reference to Prattvillle-Grouby Field Airport to Prattville/Grouby Field Airport, AL; add the state abbreviation to the Wetumpka Municipal Airport reference; and add the state abbreviation to the Maxwell AFB reference.

Additionally, this action proposes to revoke the Class E airspace designated as a surface area at Maxwell AFB. This airspace is no longer required because the airport does not have the weather reporting capability necessary to support the Class E surface area when the air traffic control tower is closed.

**Regulatory Notices and Analyses**

The FAA has determined that this proposed 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 Order 2100.6B, ''Rulemaking and Guidance Procedure'' (March 10, 2025); and (3) is expected to result in, at most, de minimis costs from compliance with applicable operating requirements or minor flight rerouting for operators choosing to navigate around the controlled airspace. Since these proposed amendments are routine and the expected impact to operators is de minimis, the FAA certifies that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**Environmental Review**

This proposal will be subject to an environmental analysis in accordance the National Environmental Policy Act (42 U.S.C. 4321, *et seq.*) and FAA Order 1050.1G, ''FAA National Environmental Policy Act Implementing Procedures'' prior to any FAA final regulatory action.

**Lists of Subjects in 14 CFR Part 71**

Airspace, Incorporation by reference, Navigation (air).

**The Proposed Amendment**

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 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 Federal Aviation Administration Order JO 7400.11M, Airspace Designations and Reporting Points, dated July 30, 2026, and effective September 15, 2026, is amended as follows:

* * * * *

*Paragraph 5000 Class D Airspace.*

* * * * *

**ASO AL D Montgomery, AL [Amended]**

Maxwell AFB, AL
(Lat. 32°22′59″ N, long. 86°21′57″ W)
Montgomery Regional Airport (Dannelly Field), AL
(Lat. 32°18′02″ N, long. 6°23′38″ W)
Montgomery VORTAC
(Lat. 32°13′20″ N, long. 86°19′11″ W)

That airspace extending upward from the surface to and including 2,200 feet MSL within a 5-mile radius of Maxwell AFB, excluding that airspace south of a line 2.5 miles north of and parallel to RWY 10–28 at Montgomery Regional Airport (Dannelly Field) and southwest of a line along the Montgomery VORTAC 320° radial. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

* * * * *

*Paragraph 6002 Class E Airspace Areas Designated as Surface Areas.*

* * * * *

**ASO AL E2 Maxwell AFB, AL [Revoked]**

* * * * *

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

* * * * *

**ASO AL E5 Montgomery, AL [Amended]**

Montgomery Regional Airport (Dannelly Field), AL
(Lat. 32°18′02″ N, long. 86°23′38″ W)
Montgomery VORTAC
(Lat. 32°13′20″ N, long. 86°19′11″ W)
Maxwell AFB, AL
(Lat. 32°22′59″ N, long. 86°21′57″ W)
Prattville/Grouby Field Airport, AL
(Lat. 32°26′19″ N, long. 86°30′46″ W)
Wetumpka Municipal Airport, AL
(Lat. 32°31′38″ N, long. 86°19′52″W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of Montgomery Regional Airport (Dannelly Field), and within 4 miles east and 8 miles west of the Montgomery VORTAC 138° radial extending from the 7-mile radius to 16 miles southeast of the Montgomery VORTAC, and within a 7.5-mile radius of Maxwell AFB, and within a 7-mile radius of Prattville/Grouby Field Airport, and within a 6.3-mile radius of Wetumpka Municipal Airport.

* * * * *

Issued in College Park, Georgia, on September 25, 2026.

**Kristen Leake,**

*Acting Manager, Airspace and Procedures South Team, Eastern Service Center, Air Traffic Organization.*

[FR Doc. 2026–20202 Filed 10–1–26; 8:45 am]

**BILLING CODE 4910–13–P**

**DEPARTMENT OF THE INTERIOR**

**National Park Service**

**36 CFR Part 7**

**[NPS–BICY–NPS0042712; PPSEBICYS0// 266P103601/PPMPSPD1Z.000000]**

**RIN 1024–AE54**

## Big Cypress National Preserve; Off-Road Motor Vehicles

**AGENCY:** National Park Service, Interior.

**ACTION:** Proposed rule.

**SUMMARY:** The National Park Service proposes to amend special regulations for Big Cypress National Preserve that regulate the use of motorized vehicles off roads. The current regulations refer to a map that identifies areas within the National Preserve where motorized vehicles can be used unless closed by the Superintendent. This map is outdated and does not depict the current boundary of the National Preserve, which was expanded in 1988 by approximately 147,000 acres. This rule would replace references to the outdated map with references to a map showing the current boundary of the National Preserve, with the effect of expanding the areas within the National Preserve where motorized vehicle use could occur, subject to the discretion of the Superintendent.

**DATES:** Comments must be received by 11:59 p.m. EDT on December 1, 2026.

**ADDRESSES:** You may submit comments by any of the following methods:

(1) *Electronically:*

• Go to the **Federal Register** website: *https://www.federalregister.gov.* In the search box, enter 1024–AE54, the regulation identifier number (RIN) for this rulemaking. Click on the green ''Submit a Public Comment'' button at the top of the document and follow the instructions for submitting comments; or

• Go to the Federal eRulemaking Portal: *https://www.regulations.gov.* In the Search box, enter 1024–AE54, the RIN for this rulemaking. On the resulting page, select the Dockets tab and then click on the title of the rule. Next, click the ''Open for Comments'' box, then click the blue ''Comment'' box and follow the instructions for submitting comments.

(2) *By hard copy:*

• *Mail to:* Superintendent, Big Cypress National Preserve, 33100 Tamiami Trail E, Ochopee, FL 34141.

*Document Availability:* The Final Backcountry Access Plan/Wilderness Study/Final Environmental Impact Statement and related Record of Decision provide information and context for this proposed rule and are available online at *https://parkplanning.nps.gov/bicy* by clicking the link titled ''Backcountry Access Plan'' and then the link titled ''Document List.''

*Instructions:* Comments will not be accepted by fax, email, or in any way other than those specified above. All submissions received must include the words ''National Park Service'' or ''NPS'' and must include the docket number or RIN (1024–AE54) for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov,* including any personal information provided.

*Docket:* Docket: For access to the docket to view the proposed rule and comments received, go to *https://www.regulations.gov* and search for ''1024–AE54.'' Be sure to check the Dockets Tab, Documents Tab, and Comment Tab for possible results.

**FOR FURTHER INFORMATION CONTACT:** Tom Forsyth, Superintendent, Big Cypress National Preserve; (239) 695–1103; *tom_forsyth@nps.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. In compliance with the Providing Accountability Through Transparency Act of 2023, the plain language summary of the proposal is available on *Regulations.gov* in the docket for this rulemaking.

**SUPPLEMENTARY INFORMATION:**

### Purpose and Significance of Big Cypress National Preserve

Congress established Big Cypress National Preserve in 1974 ''to assure the preservation, conservation, and protection of the natural, scenic, hydrologic, floral and faunal, and recreational values of the Big Cypress Watershed in the State of Florida and to provide for the enhancement and public enjoyment thereof. . . .'' 16 U.S.C. 698f. The original boundary of the preserve surrounded 582,000 acres. This area is referred to as the Original Preserve. In 1988, Congress expanded the boundary to include within the National Preserve an additional approximately 147,000 acres, an area referred to as the Addition.

The National Preserve is part of the Big Cypress Swamp, which covers more than 2,400 square miles of southern Florida. Protecting over 729,000 acres of this vast swamp, the National Preserve contains a mixture of tropical and temperate plant communities that are home to a diversity of wildlife, including the Florida panther. Visitors to the National Preserve can travel for miles through an expanse of open prairies dotted with cypress trees, distant pinelands, and tree islands broken at intervals by dark, forested swamps. Wildlife is abundant; great blue herons, kingfishers, and alligators line the roadside canals and give visitors an exciting visual focus. Naturalists study the area's rich natural history and its delicate ecological balances. Some Miccosukee and Seminole Indians who make their homes in the area depend on the resources of the preserve for food, shelter, and spiritual needs.

### Authority To Promulgate Regulations

The National Park Service (NPS) manages the National Preserve under the NPS Organic Act of 1916, which gives the NPS authority to regulate the use of the park areas under its jurisdiction. 54 U.S.C. 100101. In the National Preserve's enabling act, Congress directed the Secretary to administer the preserve by developing and publishing in the **Federal Register** ''such rules and regulations as he deems necessary and appropriate to limit or control the use of Federal lands and waters with respect to . . . motor vehicles . . . and such other uses as the Secretary determines must be limited or controlled in order to carry out the purposes of [the National Preserve's enabling act].'' 16 U.S.C. 698i(b). The legislative history of the enabling act indicates that Congress intended to allow off-road motorized vehicles (ORVs) in the National Preserve, but only if their use is carefully regulated to protect the natural, wildlife, and wilderness values of the preserve. (S. Rept. 9301128; H. Rept. 93–502).

Under 36 CFR 4.10, the use of motor vehicles off established roads is not permitted unless routes and areas are designated for off-road motor vehicle use by special regulation. Under 36 CFR 4.10(b), such routes and areas may be designated only in national recreation areas, national seashores, national lakeshores and national preserves. The special regulations for the National Preserve in 36 CFR 7.86 designate certain areas for ORV use in compliance with NPS general regulations at 36 CFR 4.10(b) and the Executive Orders.

**ORV Management**

Since the 1930s, people have accessed areas that are now within the boundary of the National Preserve using ORVs, including swamp buggies, tracked vehicles, and smaller all-terrain vehicles. The NPS promulgated 36 CFR 7.86(a) in 1979 to govern the use of motorized vehicles in the Original Preserve. This provision designates areas where ORVs may be used within the preserve. ORVs are defined broadly to include automobiles, trucks, glades or swamp buggies, airboats, amphibious or air cushion vehicles or any other device propelled by a motor and designed, modified for or capable of cross country travel on or immediately over land, water, marsh, swampland or other terrain, except boats which are driven by a propeller in the water. The special regulations establish certain areas within the Original Preserve where ORVs are prohibited. ORVs are prohibited in the areas between the Loop Road (State Hwy. #B94) and the Tamiami Trail (U.S. Hwy. #B41), except that the Superintendent may issue a permit to provide for reasonable access by legal residents or to provide access by authorized oil and gas companies. ORVs are prohibited on a segment of the main hiking trail that is part of Section 1 of the Big Cypress Florida Trail, from Tamiami Trail to Alligator Alley. Finally, ORVs are prohibited on the two marked loop trails in Section 1 of the Big Cypress Florida Trail, except that vehicles may cross the trails. All other areas within the Original Preserve are open to ORV use under the special regulations, unless closed by the Superintendent. These are the areas south and west of Loop Road (State Road #84) and north of Tamiami Trail, which make up a substantial portion of the Original Preserve. The outermost boundaries of these areas are not described in the special regulations. Rather, the special regulations refer to a map numbered BC–91–001, dated November 1975. This map depicts the outer boundary of the Original Preserve, which was the extent of the National Preserve in 1975. The special regulations also establish certain requirements for ORV operation and equipment related to visitor safety, fire prevention, and resource protection.

Using the regulatory framework in the special regulations, since the issuance of the Final Recreational Off-Road Vehicle Management Plan/Supplemental Environmental Impact Statement (SEIS) in 2000, Superintendents of the National Preserve have managed ORV use in the Original Preserve by designating specific routes and areas where ORVs may be used, with the effect of closing all other locations to ORV use. Consistent with the SEIS, these designations and closures are established in a written compilation of designations, closures, permit requirements and other restrictions imposed under the discretionary authority of the superintendent, referred to as the Superintendent's Compendium. 36 CFR 1.7(b). The Superintendent's Compendium for the National Preserve is available at *www.nps.gov/bicy.* As written, the special regulations give the Superintendent no authority to allow recreational ORV use in the Addition because it was added to the National Preserve in 1988 and therefore is not depicted on the 1975 map. This means that ORV use is prohibited in the Addition under NPS general regulations that prohibit ORV use except on areas and routes designated in special regulations. 36 CFR 4.10.

ORV management in the National Preserve has been supported by various planning processes and environmental reviews over the years. In 2000, the NPS released the SEIS that evaluated the environmental impacts of ORV use in the Original Preserve, excluding the Addition. In October 2010, the NPS issued a Final General Management Plan/Wilderness Study/Off-Road Vehicle Management Plan/Environmental Impact Statement (FEIS) that evaluated ORV use in the Addition. Most recently in November 2024, the NPS published a Final Backcountry Access Plan/Wilderness Study/Final Environmental Impact Statement (BAP) that evaluated ORV use in both the Original Preserve and the Addition. On December 12, 2024, the Regional Director, Interior Region 2, signed a Record of Decision (ROD) selecting the preferred alternative in the BAP for implementation. Under the selected alternative, the NPS will allow ORV use only on designated motor vehicle and airboat routes in the Original Preserve and the Addition. The BAP planning process involved input from various stakeholders, including the U.S. Fish and Wildlife Service, the Florida Fish and Wildlife Conservation Commission, Indian Tribes, and the general public through various public comment periods.

**Proposed Rule**

This proposed rule would broaden the scope of the existing special regulations so that the long-standing regulatory framework for managing ORV use in the Original Preserve is applied to managing ORV use in the Addition. This would allow the Superintendent to designate routes for ORV use in the Addition consistent with the selected alternative in the ROD, which does not allow for dispersed ORV use. The regulatory framework for managing ORV use would be consistent throughout the National Preserve, rather than fractured as it is under the existing special regulations, which do not allow the Superintendent to designate ORV routes on more than 147,000 acres of land and water within the National Preserve. Without changing any other provisions in the special regulations, this rule would replace two references to the 1975 map with references to a map that depicts the current boundary of the National Preserve, which includes the Addition. The Addition is north of Tamiami Trail, meaning that it would become open to ORV use on designated trails consistent with the ROD, which would occur by designating specific routes and areas for ORV use in the Addition through the Superintendent's Compendium. This map would be available at *www.nps.gov/bicy.*

**Compliance With Other Laws, Executive Orders, and Department Policy**

*Regulatory Planning and Review (Executive Orders 12866 and 14192)*

This rule has been determined to be not significant for purposes of Executive Order 12866. This rule is a ''one-time'' enabling regulation that would allow the Superintendent to expand consumption options for the American public by increasing opportunities for recreation and access at the National Preserve. As a result, this rule qualifies as an E.O. 14192 deregulatory action pursuant to M–25–20, ''Guidance Implementing Section 3 of Executive Order 14192, Titled 'Unleashing Prosperity Through Deregulation''' issued by the Office of Management and Budget, Office of Information and Regulatory Affairs, on March 26, 2025.

*Regulatory Flexibility Act*

An Initial Regulatory Flexibility Analysis (IRFA) has been prepared for this proposed rule under the RFA (5 U.S.C. 601 *et seq.*). The IRFA is part of the economic analyses found in the report titled ''Regulatory Analysis of the Off-Road Motor Vehicles Proposed Rule at Big Cypress National Preserve.'' The report is available online at *https://parkplanning.nps.gov/bicy* by clicking the link titled ''Backcountry Access Plan'' and then the link titled ''Document List.''

*Congressional Review Act*

This proposed rule is not a major rule under 5 U.S.C. 804(2). This proposed rule:

(a) Would not have an annual effect on the economy of $100 million or more.

(b) Would not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(c) Would not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

*Unfunded Mandates Reform Act*

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess whether a rule would impose a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year. As of 2025, that threshold is approximately $206 million (2024 dollars). This regulation will not result in expenditures by State, local, or Tribal governments, in the aggregate, or by the private sector, in excess of the threshold. Thus, no written assessment of unfunded mandates is required.''

*Takings (Executive Order 12630)*

This proposed rule would not effect a taking of private property or otherwise have takings implications under Executive Order 12630. A takings implication assessment is not required.

*Federalism (Executive Order 13132)*

Under the criteria in section 1 of Executive Order 13132, this proposed rule would not have sufficient federalism implications to warrant the preparation of a Federalism summary impact statement. This rule would only affect use of federally administered lands and waters. It would have no direct effects on other areas. A Federalism summary impact statement is not required.

*Civil Justice Reform (Executive Order 12988)*

This proposed rule complies with the requirements of Executive Order 12988. This proposed rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

*Consultation With Indian Tribes (Executive Order 13175 and Department Policy)*

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. The National Preserve has been a home to indigenous peoples for centuries. Currently, there are 15 Miccosukee and Seminole active traditional villages in the National Preserve, and more sites that are now considered historic cultural sites, multiple active ceremonial grounds, and active burial grounds scattered throughout the preserve. The NPS has evaluated this proposed rule under the criteria in Executive Order 13175 and under the Department's Tribal consultation policy and has determined that Tribal consultation is not required because this rule will have no substantial direct effect on federally recognized Indian Tribes. Nevertheless, in support of the Department of the Interior's and the NPS's commitment to government-to-government consultation, the NPS engaged in formal consultation with the Miccosukee Tribe of Indians of Florida, the Seminole Tribe of Florida, and the Seminole Nation of Oklahoma throughout the development of the BAP. Based on information shared during Tribal consultation, the NPS understands that the Tribes' view is that it is not the presence or lack of human habitation that defines the health of a landscape, but the relationship of humans to that land that determines the land's fate. The alternative selected for implementation in the ROD was chosen in part because it is responsible to the concerns expressed by the Seminole and Miccosukee Tribes during Tribal consultation, as further discussed in the BAP.

*Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)*

This proposed rule contains no new information collections. All information collections require approval under the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501 *et seq.*). The NPS 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.

*National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 et seq.)*

The NPS prepared an environmental impact statement as part of the BAP and the ROD in compliance with NEPA. This proposed rule implements the ROD, which identifies specific routes for ORV use. Copies of these documents are available online at *https://parkplanning.nps.gov/bicy* by clicking the link by clicking the link titled ''Backcountry Access Plan'' and then the link titled ''Document List.''

*Effects on the Energy Supply (Executive Order 13211)*

This proposed rule is not a significant energy action under the definition in Executive Order 13211; this proposed rule is not likely to have a significant adverse effect on the supply, distribution, or use of energy, and this proposed rule has not otherwise been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. A Statement of Energy Effects in not required.

**List of Subjects in 36 CFR Part 7**

National parks, Reporting and recordkeeping requirements.

In consideration of the foregoing, the National Park Service proposes to amend 36 CFR part 7 as set forth below:

## PART 7—SPECIAL REGULATIONS, AREAS OF THE NATIONAL PARK SYSTEM

■ 1. The authority citation for part 7 continues to read as follows:

**Authority:** 54 U.S.C. 100101, 100751, 320102; Sec. 7.96 also issued under DC. Code 10–137 and DC. Code 50–2201.07.

■ 2. In § 7.86, revise the introductory text in paragraphs (a)(2)(i) and (a)(2)(ii) as follows:

**§ 7.86 Big Cypress National Preserve.**

(a) * * *

(1) * * *

(2) * * *

(i) Unless closed or restricted by action of the Superintendent under paragraph (a)(2)(iii), the following areas, which are shown on a map numbered 26–001, dated May 1, 2026, and available for public inspection at the office of the Superintendent, are open to motorized vehicles:

(A) * * *

(B) * * *

(ii) The following areas which are shown on a map numbered 26–001, dated May 1, 2026, and available for public inspection at the office of the Superintendent, are closed to motorized vehicles:

* * * * *

**Kevin J. Lilly,**

*Assistant Secretary for Fish and Wildlife and Parks.*

[FR Doc. 2026–20251 Filed 10–1–26; 8:45 am]

**BILLING CODE 4312–52–P**

# Notices

Federal Register
Vol. 91, No. 190
Friday, October 2, 2026

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

## DEPARTMENT OF AGRICULTURE

### Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments regarding this information collection received by November 2, 2026 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

**Agricultural Research Service**

*Title:* Peer Review Related Forms for the Office of Scientific Quality Review.

*OMB Control Number:* 0518–0028.

*Summary of Collection:* The Office of Scientific Quality Review (OSQR) oversees peer review of Agricultural Research Service (ARS) research plans in response to Congressional mandate in the Agricultural Research Extension, and Education Reform Act of 1998 (Pub. L. 105–185, section 103d). The ARS peer-review panels are comprised of scientists who review current scientific research projects and who have expert knowledge in the fields being reviewed. The OSQR oversees the process of panel member selection, their personal documentation and certification for review, and the recording, and transmittal of panel reviews.

*Need and Use of the Information:* ARS will collect the information using the following forms:

ARS–199A, Ad Hoc Peer Review of ARES Research Project
ARS–200PA, Confidentiality Agreement
ARS–202P, Chair & Panelist Information Form
ARS–209P, OSQR Expense Report
ARS–223P Panel Recommendation on ARS Research Project Plan
ARS–225P, Panelist Peer Review of ARS Research Project
ARS–231 Reviewer Comment Form

The information collected is used to manage travel and stipend payments to panel reviewers and provide well-organized feedback to ARS's researchers about their projects. If information were not collected, ARS would not meet the administrative or legislative requirements of the Peer Review Process as mandated by Public Law 105–185; section 103(d).

*Description of Respondents:* Individuals or households.

*Number of Respondents:* 185.

*Frequency of Responses:* Reporting: Quarterly; Weekly; Annually.

*Total Burden Hours:* 763.

**Rachelle Ragland-Greene**

*Departmental Information Collection Clearance Officer.*

[FR Doc. 2026–20267 Filed 10–1–26; 8:45 am]

BILLING CODE 3410–03–P

## DEPARTMENT OF AGRICULTURE

### Submission for OMB Review; Comment Request

The Department of Agriculture will submit the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. Comments are requested regarding: (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden 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 through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding these information collections are best assured of having their full effect if received by November 2, 2026. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

**National Agricultural Statistics Service (NASS)**

*Title:* Field Crops Production—Substantive Change.

*OMB Control Number:* 0535–0002.

*Summary of Collection:* General authority for these data collection

activities is granted under U.S. Code Title 7, Section 2204 which specifies that ''The Secretary of Agriculture shall procure and preserve all information concerning agriculture which he can obtain . . . by the collection of statistics . . .''. The primary objective of the National Agricultural Statistics Service (NASS) is to provide data users with timely and reliable agricultural production and economic statistics, as well as environmental and specialty agricultural related statistics. To accomplish this objective, NASS relies on the use of diverse surveys that show changes within the farming industry over time.

The primary functions of the National Agricultural Statistics Services' (NASS) are to prepare and issue State and national estimates of crop and livestock production, disposition, and prices and to collect information on related environmental and economic factors. The Field Crops Production Program consists of probability field crops surveys and supplemental panel surveys. NASS will use surveys to collect information through a combination of the internet, mail, telephone, and personnel interviews. The general authority for these data collection activities is granted under U.S. Code Title 7, Section 2204.

The National Agricultural Statistics Service (NASS) is requesting a substantive change to the Field Crops Production information collection request (OMB No. 0535–0002). This revision adds two questions to the January and June Sugarcane Inquiry questionnaires, to more accurately capture sugarcane production changes. NASS is also requesting to use text message and email reminders for respondents who have opted to receive these messages, which results in an increase in 483 burden hours. There are no other changes to the survey methodology or procedures previously approved.

*Need and Use of the Information:* NASS collects information on field crops to monitor agricultural developments across the country that may impact on the nation's food supply. The Secretary of Agriculture uses estimates of crop production to administer farm program legislation and import and export programs. Collecting this information less frequently would eliminate the data needed to keep the Department abreast of changes at the State and national level.

*Description of Respondents:* Farms; Business or other for-profits.

*Number of Respondents:* 426,675.

*Frequency of Responses:* Reporting: Weekly, Monthly, Quarterly, Annually.

*Total Burden Hours:* 140,289.

**Levi S. Harrell,**

*Departmental Information Collection Clearance Officer.*

[FR Doc. 2026–20237 Filed 10–1–26; 8:45 am]

**BILLING CODE 3410–20–P**

## DEPARTMENT OF AGRICULTURE

### Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding: whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by November 2, 2026 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

### National Institute of Food and Agriculture

*Title:* Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Programs to Request a New Lifecycle Certification Form.

*OMB Control Number:* 0524–0052.

*Summary of Collection:* The USDA SBIR/STTR Programs are administered by the National Institute of Food and Agriculture (NIFA) of the USDA. NIFA exercises overall oversight for the policies and procedures governing SBIR/STTR grants awarded to the U.S. small business community. In 1982, the Small Business Innovation Research (SBIR) Grants Program (Pub. L. 97–219, 96 stat. 217), 15 U.S.C. 638, was authorized. In 1992, the Small Business Technology Transfer (STTR) Grants Program was authorized by the Small Business Research and Development Enhancement Act (15 U.S.C. 638). In 2026, the Small Business Innovation and Economic Security Act reauthorized the SBIR and STTR programs through September 30, 2031.

*Need and Use of the Information:* USDA uses the SBIR/STTR Funding Agreement Certification form to ensure SBCs meet specific eligibility requirements for a Small Business Innovation and Research or Small Business Technology Transfer award. The form asks applicants to certify a series of ten statements in order to ensure the grantee is complying with specific program requirements during the life of the funding agreement. If SBC is majority-owned by venture capital companies, hedge funds, or private equity firms, then they will be required to fill out an eight-question form in addition to the SBIR/STTR Funding Agreement Certification. The small business concern may be required to update the SBIR/STTR Funding Agreement Certification form to assure continued eligibility and compliance when changes in the SBC apply.

*Description of Respondents:* Individuals/Business-for-profit.

*Number of Respondents:* 180.

*Frequency of Responses:* Reporting: On occasion.

*Total Burden Hours:* 93.

**Rachelle Ragland-Greene,**

*Departmental Information Collection Clearance Officer.*

[FR Doc. 2026–20278 Filed 10–1–26; 8:45 am]

**BILLING CODE 3410–09–P**

## DEPARTMENT OF AGRICULTURE

### Food and Nutrition Administration

### Supplemental Nutrition Assistance Program: State of Nebraska SNAP Demonstration Project

**AGENCY:** Food and Nutrition Administration, U.S. Department of Agriculture.

**ACTION:** Notice of request for public comments.

**SUMMARY:** This notice invites the public to comment on the State of Nebraska's proposed demonstration project under section 17(b) of the Food and Nutrition Act of 2008. The Food and Nutrition Administration (FNA) will take appropriate action as necessary in response to comments, including authorizing or refusing to authorize the proposed project.

**DATES:** Written comments must be received on or before November 2, 2026.

**ADDRESSES:** Comments on this notice may be submitted to FNA by one of the following methods:

—*Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

—*Website:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

—All written comments submitted in response to this notice will be included in the record and will be made available to the public. Please be advised that the substance of the comments and the identity of the individuals or entities submitting the comments will be subject to public disclosure. FNA will make the written comments publicly available on the internet via *http://www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Shiela Corley, Acting FNA Administrator, at *SM.FN.RPMDHQ-WEB@usda.gov* with subject line of ''NE SNAP Demonstration Project''.

**SUPPLEMENTARY INFORMATION:** Section 17(b) of the Food and Nutrition Act of 2008, 7 U.S.C. 2026(b), authorizes FNA to approve demonstration projects to test changes to the Supplemental Nutrition Assistance Program (SNAP) that may increase programmatic efficiency and improve the delivery of SNAP benefits to raise levels of nutrition among eligible households. If approved, this proposed demonstration project would be implemented by the State, and FNA would carefully review the results of the project based on the State's evaluation data. All relevant documents, including the State's demonstration project request, can be found in the supporting document section. Additionally, to support implementation and ensure transparency, FNA created a central web page on May 21, 2025, to post State agencies' project requests and approvals and provide exact implementation timelines. That web page is accessible at the following address: *https://www.fna.usda.gov/snap/waivers/foodrestriction.*

**Discussion of Demonstration Project**

*State of Nebraska Demonstration Project Request*

Following the vacatur of Nebraska's demonstration project and four others in *Aragon* v. *Rollins,* No. 26–0861 (D.D.C. June 22, 2026), the State of Nebraska submitted a new request to conduct a demonstration project to amend the SNAP definition of food for purchase to exclude ''soda, soft drinks, and energy drinks'' with a proposed implementation date of December 1, 2026. In addition, the State requested to also exclude ''candy'' with a proposed implementation date of March 1, 2027. The State formally requested to conduct this project on September 1, 2026. The State's project request can be found in the supporting document section and on the FNA website on the following page: *https://www.fna.usda.gov/snap/waivers/foodrestriction/nebraska.*

*Request for Public Comments:* FNA is considering whether to approve Nebraska's proposed demonstration project. Although not required by statute, interested parties are invited to submit written comments regarding the State of Nebraska's proposed demonstration project. FNA is particularly interested in comments regarding the state's proposed plan for implementation and operation of the demonstration project. FNA will consider any comments submitted by November 2, 2026 and take appropriate action, including authorizing or refusing to authorize the project. In light of the district court's decision in *Aragon,* FNA will issue a separate **Federal Register** notice authorizing or refusing to authorize the project; although Nebraska has requested a December 1st implementation date, any notice authorizing the project would issue at least ten days before the project's implementation date. Further information related to the implementation of the demonstration project is included on the FNA website (*https://www.fna.usda.gov/snap/waivers/foodrestriction*) and the State's website (*https://dhhs.ne.gov/Pages/Healthy-Choices-Waiver.aspx*).

**Shiela Corley,**

*Acting Administrator, Food and Nutrition Administration, USDA.*

[FR Doc. 2026–20211 Filed 10–1–26; 8:45 am]

**BILLING CODE 3410–30–P**

## DEPARTMENT OF COMMERCE

### Census Bureau

**[Docket Number: 260928–0003; RTID 0607–XC087]**

### Notice of Data Sharing Activity

**AGENCY:** Census Bureau, Department of Commerce.

**ACTION:** Notice of Data Sharing Activity.

**SUMMARY:** The U.S. Bureau of the Census (Census Bureau) of the Department of Commerce intends to share business data with the U.S. Bureau of Economic Analysis (BEA) of the Department of Commerce. BEA will use select data from the Census Bureau's economic surveys to achieve efficiencies and increased accuracy in the preparation of U.S. economic statistics. The Census Bureau will share data collected through surveys that request voluntary response and that impose no legal obligation to supply information. Only authorized BEA employees who have sworn to uphold the confidentiality provisions of Title 13 will have access to Census Bureau data.

**DATES:** The effective date for data sharing is October 2, 2026.

**FOR FURTHER INFORMATION CONTACT:** For additional information concerning this notice, contact Lisa Donaldson, Assistant Associate Director for Economic Programs, U.S. Census Bureau, 4600 Silver Hill Road, Washington, DC 20233–6010, Telephone: 301–763–9844; by email at *Lisa.E.Donaldson@census.gov.*

**SUPPLEMENTARY INFORMATION:**

**Background**

The Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA) allows the Census Bureau to share business data for statistical purposes with BEA. The Census Bureau and BEA are providing this notice to ensure compliance with the *Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002* (*CIPSEA Implementation Guidance*), Paragraph VII.B., which requires designated statistical agencies to generally inform respondents about the intention to share business data.

Both the Census Bureau and BEA are primary statistical agencies within the Department of Commerce and ''designated statistical agencies'' under CIPSEA (44 U.S.C. 3576(e)). BEA and the Census Bureau are authoritative sources on economic data and statistics, including principal economic

indicators. These statistics inform the government, private industry, statistical researchers, and the American public about our nation's economic status and progress. To ensure accurate and timely reporting of economic data and indicators, the Census Bureau and BEA partner to measure the U.S. economy. Both the Census Bureau and BEA conduct survey collections, which are critical to the quality of source data and the timely preparation of many key indicators of U.S. economic performance. However, the Census Bureau and BEA recognize that these surveys impose some reporting burden on businesses that are required to respond. Both the Director of the Census Bureau and the Director of BEA are required to identify opportunities to eliminate duplicative collections, reduce reporting burdens, and reduce statistical program costs, while improving the quality of the resulting statistics and protecting the confidentiality of the data collected from survey respondents. (44 U.S.C. 3576(b)). To do so, the Census Bureau and BEA have shared and continue to consider increased opportunities to share business data pursuant to CIPSEA.

The Census Bureau and BEA can achieve major qualitative enhancements and cost efficiencies for Department of Commerce statistical programs, through BEA's increased access to certain data collected by the Census Bureau through the voluntary surveys listed below.

**Shared Data**

BEA will benefit from data which already exists in the following Census Bureau surveys:

Business Trends and Outlook Survey (BTOS); Monthly Retail Trade Survey (MRTS/MARTS); Monthly Wholesale Trade Survey (MWTS); Manufacturers' Shipments, Inventories, & Orders (M3); Quarterly Services Survey (QSS); Quarterly Survey of Plant Capacity Utilization; Emergency Economic Collections; Survey of Housing Starts, Sales, and Completions; and Construction Progress Reporting Surveys.

All of these Census Bureau data are collected under the provisions of 13 U.S.C. 131 and 193. Response to the surveys listed above is voluntary. The Census Bureau will not provide any Federal Tax Information to BEA.

**Statistical Purposes for the Shared Data**

BEA will use the shared data exclusively for authorized statistical purposes, as defined in 44 U.S.C. 3561(12). A number of benefits will accrue to the Federal government from this data-sharing initiative. Census Bureau aggregated data are a key source of information for BEA national, regional, and international statistics. BEA intends to use the company-level data to better understand trends, anomalies, coverage, completeness, and other characteristics of the aggregated data; to enhance the reliability of the nation's most important economic indicators, such as the National Income and Product Accounts; and increase understanding of the United States economy, especially for key national, industry, international, and regional statistics.

In addition, Census Bureau data may be compared at the company-level with data from BEA surveys. This will help improve coverage and accuracy of the data from both bureaus and may lead to collaborative efforts to provide new or expanded data products for the public without adding burden to respondents.

**Data Access and Confidentiality**

The sharing of confidential Census Bureau business data is authorized under 44 U.S.C. 3576. Pursuant to the *CIPSEA Implementation Guidance,* the Census Bureau and BEA are providing notice that they intend to enter into a written agreement for this data sharing action.

The Census Bureau data are confidential under 13 U.S.C. 9 and 214. The BEA employees who will have authorized access to confidential Census Bureau data are required to be sworn to observe the provisions of 13 U.S.C. 9 and will be advised of the penalties for improper disclosure under 13 U.S.C. 214. The penalties are imprisonment for no more than five years, a fine of no more than $250,000, or both. These BEA employees must complete annual Title 13 Awareness Training. Authorized BEA employees will use the accessed data for exclusively statistical purposes, as outlined in this Notice.

Dated: September 25, 2026.

**George Cook,**

*Deputy Under Secretary for Economic Affairs, performing the non-exclusive functions and duties of the Director of the Census Bureau.*

[FR Doc. 2026–20249 Filed 10–1–26; 8:45 am]

**BILLING CODE 3510–07–P**

## DEPARTMENT OF COMMERCE

### Foreign-Trade Zones Board

**[B–7–2026]**

### Foreign-Trade Zone (FTZ) 45; Authorization of Limited Production Activity; Qorvo US, Inc.; (Semiconductor Wafers and Modules); Hillsboro, Oregon

On January 15, 2026, Qorvo US, Inc. submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 45K in Hillsboro, Oregon.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (91 FR 2724, January 22, 2026). On September 29, 2026, the applicant was notified of the FTZ Board's decision that further review of part of the proposed activity is warranted. The FTZ Board authorized the production activity described in the notification on a limited basis, subject to the FTZ Act and the Board's regulations, including section 400.14, and further subject to a two-year time limitation on the use of printed circuit boards as foreign status components.

Dated: September 29, 2026.

**Colin Agostisi,**

*Executive Secretary.*

[FR Doc. 2026–20254 Filed 10–1–26; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### Foreign-Trade Zones Board

**[B–8–2026]**

### Foreign-Trade Zone (FTZ) 230; Authorization of Limited Production Activity; Qorvo US, Inc.; (Semiconductor Wafers, Modules, and Chips); Greensboro, North Carolina

On January 15, 2026, Qorvo US, Inc. submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 230K, in Greensboro, North Carolina.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (91 FR 2725, January 22, 2026). On September 29, 2026, the applicant was notified of the FTZ Board's decision that further review of part of the proposed activity is warranted. The FTZ Board authorized the production activity described in the notification on a limited basis, subject to

the FTZ Act and the Board's regulations, including § 400.14, and further subject to a two-year time limitation on the use of printed circuit boards as foreign status components.

Dated: September 29, 2026.

**Colin Agostisi,**

*Executive Secretary.*

[FR Doc. 2026–20255 Filed 10–1–26; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### Foreign-Trade Zones Board

**[B–49–2026]**

### Foreign-Trade Zone (FTZ) 75; Authorization of Production Activity; Essai, Inc.; (Semiconductor Test Equipment); Chandler, Arizona

On May 15, 2026, Essai, Inc. submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 75 in Chandler, Arizona.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (91 FR 30275, May 22, 2026). On September 28, 2026, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including § 400.14.

Dated: September 28, 2026.

**Colin Agostisi,**

*Executive Secretary.*

[FR Doc. 2026–20253 Filed 10–1–26; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### Foreign-Trade Zones Board

**[B–41–2026]**

### Foreign-Trade Zone 27; Withdrawal of Application for Subzone; Applied Materials, Inc.; Boylston, Gloucester, Newburyport, and Rowley, Massachusetts

Notice is hereby given of the withdrawal of the application submitted by the Massachusetts Port Authority, grantee of Foreign-Trade Zone 27, requesting subzone status for the facilities of Applied Materials, Inc. in Boylston, Gloucester, Newburyport, and Rowley, Massachusetts.

The application was docketed on April 15, 2026 (91 FR 20973, April 20, 2026). The withdrawal was requested by the applicant due to outstanding issues that need to be addressed. The case has been closed without prejudice.

Dated: September 28, 2026.

**Colin Agostisi,**

*Executive Secretary.*

[FR Doc. 2026–20260 Filed 10–1–26; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### Foreign-Trade Zones Board

**[B–22–2026]**

### Foreign-Trade Zone (FTZ) 153; Authorization of Limited Production Activity; CMS Circuits, Inc.; (Electronic Manufacturing Services in Aerospace, Industrial, and Medical Applications); Murrieta, California

On February 23, 2026, the City of San Diego, grantee of FTZ 153, submitted a notification of proposed production activity to the FTZ Board on behalf of CMS Circuits, Inc., within FTZ 153, in Murrieta, California.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (91 FR 10053, March 2, 2026). On September 29, 2026, the applicant was notified of the FTZ Board's decision that further review of part of the proposed activity is warranted. The FTZ Board authorized the production activity described in the notification on a limited basis, subject to the FTZ Act and the Board's regulations, including section 400.14, and further subject to a two-year time limit for admitting fiber optic bundles to the zone under foreign status.

Dated: September 29, 2026.

**Colin Agostisi,**

*Executive Secretary.*

[FR Doc. 2026–20261 Filed 10–1–26; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–570–242, A–557–838, A–489–860, C–489–861]**

### Notice of Extension of the Deadline for Determining the Adequacy of the Antidumping and Countervailing Duty Petitions: Certain Corrugated Die-Cut Cardboard Boxes From the People's Republic of China, Malaysia, and the Republic of Türkiye

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**DATES:** Applicable September 29, 2026.

**FOR FURTHER INFORMATION CONTACT:** Mira Warrier at (202) 482–8031 (the People's Republic of China (China)); Anne Entz at (202) 482–3845 (Malaysia); Howard Smith at (202) 482–5193 (the Republic of Türkiye (Türkiye) AD); and Danielle Buffa at (202) 482–8021 (Türkiye CVD), AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

**Extension of Initiation of Investigations**

*The Petitions*

On September 9, 2026, the U.S. Department of Commerce (Commerce) received antidumping duty (AD) and countervailing duty (CVD) petitions on imports of certain corrugated die-cut cardboard boxes (corrugated die-cut boxes) from China, Malaysia, and Türkiye filed in proper form on behalf of the American Pizza Boxes Manufacturers Coalition [1] and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union (collectively, the petitioners), the members of which are domestic producers of corrugated die-cut boxes and a certified union, which represents workers engaged in the production of corrugated die-cut boxes in the United States.[2]

*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,

[1] The members of the American Pizza Boxes Manufacturers Coalition are Smurfit Westrock plc and Pratt Industries, Inc.

[2] *See* Petitioners' Letter, ''Petition for the Imposition of Antidumping and Countervailing Duties,'' dated September 9, 2026 (Petitions).

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 AD or CVD 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 should extend the time period for determining whether to initiate the AD and CVD 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 determinations will now be due no later than October 19, 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: September 29, 2026.

**Scot Fullerton,**

*Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

[FR Doc. 2026–20257 Filed 10–1–26; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–583–837]**

### Polyethylene Terephthalate Film, Sheet, and Strip From Taiwan: Preliminary Results and Preliminary Intent To Rescind, In Part, of Antidumping Duty Administrative Review; 2024–2025

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The U.S. Department of Commerce (Commerce) preliminarily determines that Nan Ya Plastics Corporation (Nan Ya) made sales of polyethylene terephthalate film, sheet, and strip (PET film) from Taiwan at less than normal value (NV) during the period of review (POR) July 1, 2024, through June 30, 2025. Further, we preliminarily find that Shinkong Materials Technology Corporation (SMTC) and Shinkong Synthetic Fiber Corporation (SSFC), which we consider to be a single entity (SMTC/SSFC), had no reviewable entries during the POR. Interested parties are invited to comment on the preliminary results of this review.

**DATES:** Applicable October 2, 2026.

**FOR FURTHER INFORMATION CONTACT:** Charles DeFilippo, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482- 3797.

**SUPPLEMENTARY INFORMATION:**

## Background

On June 30, 2025, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty (AD) order on PET film from Taiwan.[1] On August 22, 2025, in accordance with 19 CFR 351.221(c)(1)(i), Commerce published a notice of initiation of an administrative review of *Order.*[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] On June 2, 2026, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), Commerce extended the deadline to issue the preliminary results by 113 days, until September 30, 2026.[5]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[6] A list of the topics included in the Preliminary Decision Memorandum is included as an appendix to this notice. The Preliminary 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 Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/frnotices.*

## Scope of the Order

The merchandise subject to the *Order* is PET film. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

## Preliminary Intent To Rescind Review, In Part

On September 3, 2025, Commerce placed U.S. Customs and Border Protection (CBP) entry data for U.S. imports of PET film from Taiwan during the POR, which showed that SMTC/

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review and Join Annual Inquiry Service List,* 90 FR 27841 (June 30, 2025).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 90 FR 41043 (August 22, 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, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated June 2, 2026.

[6] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review of Polyethylene Terephthalate Film, Sheet, and Strip from Taiwan; 2024–2025,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

SSFC[7] did not make any shipments of PET film during the POR, on the record of this review and invited interested parties to comment.[8] No party commented on the CBP data. Therefore, the record demonstrates that SMTC/SSFC had no suspended entries during the POR. On this basis, we intend to rescind the review with respect to SMTC/SSFC in accordance with 19 CFR 351.213(d)(3).

In the absence of any suspended entries of subject merchandise from SMTC/SSFC during the POR, Commerce hereby notifies all interested parties of its intent to rescind this administrative review with respect to SMTC/SSFC. Commerce is providing interested parties with an opportunity to submit comments on this preliminary decision, including factual information. Comments, including factual information from interested parties, are due to Commerce seven calendar days after the publication date of this notice. Rebuttal comments, including rebuttal factual information, are due seven calendar days thereafter. In accordance with 19 CFR 351.303, all submissions must be filed electronically in ACCESS.

## Methodology

Commerce is conducting this review in accordance with section 751(a) of the Act. Export price is calculated in accordance with section 772 of the Act. NV is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Memorandum.

## Preliminary Results of Review

Commerce preliminarily determines that the following estimated weighted-average dumping margin exists for the period July 1, 2024, through June 30, 2025:

| Producer/exporter | Weighted-average dumping margin (percent) |
|---|---|
| Nan Ya Plastics Corporation ..... | 3.95 |

## Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties under administrative protective order for these preliminary results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

## Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance. A timeline for the submission of case briefs and written comments will be notified to parties at a later date. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[9] Interested parties who submit case or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[10] All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety in ACCESS by 5:00 p.m. Eastern Time on the established deadline.

As provided under 19 CFR 351.309(c)(2)(iii) and (d)(2)(iii), we request that interested parties provide at the beginning of their briefs a public executive summary for each issue raised in their briefs.[11] Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[12]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants, and whether any participant is a foreign national; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. Oral presentations at the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined.[13]

## Assessment Rates

Upon completion of this administrative review, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries in accordance with 19 CFR 351.212(b). If Nan Ya's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review, we will calculate importer-specific assessment rate on the basis of the ratio of the total amount of dumping calculated for an importer's examined sales and the total entered value of such sales in accordance with 19 CFR 351.212(b)(1).[14] If the weighted-average dumping margin is zero or *de minimis* in the final results of review, or an importer-specific rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review and for future deposits of estimated duties, where applicable.[15]

For entries of subject merchandise during the POR produced by Nan Ya for which it did not know its merchandise was destined for the United States, we intend to instruct CBP to liquidate such entries at the all-others rate (*i.e.,* 2.40

[7] In the 2011–2012 administrative review, we treated SMTC and SSFC as a single entity. *See Polyethylene Terephthalate Film, Sheet, and Strip from Taiwan; Preliminary Results of Antidumping Duty Administrative Review; 2011–2012,* 78 FR 48651 (August 9, 2013), and accompanying Preliminary Decision Memorandum, unchanged in *Polyethylene Terephthalate Film, Sheet, and Strip from Taiwan: Final Results of Antidumping Duty Administrative Review; 2011–2012,* 79 FR 11407 (February 28, 2014). We have treated SMTC and SSFC as a single entity in all subsequent reviews. There is no information on the record of this administrative review that would lead Commerce to reconsider that determination. Accordingly, we continue to treat SMTC and SSFC as a single entity for purposes of this administrative review.

[8] *See* Memorandum, ''Release of Customs Entry Data,'' dated September 3, 2025 (CBP data).

[9] *See* 19 CFR 351.309(d)(1); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[10] *See* 19 CFR 351.309(c)(2) and (d)(2).

[11] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[12] *See APO and Service Final Rule.*

[13] *See* 19 CFR 351.310(c).

[14] 14 *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101, 8103 (February 14, 2012).

[15] *See* section 751(a)(2)(C) of the Act.

percent) [16] if there is no rate for the intermediate company(ies) involved in the transaction.[17]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this administrative 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). The final results of this administrative review shall be the basis for the assessment of antidumping duties on entries of merchandise under review and for future cash deposits of estimated antidumping duties, where applicable.

**Cash Deposit Requirements**

The following cash deposit requirements will be effective for all shipments of PET film from Taiwan entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Nan Ya will be the rate established in the final results of this review (except, if the rate is zero or *de minimis,* no cash deposit will be required); (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair value investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other producers or exporters is 2.40 percent.[18] These cash deposit requirements, when imposed, shall remain in effect until further notice.

[16] 16 *See Notice of Amended Final Antidumping Duty Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Polyethylene Terephthalate Film, Sheet, and Strip (PET Film) from Taiwan,* 67 FR at 44175 (July 1, 2002), unchanged in *Notice of Amended Final Antidumping Duty Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Polyethylene Terephthalate Film, Sheet, and Strip (PET Film) from Taiwan* {*sic*}, 67 FR at 46566 (July 15, 2002).

[17] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[18] *See Order.*

**Final Results of Review**

Unless extended, Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

**Notification to Importers**

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

**Notification to Interested Parties**

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: September 29, 2026.

**Scot Fullerton,**

*Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

**Appendix**

**List of Topics Discussed in the Preliminary Decision Memorandum**

I. Summary
II. Background
III. Scope of the *Order*
IV. Preliminary Intent to Rescind Review, In Part
V. Discussion of the Methodology
VI. Currency Conversion
VII. Recommendation

[FR Doc. 2026–20273 Filed 10–1–26; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–570–073, C–570–074]**

### Common Alloy Aluminum Sheet From the People's Republic of China: Initiation of Circumvention Inquiry of the Antidumping Duty and Countervailing Duty Orders

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** Based on available information, the U.S. Department of Commerce (Commerce) is self-initiating a circumvention inquiry to determine whether imports of certain aluminum composite panels (ACPs) produced in the People's Republic of China (China) by Shanghai Alumetal Decorative Material Co. (Alumetal) are circumventing the antidumping duty (AD) and countervailing duty (CVD) orders on common alloy aluminum sheet (CAAS) from China.

**DATES:** Applicable October 2, 2026.

**FOR FURTHER INFORMATION CONTACT:** Samuel Frost, Office of Policy, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–8180.

**SUPPLEMENTARY INFORMATION:**

**Background**

On February 6 and 8, 2019, respectively, Commerce published the CVD and AD orders on CAAS from China.[1] On April 14, 2025, Commerce initiated a scope inquiry on certain ACPs produced by Alumetal and imported by Aluminum Line Products Company (ALPCO).[2] As discussed below, Commerce's decision to self-initiate this circumvention inquiry is based on information gathered in the scope inquiry on certain ACPs produced by Alumetal and imported by ALPCO.

**Scope of the Orders**

The merchandise covered by the *Orders* is CAAS from China. For a complete description of the scope of the *Orders, see* Appendix II.

**Merchandise Subject to the Circumvention Inquiry**

The circumvention inquiry concerns ACPs that consist of a low-density polyethylene (LDPE) core sandwiched and permanently bonded between two aluminum sheets (each with a thickness less than or equal to 0.2 millimeters (mm)), with a cumulative panel thickness of 6.3 mm or less, but greater than 0.2 mm and manufactured from 1100 alloy, that are produced by Alumetal in China and exported to the United States.

**Statutory and Regulatory Requirements to Initiate Circumvention Inquiries**

Section 351.226(b) of Commerce's regulations states that if Commerce ''determines from available information

[1] *See Common Alloy Aluminum Sheet from the People's Republic of China: Countervailing Duty Order,* 84 FR 2157 (February 6, 2019); *see also Common Alloy Aluminum Sheet from the People's Republic of China: Antidumping Duty Order,* 84 FR 2813 (February 8, 2019) (collectively, *Orders*).

[2] *See* Memorandum, ''Initiation of Scope Inquiry,'' dated April 14, 2025.

that an inquiry is warranted into the question of whether the elements necessary for a circumvention determination under section 781 of the Tariff Act of 1930, as amended (the Act) exist,'' Commerce ''may initiate a circumvention inquiry and publish a notice of initiation in the **Federal Register**.''

Section 781(c)(1) of the Act provides that the class or kind of merchandise subject to an AD or CVD order shall include articles that have been ''altered in form or appearance in minor respects . . . whether or not included in the same tariff classification.'' Section 781(c)(2) of the Act provides an exception that section 781(c)(1) of the Act ''shall not apply with respect to altered merchandise if the administering authority determines that it would be unnecessary to consider the altered merchandise within the scope of the {order}.'' When evaluating minor alterations under section 781(c) of the Act and 19 CFR 351.226(j), Commerce may consider criteria including, but not limited to: (1) overall physical characteristics of the merchandise; (2) expectations of ultimate users; (3) use of the merchandise; (4) channels of marketing; and (5) cost of any modification relative to the value of the imported products.

In accordance with 19 CFR 351.226(m)(2), for companion AD and CVD proceedings, ''{Commerce} will initiate and conduct a single inquiry with respect to the product at issue for both orders only on the record of the antidumping proceeding. Further, ''once {Commerce} issues a final circumvention determination on the record of the antidumping duty proceeding, {Commerce} will include on the record of the countervailing duty proceeding copies of the final circumvention determination memoranda, the final circumvention determination **Federal Register** notice, the preliminary circumvention determination memoranda, the preliminary circumvention determination **Federal Register** notice, and all relevant instructions to U.S. Customs and Border Protection {CBP}}.'' Accordingly, once Commerce concludes this circumvention inquiry, Commerce intends to place its final circumvention determination on the record of the companion CVD proceeding.

**Available Information Supports Initiation of a Circumvention Inquiry**

After analyzing record evidence in the scope inquiry on ACPs produced by Alumetal in China and imported by ALPCO, we determine initiation of these circumvention inquiries is warranted to determine whether imports of certain ACPs produced in China by Alumetal, if not found to be covered by the scope of the *Orders,* are circumventing the *Orders.* Commerce has made this determination in accordance with its analysis of the factors set forth in section 781(c) of the Act and 19 CFR 351.226(j). For a full discussion of the basis for our decision to self-initiate this circumvention inquiry, *see* the Initiation Memorandum.[3] The Initiation Memorandum is a public document and is made available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS), which is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Initiation Memorandum can be accessed directly at *https://access.trade.gov/frnotices.*

**Suspension of Liquidation**

Pursuant to 19 CFR 351.226(I)(1), when Commerce self-initiates a circumvention inquiry under 19 CFR 351.226(b), Commerce will notify CBP of the initiation and direct CBP to continue the suspension of liquidation of entries of products subject to the circumvention inquiry that were already subject to the suspension of liquidation, and to apply the cash deposit rate that would be applicable if the product were determined to be circumventing the order. Accordingly, Commerce will notify CBP of the initiation of the circumvention inquiry and direct CBP to continue to suspend (unliquidated) entries of the products subject to the circumvention inquiry that were already subject to the suspension of liquidation. In addition, Commerce will direct CBP to apply the cash deposit rate that would be applicable if the products were determined to be covered by the scope of the *Orders.*

Should Commerce issue preliminary or final circumvention determinations, Commerce will follow the suspension of liquidation rules under 19 CFR 351.226(I)(2)–(4). In the event Commerce issues affirmative preliminary or final circumvention determinations that the products are circumventing the *Orders,* Commerce will instruct CBP to continue the suspension of liquidation of previously suspended entries and to apply the applicable cash deposit rate. Commerce will also instruct CBP to begin the suspension of liquidation and application of cash deposits for any unliquidated entries not yet suspended, entered, or withdrawn from warehouse, for consumption, on or after the date of publication of the notice of initiation of the circumvention inquiry pursuant to paragraphs (I)(2)(ii) and (I)(3)(ii). In addition, pursuant to paragraphs (I)(2)(iii)(A) and (I)(3)(iii)(A), Commerce may instruct CBP to begin the suspension of liquidation and application of cash deposits for any unliquidated entries not yet suspended, entered, or withdrawn from warehouse, for consumption, prior to the date of initiation of the circumvention inquiry, but not for such entries prior to November 4, 2021, the effective date of these provisions in the *Final Rule.*[4] These rules will not affect CBP's authority to take any additional action with respect to the suspension of liquidation or related measures for these entries, as stated in 19 CFR 351.226(I)(5).

**Notification to Interested Parties**

In accordance with section 19 CFR 351.226(b) and 781(c) of the Act, Commerce determines that available information supports initiating a circumvention inquiry to determine whether ACPs that consist of an LDPE core sandwiched and permanently bonded between two aluminum sheets (each with a thickness less than or equal to 0.2 mm), with a cumulative panel thickness of 6.3 mm or less, but greater than 0.2 mm and manufactured from 1100 alloy, that are produced by Alumetal in China and exported to the United States, are circumventing the *Orders.* Accordingly, Commerce is notifying all interested parties of the initiation of the circumvention inquiry. In addition, we have included a description of the products that are the subject of these inquiries, and an explanation of the reasons for Commerce's decision to initiate these inquiries as provided above and in the accompanying Initiation Memorandum.

In accordance with section 781(f) of the Act and 19 CFR 351.226(e)(2), unless the circumvention inquiry is rescinded, in whole or in part, Commerce intends to issue its final determinations within 300 days from the date of publication of the notice of initiation of a circumvention inquiry in the **Federal Register**.

[3] *See* Memorandum, ''Initiation of Circumvention Inquiry on the Antidumping and Countervailing Duty Orders,'' dated concurrently with, and hereby adopted by, this notice (Initiation Memorandum).

[4] *See Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws,* 86 FR 52300, 52345 (Sept. 20, 2021) (*Final Rule*).

This notice is published in accordance with 19 CFR 351.226(b) and section 781(b) of the Act.

Dated: September 24, 2026.

**Scot Fullerton,**

*Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

## Appendix I

**List of Topics Discussed in the Initiation Memorandum**

I. Summary
II. Background
III. Scope of the *Orders*
IV. Merchandise Subject to the Circumvention Inquiry
V. Statutory and Regulatory Framework for the Circumvention Inquiry
VI. Statutory Analysis for the Circumvention Inquiry
VII. Recommendation

## Appendix

**Scope of the Orders**

The merchandise covered by the *Orders* is aluminum common alloy sheet (common alloy sheet) which is a flat-rolled aluminum product having a thickness of 6.3 mm or less, but greater than 0.2 mm, in coils or cut-to-length, regardless of width. Common alloy sheet within the scope of the *Orders* includes both not clad aluminum sheet, as well as multi-alloy, clad aluminum sheet. With respect to not clad aluminum sheet, common alloy sheet is manufactured from a 1XXX-, 3XXX-, or 5XXX-series alloy as designated by the Aluminum Association. With respect to multi-alloy, clad aluminum sheet, common alloy sheet is produced from a 3XXX-series core, to which cladding layers are applied to either one or both sides of the core.

Common alloy sheet may be made to ASTM specification B209–14, but can also be made to other specifications. Regardless of specification, however, all common alloy sheet meeting the scope description is included in the scope. Subject merchandise includes common alloy sheet that has been further processed in a third country, including but not limited to annealing, tempering, painting, varnishing, trimming, cutting, punching, and/or slitting, or any other processing that would not otherwise remove the merchandise from the scope of the *Orders* if performed in the country of manufacture of the common alloy sheet.

Excluded from the scope of the *Orders* is aluminum can stock, which is suitable for use in the manufacture of aluminum beverage cans, lids of such cans, or tabs used to open such cans. Aluminum can stock is produced to gauges that range from 0.200 mm to 0.292 mm, and has an H–19, H–41, H–48, or H–391 temper. In addition, aluminum can stock has a lubricant applied to the flat surfaces of the can stock to facilitate its movement through machines used in the manufacture of beverage cans. Aluminum can stock is properly classified under Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7606.12.3045 and 7606.12.3055.

Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set for the above.

Common alloy sheet is currently classifiable under HTSUS subheadings 7606.11.3060, 7606.11.6000, 7606.12.3090, 7606.12.6000, 7606.91.3090, 7606.91.6080, 7606.92.3090, and 7606.92.6080. Further, merchandise that falls within the scope of the *Orders* may also be entered into the United States under HTSUS subheadings 7606.11.3030, 7606.12.3030, 7606.91.3060, 7606.91.6040, 7606.92.3060, 7606.92.6040, 7607.11.9090. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the *Orders* is dispositive.

[FR Doc. 2026–20256 Filed 10–1–26; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

### Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review and Join Annual Inquiry Service List; Note Regarding Format of Review Requests

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**FOR FURTHER INFORMATION CONTACT:** Brenda E. Brown, AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–4735.

**Background**

Each year during the anniversary month of the publication of an antidumping duty (AD) or countervailing duty (CVD) order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended (the Act), may request, in accordance with 19 CFR 351.213, that the U.S. Department of Commerce (Commerce) conduct an administrative review of that AD or CVD order, finding, or suspended investigation.

All deadlines for the submission of comments or actions by Commerce discussed below refer to the number of calendar days from the applicable starting date.

Commerce asks that requests for review of multiple companies include an appendix listing, in alphabetical order, the company names for which a review is requested. *See infra* for additional details regarding this request.

**Respondent Selection**

In the event Commerce limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the period of review (POR). We intend to release the CBP data under administrative protective order (APO) to all parties having an APO within five days of publication of the initiation notice and to make our decision regarding respondent selection within 35 days of publication of the initiation **Federal Register** notice. Therefore, we encourage all parties interested in commenting on respondent selection to submit their APO applications on the date of publication of the initiation notice, or as soon thereafter as possible. Commerce invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the review.

In the event Commerce decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

1. In general, Commerce finds that determinations concerning whether particular companies should be ''collapsed'' (*i.e.,* treated as a single entity for purposes of calculating AD rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, Commerce will not conduct collapsing analyses at the respondent selection phase of a review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this AD proceeding (*i.e.,* investigation, administrative review, new shipper review, or changed circumstances review).

2. For any company subject to a review, if Commerce determined, or continued to treat, that company as collapsed with others, Commerce will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, Commerce will not collapse companies for purposes of respondent selection.

3. Parties are requested to: (a) identify which companies subject to review previously were collapsed; and (b) provide a citation to the proceeding in which they were collapsed.

4. Further, if companies are requested to complete a Quantity and Value Questionnaire for purposes of respondent selection, in general, each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of a proceeding where Commerce considered collapsing that entity, complete quantity and value data for that collapsed entity must be submitted.

**Deadline for Withdrawal of Request for Administrative Review**

Pursuant to 19 CFR 351.213(d)(1), a party that requests a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that Commerce may extend this time if it is reasonable to do so. Determinations by Commerce to extend the 90-day deadline will be made on a case-by-case basis.

**Deadline for Particular Market Situation Allegation**

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of particular market situation (PMS) for purposes of constructed value under section 773(e) of the Act.[1] Section 773(e) of the Act states that ''if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.'' When an interested party submits a PMS allegation, pursuant to section 773(e) of the Act, Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(2)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(2)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of initial Section D responses.

*Opportunity To Request a Review:* Not later than the last day of October 2026,[2] interested parties may request an administrative review of the following orders, findings, or suspended investigations, with anniversary dates in October for the following periods:

| | Period |
|---|---|
| **Antidumping Duty Proceedings** | |
| Australia: Certain Hot-Rolled Steel Flat Products, A–602–809 | 10/1/25–9/30/26 |
| Brazil: Carbon and Certain Alloy Steel Wire Rod, A–351–832 | 10/1/25–9/30/26 |
| India: Stainless Steel Flanges, A–533–877 | 10/1/25–9/30/26 |
| Indonesia: Carbon and Certain Alloy Steel Wire Rod, A–560–815 | 10/1/25–9/30/26 |
| Japan: Certain Hot-Rolled Steel Flat Products, A–588–874 | 10/1/25–9/30/26 |
| Mexico: Carbon and Certain Alloy Steel Wire Rod, A–201–830 | 10/1/25–9/30/26 |
| Moldova: Carbon and Certain Alloy Steel Wire Rod, A–841–805 | 10/1/25–9/30/26 |
| Republic of Korea: Certain Hot-Rolled Steel Flat Products, A–580–883 | 10/1/25–9/30/26 |
| Republic of Türkiye: Certain Hot-Rolled Steel Flat Products, A–489–826 | 10/1/25–9/30/26 |
| Socialist of Vietnam: Gas Powered Pressure Washers, A–552–008 | 10/1/25–9/30/26 |
| Taiwan: Steel Concrete Reinforcing Bar, A–583–859 | 10/1/25–9/30/26 |
| Thailand: Glycine, A–549–837 | 10/1/25–9/30/26 |
| The Netherlands: Certain Hot-Rolled Steel Flat Products, A–421–813 | 10/1/25–9/30/26 |
| The People's Republic of China: | |
| Boltless Steel Shelving Units Prepackaged for Sale, A–570–018 | 10/1/25–9/30/26 |
| Electrolytic Manganese Dioxide, A–570–919 | 10/1/25–9/30/26 |
| Polyvinyl Alcohol, A–570–879 | 10/1/25–9/30/26 |
| Steel Wire Garment Hangers, A–570–918 | 10/1/25–9/30/26 |
| Trinidad and Tobago: Carbon and Certain Alloy Steel Wire Rod, A–274–804 | 10/1/25–9/30/26 |
| United Kingdom: Certain Hot-Rolled Steel Flat Products, A–412–825 | 10/1/25–9/30/26 |
| **Countervailing Duty Proceedings** | |
| Brazil: Carbon and Certain Alloy Steel Wire Rod, C–351–833 | 1/1/25–12/31/25 |
| India: Stainless Steel Flanges, C–533–878 | 1/1/25–12/31/25 |
| Iran: Roasted In Shell Pistachios, C–507–601 | 1/1/25–12/31/25 |
| Republic of Korea: Certain Hot-Rolled Steel Flat Products, C–580–884 | 1/1/25–12/31/25 |
| The People's Republic of China: Boltless Steel Shelving Units Prepackaged For Sale, C–570–019 | 1/1/25–12/31/25 |
| **Suspension Agreements** | |
| Argentina: Lemon Juice, A–357–818 | 10/1/25–9/30/26 |
| Russia: Uranium, A–821–802 | 10/1/25–9/30/26 |

In accordance with 19 CFR 351.213(b), an interested party as defined by section 771(9) of the Act may request in writing that Commerce conduct an administrative review. For both AD and CVD reviews, the interested party must specify the individual producers or exporters covered by an AD finding or an AD or CVD order or suspension agreement for which it is requesting a review. In addition, a domestic interested party or an interested party described in section 771(9)(B) of the Act must state why it desires Commerce to review those

[1] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

[2] Or the next business day, if the deadline falls on a weekend, Federal holiday or any other day when Commerce is closed.

particular producers or exporters. If the interested party intends for Commerce to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which was produced in more than one country of origin and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Note that, for any party Commerce was unable to locate in prior segments, Commerce will not accept a request for an administrative review of that party absent new information as to the party's location. Moreover, if the interested party who files a request for review is unable to locate the producer or exporter for which it requested the review, the interested party must provide an explanation of the attempts it made to locate the producer or exporter at the same time it files its request for review, in order for Commerce to determine if the interested party's attempts were reasonable, pursuant to 19 CFR 351.303(f)(3)(ii).

Commerce is instituting a new formatting request. Specifically, Commerce asks that requests for review of multiple companies also include an appendix listing, in alphabetical order, the company names for which a review is requested. The list should be limited solely to company names and formatted as a single column, with each company name identified on a separate line, except in the case of companies that Commerce previously determined should be collapsed into a single entity or found to be cross-owned with other companies. Companies that Commerce previously determined should be collapsed or found to be cross-owned with one another should be listed together as a group, on one line—or more, as needed, for the group—with the company names within each group listed alphabetically and separated by semicolons.

As explained in *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (June 6, 2003), and *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011), Commerce clarified its practice with respect to the collection of final antidumping duties on imports of merchandise where intermediate firms are involved. The public should be aware of this clarification in determining whether to request an administrative review of merchandise subject to AD findings and orders.[3]

Commerce no longer considers the non-market economy (NME) entity as an exporter conditionally subject to an AD administrative review.[4] Accordingly, the NME entity will not be under review unless Commerce specifically receives a request for, or self-initiates, a review of the NME entity.[5] In administrative reviews of AD orders on merchandise from NME countries where a review of the NME entity has not been initiated, but where an individual exporter for which a review was initiated does not qualify for a separate rate, Commerce will issue a final decision indicating that the company in question is part of the NME entity. However, in that situation, because no review of the NME entity was conducted, the NME entity's entries were not subject to the review and the rate for the NME entity is not subject to change as a result of that review (although the rate for the individual exporter may change as a function of the finding that the exporter is part of the NME entity). Following initiation of an AD administrative review when there is no review requested of the NME entity, Commerce will instruct CBP to liquidate entries for all exporters not named in the initiation notice, including those that were suspended at the NME entity rate.

All requests must be filed electronically in Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) on Enforcement and Compliance's ACCESS website at *https://access.trade.gov*.[6] Further, in accordance with 19 CFR 351.303(f)(l)(i), a copy of each request must be served on the petitioner and each exporter or producer specified in the request. Interested parties should note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[7]

Commerce will publish in the **Federal Register** a notice of ''Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation'' for requests received by the last day of October 2026. If Commerce does not receive, by the last day of October 2026, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, Commerce will instruct CBP to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period of the order, if such a gap period is applicable to the period of review.

**Establishment of and Updates to the Annual Inquiry Service List**

On September 20, 2021, Commerce published the final rule titled ''*Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws*'' in the **Federal Register**.[8] On September 27, 2021, Commerce also published the notice entitled ''*Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions*'' in the **Federal Register**.[9] The *Final Rule* and *Procedural Guidance* provide that Commerce will maintain an annual inquiry service list for each order or suspended investigation, and any interested party submitting a scope ruling application or request for circumvention inquiry shall serve a copy of the application or request on the persons on the annual inquiry service list for that order, as well as any companion order covering the same merchandise from the same country of origin.[10]

In accordance with the *Procedural Guidance,* for orders published in the

[3] *See* Enforcement and Compliance's website at *https://www.trade.gov/us-antidumping-and-countervailing-duties-home-page.*

[4] *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).

[5] In accordance with 19 CFR 351.213(b)(1), parties should specify that they are requesting a review of entries from exporters comprising the entity, and to the extent possible, include the names of such exporters in their request.

[6] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

[7] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule,* 88 FR 67069 (September 29, 2023).

[8] *See Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws,* 86 FR 52300 (September 20, 2021) (*Final Rule*).

[9] *See Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions,* 86 FR 53205 (September 27, 2021) (*Procedural Guidance*).

[10] *Id.*

**Federal Register** before November 4, 2021, Commerce created an annual inquiry service list segment for each order and suspended investigation. Interested parties who wished to be added to the annual inquiry service list for an order submitted an entry of appearance to the annual inquiry service list segment for the order in ACCESS and, on November 4, 2021, Commerce finalized the initial annual inquiry service lists for each order and suspended investigation. Each annual inquiry service list has been saved as a public service list in ACCESS, under each case number, and under a specific segment type called ''AISL-Annual Inquiry Service List.'' [11]

As mentioned in the *Procedural Guidance,* beginning in January 2022, Commerce will update these annual inquiry service lists on an annual basis when the *Opportunity Notice* for the anniversary month of the order or suspended investigation is published in the **Federal Register**.[12] Accordingly, Commerce will update the annual inquiry service lists for the above-listed AD and CVD proceedings. All interested parties wishing to appear on the updated annual inquiry service list must take one of the two following actions: (1) new interested parties who did not previously submit an entry of appearance must submit a new entry of appearance at this time; (2) interested parties who were included in the preceding annual inquiry service list must submit an amended entry of appearance to be included in the next year's annual inquiry service list. For these interested parties, Commerce will change the entry of appearance status from ''Active'' to ''Needs Amendment'' for the annual inquiry service lists corresponding to the above-listed proceedings. This will allow those interested parties to make any necessary amendments and resubmit their entries of appearance. If no amendments need to be made, the interested party should indicate in the area on the ACCESS form requesting an explanation for the amendment that it is resubmitting its entry of appearance for inclusion in the annual inquiry service list for the following year. As mentioned in the *Final Rule,*[13] once the petitioners and foreign governments have submitted an entry of appearance for the first time, they will automatically be added to the updated annual inquiry service list each year.

Interested parties have 30 days after the date of this notice to submit new or amended entries of appearance. Commerce will then finalize the annual inquiry service lists five business days thereafter. For ease of administration, please note that Commerce requests that law firms with more than one attorney representing interested parties in a proceeding designate a lead attorney to be included on the annual inquiry service list.

Commerce may update an annual inquiry service list at any time as needed based on interested parties' amendments to their entries of appearance to remove or otherwise modify their list of members and representatives, or to update contact information. Any changes or announcements pertaining to these procedures will be posted to the ACCESS website at *https://access.trade.gov.*

### Special Instructions for Petitioners and Foreign Governments

In the *Final Rule,* Commerce stated that, ''after an initial request and placement on the annual inquiry service list, both petitioners and foreign governments will automatically be placed on the annual inquiry service list in the years that follow.'' [14] Accordingly, as stated above and pursuant to 19 CFR 351.225(n)(3), the petitioners and foreign governments will not need to resubmit their entries of appearance each year to continue to be included on the annual inquiry service list. However, the petitioners and foreign governments are responsible for making amendments to their entries of appearance during the annual update to the annual inquiry service list in accordance with the procedures described above.

### Notification to Interested Parties

This notice is not required by statute but is published as a service to the international trading community.

Dated: September 23, 2026.

**Scot Fullerton,**

*Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

[FR Doc. 2026–20269 Filed 10–1–26; 8:45 am]

**BILLING CODE 3510–DS–P**

[11] This segment has been combined with the ACCESS Segment Specific Information (SSI) field which will display the month in which the notice of the order or suspended investigation was published in the **Federal Register**, also known as the anniversary month. For example, for an order under case number A–000–000 that was published in the **Federal Register** in January, the relevant segment and SSI combination will appear in ACCESS as ''AISL-January Anniversary.'' Note that there will be only one annual inquiry service list segment per case number, and the anniversary month will be pre-populated in ACCESS.

[12] *See Procedural Guidance,* 86 FR at 53206.

[13] *See Final Rule,* 86 FR at 52335.

[14] *Id.*

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[C–489–845]**

## Certain Aluminum Foil From the Republic of Türkiye: 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 producers and exporters of certain aluminum foil (aluminum foil) from the Republic of Türkiye (Türkiye), during the period of review (POR) January 1, 2023, through December 31, 2023.

**DATES:** Applicable October 2, 2026.

**FOR FURTHER INFORMATION CONTACT:** Ian Riggs or Caroline Carroll, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3810 and (202) 482–4948, respectively.

**SUPPLEMENTARY INFORMATION:**

### Background

On May 6, 2026, Commerce published the *Preliminary Results* of this administrative review in the **Federal Register** and invited interested parties to comment.[1] On August 19, 2026, Commerce extended the deadline for the final results of this review to no later than September 25, 2026.[2] For a complete description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[3]

### Scope of the Order [4]

The merchandise covered by this *Order* is aluminum foil from Türkiye. For a complete description of the scope

[1] *See Certain Aluminum Foil from Republic of Türkiye: Preliminary Results and Rescission, in Part, of Countervailing Duty Administrative Review; 2023,* 91 FR 24513 (May 6, 2026) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Extension of Deadline for Final Results of 2023 Countervailing Administrative Review,'' dated August 19, 2026.

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Countervailing Duty Administrative Review of Certain Aluminum Foil from the Republic of Türkiye; 2023,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See Certain Aluminum Foil from the Sultanate of Oman and the Republic of Türkiye: Countervailing Duty Orders,* 86 FR 62782 (November 12, 2021) (*Order*).

of the *Order, see* Issues and Decision Memorandum.

**Analysis of Comments Received**

All issues raised in the case briefs and rebuttal briefs are addressed in the Issues and Decision Memorandum. A list of the issues addressed is attached as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS), 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/frnotices.*

**Methodology**

Commerce conducted this 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 find that there is a subsidy, *i.e.,* a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific.[5] For a full description of the methodology underlying all of Commerce's conclusions, *see* the Issues and Decision Memorandum.

**Analysis of Comments Received**

All issues raised in the case and rebuttal briefs by parties in these inquiries are addressed in the Issues and Decision Memorandum. A list of the issues raised is attached as an appendix to this notice. Based on our analysis of the comments received from interested parties, we made no changes to the *Preliminary Results.*

**Final Results of Review**

As a result of this review, we determine the following net countervailable subsidy rates exist for the period January 1, 2023, through December 31, 2023:

| Producer/exporter | Subsidy rate (percent *ad valorem*) |
|---|---|
| Assan Aluminyum Sanayi ve Ticaret A.S.[6] | 2.65 |
| Panda Aluminyum A.S.[7] | 3.82 |

[5] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

**Disclosure**

Normally, Commerce will disclose to the parties in a proceeding the calculations performed in connection with the final results of a review 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). However, as we have made no changes from the *Preliminary Results,* there are no new calculations to disclose.

**Assessment Rates**

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(2), Commerce has determined, and CBP shall assess, countervailing duties on all appropriate entries of subject merchandise in accordance with the final results of this review for Assan and Panda at the applicable *ad valorem* assessment rate listed in the table above. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

**Cash Deposit Requirements**

In accordance with section 751(a)(1) of the Act, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown above for Assan and Panda on shipments of the subject merchandise entered, or withdrawn from warehouse for consumption on or after the date of publication of the final results of this administrative review.

For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the most recent company-specific rate applicable to the company or the all-others rate, as appropriate. These cash deposits requirements, effective upon the 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 APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

**Notification to Interested Parties**

These final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: September 29, 2026.

**Scot Fullerton,**

*Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

**Appendix**

**List of Topics Discussed in the Issues and Decision Memorandum**

I. Summary
II. Background
III. Scope of the *Order*
IV. Subsidies Valuation Information
V. Analysis of Programs
VI. Discussion of the Issues
Comment 1: Whether the Provision of Unwrought Aluminum by the Government of the Russian Federation for Less Than Adequate Remuneration is Countervailable
Comment 2: Whether the Banking Insurance and Transaction Tax (BITT)—Tax Exemption for Export Loans Program is Countervailable
Comment 3: Whether the Exemptions on BITT—Exemptions on Exchange Tax for Foreign Exchange Transactions is Countervailable
Comment 4: Whether Provisional Article 14 to Corporate Tax Law No 5520 and Tax Deduction for Capital Increases Programs are *de facto* Specific
Comment 5: Whether to Apply Türkiye's Standard Corporate Income Tax Rate to Calculate Benefits for Income Tax Programs
Comment 6: Whether Certain Sales Accounts Should be Included in Assan's and Ispak's Sales Denominators

[6] As discussed in the *Preliminary Results* PDM, Commerce has found the following companies to be cross-owned with Assan Aluminyum Sanayi ve Ticaret A.S. (Assan): Ispak Esnek Ambalaj Sanayi A.S.; and Kibar Holding A.S. We note that Assan has an affiliated trading company through which it exported certain subject merchandise, Kibar Dis Ticaret A.S. (Kibar Dis). Therefore, because Kibar Dis' subsidies are included as part of Assan's total subsidy rate, we have not assigned a subsidy rate to Kibar Dis. Entries of subject merchandise exported by Kibar Dis will receive the rate of the producer listed on the U.S. Customs and Border Protection (CBP) entry form.

[7] We note that Panda Aluminyum A.S. (Panda) has an affiliated trading company through which it exported certain subject merchandise, Seherli Danışmanlık A.Ş. (Seherli). Seherli was not selected as a mandatory respondent but was examined in the context of Panda. Therefore, because Seherli's subsidies are included as part of Panda's total subsidy rate, we have not assigned a subsidy rate to Seherli. Entries of subject merchandise exported by Seherli will receive the rate of the producer listed on the CBP entry form.

VII. Recommendation

[FR Doc. 2026–20272 Filed 10–1–26; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–570–814]**

### Certain Carbon Steel Butt-Weld Pipe Fittings From the People's Republic of China: Notice of Court Decision Not in Harmony With Final Covered Merchandise Determination and Notice of Amended Covered Merchandise Determination Pursuant to Court Decision; Correction

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**ACTION:** Notice; correction.

**SUMMARY:** The U.S. Department of Commerce (Commerce) published notice to the public in the **Federal Register** of August 28, 2026 that the U.S. Court of International Trade's (CIT) final judgment was not in harmony with Commerce's covered merchandise inquiry (CMI) determination. Specifically, Commerce amended the CMI determination to find that products cut to length and formed into the rough shape of certain carbon steel butt-weld pipe fittings (butt-weld pipe fittings) in the People's Republic of China (China) represent ''unfinished'' fittings, which are covered by the scope of the *Order,* and that when such products are further processed in the Socialist Republic of Vietnam (Vietnam), they remain subject to the antidumping (AD) order on butt-weld pipe fittings from China. This notice did not provide clear notice to parties that the liquidation of entries of these unfinished fittings will be retroactively suspended.

**FOR FURTHER INFORMATION CONTACT:** Miranda Bourdeau, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2021.

**SUPPLEMENTARY INFORMATION:**

#### Background

On August 28, 2026, Commerce published in the **Federal Register** a notice that the CIT's final judgment was not in harmony with Commerce's CMI determination.[1] Specifically, Commerce amended the CMI determination to find that products cut to length and formed into the rough shape of a butt-weld pipe fitting in China represent unfinished fittings, which are covered by the scope of the *Order,*[2] and that when such products are further processed in the Vietnam, they remain subject to the AD order on butt-weld pipe fittings from China.[3] We did not provide clear notice to parties that that liquidation of entries of these unfinished fittings will be retroactively suspended.

#### Correction

In the **Federal Register** of August 28, 2026, in FR Doc 2026–17621, on page 55518, in the third column, correct the notice to include the following paragraph before the ''Liquidation of Suspended Entries'' section.

#### Continuation of Suspension of Liquidation

As stated above, Commerce has made an affirmative finding that unfinished fittings originating from China that undergo the second and third stages of production in Vietnam, which were the subject of this referral from U.S. Customs and Border Protection (CBP), are subject to the scope of the *Order.* This affirmative in-scope finding applies on a country-wide exporter, or importer, basis to all products from the same country with the same relevant physical characteristics as the products at issue. Therefore, in accordance with 19 CFR 351.227(l)(3), for these products, Commerce will direct CBP to: (1) continue the suspension of liquidation of previously suspended entries and apply the applicable cash deposit rate; (2) suspend liquidation and require a cash deposit of estimated duties, at the applicable rate, for each unliquidated entry of the product not yet suspended, entered, or withdrawn from warehouse, for consumption on or after September 26, 2022, the date of publication of the notice of initiation of this covered merchandise inquiry in the **Federal Register**; and (3) suspend liquidation and require a cash deposit of estimated duties, at the applicable rate, for each unliquidated entry of the product not yet suspended, entered, or withdrawn from warehouse, for consumption prior to September 26, 2022, but after November 4, 2021.[4]

#### Notification to Interested Parties

This notice is issued and published in accordance with 19 CFR 351.227(e)(2).

Dated: September 29, 2026.

**Scot Fullerton,**

*Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

[FR Doc. 2026–20258 Filed 10–1–26; 8:45 am]

**BILLING CODE 3510–DS–P**

[1] *See Certain Carbon Steel Butt-Weld Pipe Fittings from the People's Republic of China: Notice of Court Decision Not in Harmony with Final Covered Merchandise Determination and Notice of Amended Covered Merchandise Determination Pursuant to Court Decision,* 91 FR 55518 (August 28, 2026) (*Butt-Weld Pipe Fittings CMI Timken*); *see also Certain Carbon Steel Butt-Weld Pipe Fittings from the People's Republic of China: Final Determination of Covered Merchandise Inquiry,* 88 FR 69909 (October 10, 2023).

[2] *See Antidumping Duty Order and Amendment to the Final Determination of Sales at Less Than Fair Value; Certain Carbon Steel Butt-Weld Pipe Fittings from the People's Republic of China,* 57 FR 29702 (July 6, 1992) (*Order*); *see also Butt-Weld Pipe Fittings CMI Timken.*

[3] *See Butt-Weld Pipe Fittings CMI Timken.*

[4] *See Certain Carbon Steel Butt-Weld Pipe Fittings from the People's Republic of China: Notice of Covered Merchandise Referral and Initiation of Covered Merchandise Inquiry,* 87 FR 58310 (September 26, 2022).

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[C–570–021]**

### Melamine From the People's Republic of China: Final Results of the Expedited Second Sunset Review of the Countervailing Duty Order

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The U.S. Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) order on melamine from the People's Republic of China (China) would be likely to lead to continuation or recurrence of countervailable subsidies at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

**DATES:** Applicable October 2, 2026.

**FOR FURTHER INFORMATION CONTACT:** Alexander Cipolla, Office III, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4956.

**SUPPLEMENTARY INFORMATION:**

#### Background

On December 28, 2015, Commerce published the *Order* in the **Federal Register**.[1] On July 9, 2021, following the first five-year sunset review, Commerce published the notice of continuation of the *Order.*[2] On June 1, 2026, Commerce

[1] *See Melamine from the People's Republic of China: Antidumping Duty and Countervailing Duty Orders,* 80 FR 80751 (December 28, 2015) (*Order*).

[2] *See Melamine from the People's Republic of China: Continuation of Antidumping and Countervailing Duty Orders,* 86 FR 36252 (July 9, 2021).

published the notice of initiation of this second sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.218(c).[3] On June 12, 2026, Commerce received a notice of intent to participate in this review from Cornerstone Chemical Company (the domestic interested party), within the deadline specified in 19 CFR 351.218(d)(1)(i).[4] The domestic interested party claims that it has interested party status within the meaning of section 771(9)(C) of the Act as a manufacturer in the United States of the domestic like product.[5]

On July 1, 2026, Commerce received an adequate substantive response from the domestic interested party, within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[6] Commerce did not receive a substantive response from either the Government of China or a respondent interested party to this proceeding. On June 22, 2026, Commerce notified the U.S. International Trade Commission (ITC) that it did not receive an adequate substantive response from respondent interested parties.[7] As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce is conducting an expedited (120-day) sunset review of the *Order.*

## Scope of the Order

The product covered by this *Order* is melamine from China. For the full description of the scope of the *Order, see* the Issues and Decision Memorandum.[8]

## Analysis of Comments Received

A complete discussion of all issues raised in this sunset review, including the likelihood of continuation or recurrence of subsidization and the countervailable subsidy rates likely to prevail if the *Order* were to be revoked, is contained in the Issues and Decision Memorandum.[9] A list of the topics discussed in the Issues and Decision Memorandum is attached as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS), which is available to registered users at *https://access.trade.gov.* In addition, complete versions of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/frnotices.*

## Final Results of Sunset Review

Pursuant to sections 751(c) and 752(b) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to continuation or recurrence of countervailable subsidies at the following net countervailable subsidy rates.

| Producers/exporters | Net countervailable subsidy rate (percent *ad valorem*) |
|---|---|
| Far-Reaching Chemical Co., Ltd | 154.00 |
| M and A Chemicals Corp China | 154.00 |
| Qingdao Unichem International Trade Co., Ltd | 154.00 |
| Shandong Liaherd Chemical Industry Co., Ltd | 156.90 |
| Zhongyuan Dahua Group Co., Ltd | 154.00 |
| All Others | 154.58 |

## Notification Regarding Administrative Protective Orders (APOs)

This notice also serves as the only reminder to parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials, or conversion to judicial protective, orders is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

## Notification to Interested Parties

We are issuing and publishing these final results in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.218 and 19 CFR 351.221(c)(5)(ii).

Dated: September 29, 2026.

**Scot Fullerton,**

*Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

## Appendix

### List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. History of the *Order*
V. Legal Framework
VI. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of a Countervailable Subsidy
  2. Net Countervailable Subsidy Rates Likely to Prevail
  3. Nature of the Subsidies
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2026–20259 Filed 10–1–26; 8:45 am]

BILLING CODE 3510–DS–P

[3] *See Initiation of Five-Year (Sunset) Reviews,* 91 FR 32377 (June 1, 2026).

[4] See Cornerstone's Letter, ''Domestic Interested Party Notice of Intent to Participate,'' dated June 12, 2026.

[5] *Id.* at 2.

[6] *See* Cornerstone's Letter, '' Domestic Interested Party Substantive Response,'' dated July 1, 2026.

[7] *See* Commerce's Letter, ''Sunset Reviews Initiated on June 1, 2026,'' dated June 22, 2026.

[8] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited Second Sunset Review of the Countervailing Duty Order on Melamine from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[9] *Id.*

## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

**[RTID 0648–XG014]**

## New England Fishery Management Council; Public Meeting

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

**ACTION:** Notice of public meeting.

**SUMMARY:** The New England Fishery Management Council (Council) is scheduling a public meeting of its Joint Groundfish Committee and Advisory Panel via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will

be brought to the full Council for formal consideration and action, if appropriate.

**DATES:** This meeting will be held on Monday, October 19, 2026 at 9 a.m. EDT Webinar registration URL information: *https://nefmc-org.zoom.us/meeting/register/R1P-sfcpTCG3zhlsFz2PFg.*

**ADDRESSES:** *Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

**FOR FURTHER INFORMATION CONTACT:** Cate O'Keefe, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

**SUPPLEMENTARY INFORMATION:**

### Agenda

The Groundfish Committee and Advisory Panel will receive an update on development of Framework 74/Specifications and Management Measures. They will also receive an update on development of Framework 68, including development of draft alternatives for ABC stability tools. The Committee and Advisory Panel will discuss the draft 2027 Council Priorities for Groundfish and provide feedback for Council consideration at the December 2026 Council meeting. They will discuss other business as necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

### Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Cate O'Keefe, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: September 30, 2026.

**Rey Israel Marquez,**

*Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2026–20235 Filed 10–1–26; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[RTID 0648–XG017]**

### Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Marine Structure Maintenance and Pile Replacement Program in Puget Sound, Washington

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

**ACTION:** Notice; issuance of incidental harassment authorization.

**SUMMARY:** In accordance with regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued an incidental harassment authorization (IHA) to the United States Navy (Navy) for authorization to take marine mammals incidental to the Marine Structure Maintenance and Pile Replacement Program in Puget Sound, Washington.

**DATES:** This authorization is effective from September 25, 2026 through September 24, 2027.

**ADDRESSES:** Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.* In case of problems accessing these documents, please call the contact listed below.

**FOR FURTHER INFORMATION CONTACT:** Kate Fleming, Office of Protected Resources, NMFS, (301) 427–8401.

**SUPPLEMENTARY INFORMATION:**

### Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Section 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) directs the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed IHA is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking; other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to as ''mitigation''); and requirements pertaining to the monitoring and reporting of the takings. The definitions of all applicable MMPA statutory terms used above are included in the relevant sections below (see also 16 U.S.C. 1362; 50 CFR 216.3, 216.103).

### Summary of Request

On February 26, 2026, NMFS received a request from the Navy for an IHA to take marine mammals incidental to construction associated with the Navy's 2026 Marine Structure Maintenance and Pile Replacement project in Puget Sound, Washington. Following NMFS' review of the application, and subsequent discussions between NMFS and the Navy, the application was deemed adequate and complete on June 4, 2026. The Navy submitted a revised application reflecting the previous discussions on June 26, 2026. We received another revision on August 6, 2026 and a final revision on August 12, 2026. The Navy's request is for take of 10 species of marine mammals, by Level B harassment and, for a subset of these species, Level A harassment. Neither the Navy nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

NMFS previously promulgated regulations for (84 FR 15963, April 17, 2019) and issued two consecutive IHAs to (89 FR 47539, June 3, 2024) the Navy for related and similar work. The Navy complied with all the requirements (*e.g.,* mitigation, monitoring, and reporting) of the previous IHAs, and information regarding their monitoring results may be found in the Effects of the Specified Activity on Marine Mammals and their Habitat.

### Description of the Specified Activity

*Overview*

To ensure continuance of necessary missions at its installations, the Navy must conduct annual maintenance and repair activities at existing marine waterfront structures, including removal and replacement of piles of various

types and sizes. The Navy refers to this program as the Marine Structure Maintenance and Pile Replacement (MPR) Program. Under the MPR program, the Navy is planning to conduct repairs and maintenance of existing marine structures and replacement of degraded piles at three Navy installations within Puget Sound, Washington. Construction is planned for up to a total of 227 days, with 22 days planned at Naval Base Kitsap (NBK) Bangor between July 16 and January 15, 77 days planned at Naval Station (NS) Everett between July 16 and February 15, and 128 days planned at NBK Manchester between July 16 and February 15, up to 7 days per week, during daylight hours only. Repairs include replacing up to 234 structurally unsound concrete or steel piles with 233 concrete or steel piles over a 1-year period using impact and vibratory pile driving and removal. The activities that have the potential to take marine mammals include the impact and vibratory installation and removal of concrete and steel piles, and steel casings.

A detailed description of the planned construction project is provided in the **Federal Register** notice for the proposed IHA (91 FR 53486, August 18, 2026). Since that time, Navy has revised the size pile casings to be installed at NBK Manchester (see Changes from Proposed to Final IHA section). No other changes have been made to the planned activities, and a detailed description is not provided here. Please refer to the **Federal Register** notice for the description of the specific activity.

## Comments and Responses

A notice of NMFS' proposal to issue an IHA to the Navy was published in the **Federal Register** on August 18, 2026. That notice described, in detail, the Navy's activity, the marine mammal species that may be affected by the activity, and the anticipated effects on marine mammals. In that notice, we requested public input on the request for authorization described therein, our analyses, the proposed authorization, and any other aspect of the notice of proposed IHA, and requested that interested persons submit relevant information, suggestions, and comments.

During the 30-day public comment period, NMFS received one comment letter from a private citizen. All relevant, substantive comments, and NMFS' responses, are provided below. The comments and recommendations are available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.* Please see the comment submission for full details regarding the recommendations and supporting rationale.

*Comment 1:* Citing their status under the Endangered Species Act (ESA), a private citizen urged NMFS to require robust real-time monitoring and shutdown protocols specifically calibrated for southern resident killer whales (SRKW) at NS Everett and NBK Manchester, rather than standard harbor seal or harbor porpoise-focused mitigation measures.

*Response:* NMFS clarifies that the required mitigation for this project, at all installations, has been designed to account for all hearing groups that could be present in the project area, including ESA-listed SRKW. Measures specifically designed to mitigate impacts to ESA-listed SRKW include shutting down pile driving should a large whale or killer whale be observed within or approaching the largest harassment zone, and on at least a daily basis, contacting the Orca Network and monitoring their social media to review updated sighting locations of large whales, and shutting down or delaying pile driving if any large whale species are approaching, or within the shutdown zone. In addition to applying to killer whales, these mitigation requirements apply to all large whales, including gray whales and ESA-listed humpback whales.

*Comment 2:* A private citizen requested that NMFS consider whether additional precautionary buffers or seasonal restrictions near NS Everett are warranted, given its proximity to a gray whale feeding Biologically Important Area (BIA) and given that gray whales are currently experiencing high numbers of strandings along the Washington coast and in Puget Sound.

*Response:* While we acknowledge that the Eastern North Pacific stock of gray whales is currently experiencing elevated numbers of strandings along the Washington coast and in Puget Sound, we do not agree that this stock cannot sustain eight incidents of Level B harassment, which are likely to be relatively low-level, temporary behavioral reactions, without incurring greater than a negligible impact on the stock. As described in the notice of the proposed IHA for this action (91 FR 53486, August 18, 2026), NMFS finds that small numbers of marine mammals may be taken relative to the population size of the affected species or stocks and that the incidental take of marine mammals from the Navy's specified activities will have a negligible impact on all affected marine mammal species or stocks, including gray whales.

## Changes From the Proposed IHA to the Final IHA

Changes from the proposed IHA to the final issued IHA pertain to a revision to the size of the steel casings that are to be used to support the installation of 24-inch concrete piles at NBK Manchester. The Navy has indicated that 74 42-in steel casings may be vibratory installed and removed instead of 74 36-in steel casings, at the same production rates (table 1).

TABLE 1—[1] PILE TYPES, INSTALLATION METHODS, AND DURATIONS AT NBK BANGOR, NS EVERETT, AND NBK MANCHESTER

| Installation or removal | Pile size | Pile type | Method | Bubble curtain planned? | Location | Number of piles | Piles/day | Minutes (vibratory) or strikes (impact) per pile | Construction days |
|---|---|---|---|---|---|---|---|---|---|
| **NBK Bangor** | | | | | | | | | |
| Removal | 24-in | Concrete | Vibratory | No | Olympic Pier | 4 | 2 | [2] 10 | 2 |
| | | | Vibratory | No | EHW–1 | 11 | 3 | 10 | 4 |
| Installation | 20-in | Steel | Vibratory | No | Olympic Pier | 4 | 2 | [2] 10 | 2 |
| | | | Impact proofing | Yes | | | 2 | 500 | 2 |
| | 30-in | Steel | Vibratory | No | EHW–1 | 12 | 2 | 10 | 6 |
| | | | Impact proofing | Yes | | | 2 | 1,000 | 6 |

TABLE 1—[1]PILE TYPES, INSTALLATION METHODS, AND DURATIONS AT NBK BANGOR, NS EVERETT, AND NBK MANCHESTER—Continued

| Installation or removal | Pile size | Pile type | Method | Bubble curtain planned? | Location | Number of piles | Piles/ day | Minutes (vibratory) or strikes (impact) per pile | Construction days |
|---|---|---|---|---|---|---|---|---|---|
| **NS Everett** | | | | | | | | | |
| Removal | 12-in | Steel | Vibratory | No | Piers A, B, and South Wharf. | 144 | 4 | 10 | 36 |
| Installation | 18-in | Steel | Vibratory | No | Piers A, B, and South Wharf. | 144 (up to 20 may be impact proofed). | 4 | 10 | 36 |
| | | | Impact proofing | Yes | | | 4 | 400 | 5 |
| **NBK Manchester** | | | | | | | | | |
| Removal | 14-in H | Steel | Vibratory | No | Fuel Pier | 74 | 3 | 10 | 25 |
| | 36-in Casing ... 42-in Casing ... | Steel | Vibratory | No | | 74 | 3 | 30 | 25 |
| Installation | 36-in Casing ... 42-in Casing ... | Steel | Vibratory | No | Fuel Pier | [3]74 | 2 | 30 | 37 |
| | 24-in | Concrete | Impact | No | Fuel Pier | [4]30 | 2 | 1,000 | 15 |
| Installation and Removal. | 24-in | Steel | Vibratory | No | Fuel Pier | 52 | 4 | 15 | 26 |

[1] Impact and vibratory driving may occur on the same or separate days depending on contractor needs and scheduling.
[2] The Navy estimates that vibratory installation will take a median time of 10 minutes per pile, with a maximum time of 45 minutes.
[3] The vibratory installation and removal of 74 steel casings used to support the installation of 24-in concrete may be 42-in rather than 36-in in diameter.
[4] Up to 30 out of 74 24-inch concrete piles may be installed with impact driving. The remaining piles are expected to be placed after the casing is installed via vibratory driving and auger drilling.

This change is minor in terms of its effects on marine mammals and does not change our small numbers and negligible impact analysis and determinations. To complete the analysis to support this determination, NMFS and the Navy used a sound source proxy level of 170 referenced to 1 micropascal (dB re 1µPa) root mean square (RMS) at 10 m for vibratory installation and removal of 42-in steel casings (table 5) at the same production rates planned for vibratory installation and removal of 36-in steel casings (table 1; table 6).

This change from vibratory installation and removal of 36-in steel casings to vibratory installation and removal of 42-in steel casings increases the size of the estimated Level A and Level B harassment zones associated with this activity (table 7). However, the clearance and shutdown zones associated with vibratory pile driving and removal of 42-in steel casings are established following the same logic applied to the establishment of clearance and shutdown zones of 36-in steel casings (table 9); for Very High Frequency (VHF) cetaceans, phocids (PW), and otariids (OW), clearance zones are equivalent to the shutdown zones and are based on the Level A harassment isopleths. For large cetaceans and killer whales, the clearance zones are based on the distance that can reliably be observed by Protected Species Observers (PSOs) and remain unchanged. For large cetaceans and killer whales, the shutdown zones correspond to the Level B harassment isopleths. Although the projected Level B harassment isopleth for vibratory 42-in steel casings is much larger than the Level B harassment isopleth for 36-in steel casings (21,544 m and 13,594 m, respectively, table 7), land truncates the Level B harassment isopleth at 13.9 km at its furthest distance, requiring only a small increase in the size of the shutdown zone. As such, there is no increase to the estimated take (table 8).

## Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the reader to these descriptions, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS' Stock Assessment Reports (SARs; *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS' website (*https://www.fisheries.noaa.gov/find-species*).

Table 2 lists all species or stocks for which take is expected and authorized for this activity and summarizes information related to the population or stock, including regulatory status under the MMPA and ESA and potential biological removal (PBR), where known. PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS' SARs). While no serious injury or mortality is anticipated or authorized here, PBR and annual mortality and serious injury (M/SI) from anthropogenic sources are included here as gross indicators of the status of the species or stocks and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS' stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS' U.S. Alaska and Pacific SARs. All values presented in table 2 are the most recent available at the time of publication (including from the 2024 SARs) and are available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.*

TABLE 2—SPECIES, STOCKS, AND THE STATUS OF MARINE MAMMALS [1] WITH ESTIMATED TAKE FROM THE SPECIFIED ACTIVITIES

| Common name | Scientific name | Stock | ESA/ MMPA status; strategic (Y/N) [2] | Stock abundance (CV, $N_{min}$, most recent abundance survey) [3] | PBR | Annual M/SI [4] |
|---|---|---|---|---|---|---|
| **Order Artiodactyla—Cetacea—Mysticeti (baleen whales)** | | | | | | |
| *Family Eschrichtiidae:* | | | | | | |
| Gray Whale | *Eschrichtius robustus* | Eastern North Pacific | -, -, N | 26,960 (0.05, 25,849, 2016). | 801 | 131 |
| *Family Balaenopteridae (rorquals):* | | | | | | |
| Humpback Whale [5] | *Megaptera novaeangliae* | Mainland Mexico—CA-OR-WA | T, D, Y | 3,477 (0.101, 3,185, 2018). | 43 | 22 |
| | | Hawai'i | -, -, N | 11,278 (0.56, 7,265, 2020). | 127 | 27.09 |
| Minke Whale | *Balaenoptera acutorostrata.* | CA-OR-WA | -, -, N | 915 (0.792, 509, 2018) | 4.1 | ≥0.19 |
| **Odontoceti (toothed whales, dolphins, and porpoises)** | | | | | | |
| *Family Delphinidae:* | | | | | | |
| Killer Whale | *Orcinus orca* | Eastern North Pacific Southern Resident. | E, D, Y | 73 (N/A, 73, 2023) | 0.13 | 0 |
| | | West Coast Transient | -, -, N | 349 (N/A [6], 349, 2018) | 3.5 | 0.4 |
| *Family Phocoenidae (porpoises):* | | | | | | |
| Dall's Porpoise | *Phocoenoides dalli* | CA-OR-WA | -, -, N | 16,498 (0.61, 10,286, 2018). | 99 | ≥0.66 |
| Harbor Porpoise | *Phocoena phocoena* | Washington Inland Waters | -, -, N | 11,233 (0.37, 8,308, 2015). | 66 | ≥7.2 |
| **Order Carnivora—Pinnipedia** | | | | | | |
| *Family Otariidae (eared seals and sea lions):* | | | | | | |
| California Sea Lion | *Zalophus californianus* | U.S. | -, -, N | 257,606 (N/A, 233,515, 2014). | 14,011 | >321 |
| Steller Sea Lion | *Eumetopias jubatus* | Eastern | -, -, N | 36,308 (N/A [7], 36,308, 2022). | 2,178 | 93.2 |
| *Family Phocidae (earless seals):* | | | | | | |
| Harbor Seal | *Phoca vitulina* | Washington Inland Hood Canal | -, -, N | UNK (UNK [8], UNK, 1999) | UND | 0.2 |
| | | Washington Inland Southern Puget Sound. | -, -, N | UNK (UNK [8], UNK, 1999) | UND | 3.4 |
| | | Washington Northern Inland Waters. | -, -, N | UNK (UNK [8], UNK, 1999) | UND | 9.8 |
| Northern Elephant Seal | *Mirounga angustirostris* | California Breeding | -, -, N | 194,907 (N/A, 88,794, 2023). | 5,328 | 11.2 |

[1] Information on the classification of marine mammal species can be found on the web page for The Society for Marine Mammalogy's Committee on Taxonomy (*https://marinemammalscience.org/science-and-publications/list-marine-mammal-species-subspecies/*).

[2] Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[3] NMFS marine mammal stock assessment reports online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports.* CV is coefficient of variation; Nmin is the minimum estimate of stock abundance.

[4] These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

[5] According to Curtis *et al.* (2025), the probability that whales encountered in the Salish Sea are from the ESA-listed Central America DPS (Central America/Southern Mexico stock) is 4.3 percent. As such no take of this stock is authorized.

[6] Nest is based upon count of individuals identified from photo-ID catalogs in analysis of a subset of data from 1958 to 2018.

[7] Nest is best estimate of counts, which have not been corrected for animals at sea during abundance surveys. Estimates provided are for the U.S. only.

[8] Abundance estimates are greater than 8 years old, so stock abundance is considered unknown. Pearson *et al.,* 2024 estimates the population abundance of the Washington Northern Inland Waters stock of harbor seal to be 15,898, the Washington Inland Southern Puget Sound stock of harbor seal to be 2,529, and the population abundance of the Hood Canal stock of harbor seal to be 2,832.

A detailed description of the species likely to be affected by the MPR project, including brief introductions to the species and relevant stocks as well as available information regarding population trends and threats, and information regarding local occurrence, were provided in the **Federal Register** notice for the proposed IHA (91 FR 53486, August 18, 2026); since that time, we are not aware of any changes in the status of these species and stocks; therefore, detailed descriptions are not provided here. Please also refer to NMFS' website (*https://www.fisheries.noaa.gov/find-species*) for generalized species accounts.

*Marine Mammal Hearing*

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities or hear over the same frequency range (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007, 2019) recommended that marine mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (behavioral response data, anatomical

modeling, *etc.*). Subsequently, NMFS (2018, 2024) described generalized hearing ranges for these marine mammal hearing groups (table 3). Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from composite audiograms, previous analyses in NMFS (2018), and/or data from Southall *et al.* (2007) and Southall *et al.* (2019).

TABLE 3—MARINE MAMMAL HEARING GROUPS (NMFS, 2024)

| Hearing group | Generalized hearing range * |
|---|---|
| Low-frequency (LF) cetaceans (baleen whales) | 7 Hz to 36 kHz. |
| High-frequency (HF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales) | 150 Hz to 160 kHz. |
| Very High-frequency (VHF) cetaceans (true porpoises, *Kogia,* river dolphins, Cephalorhynchid, *Lagenorhynchus cruciger* & *L. australis*) | 200 Hz to 165 kHz. |
| Phocid pinnipeds (PW) (underwater) (true seals) | 40 Hz to 90 kHz. |
| Otariid pinnipeds (OW) (underwater) (sea lions and fur seals) | 60 Hz to 68 kHz. |

* Represents the generalized hearing range for the entire group as a composite (*i.e.,* all species within the group), where individual species' hearing ranges may not be as broad. Generalized hearing range chosen based on ~65 dB threshold from composite audiogram, previous analysis in NMFS (2018), and/or data from Southall *et al.* (2007) and Southall *et al.* (2019). Additionally, animals are able to detect very loud sounds above and below that "generalized" hearing range.

For more details concerning these groups and associated generalized hearing ranges, please see NMFS (2024) for a review of available information.

**Potential Effects of Specified Activities on Marine Mammals and Their Habitat**

The effects of underwater noise from the Navy's construction activities have the potential to result in behavioral harassment of marine mammals in the vicinity of the project area. The notice of the proposed IHA (91 FR 53486, August 18, 2026) included a discussion of the effects of anthropogenic noise on marine mammals and the potential effects of underwater noise from the Navy's construction activity on marine mammals and their habitat. That information and analysis is referenced in this final IHA determination and is not repeated here; please refer to the notice of the proposed IHA (91 FR 53486, August 18, 2026).

**Estimated Take of Marine Mammals**

This section provides an estimate of the number of incidental takes authorized through the IHA, which will inform NMFS' consideration of ''small numbers,'' the negligible impact determinations, and impacts on subsistence uses.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes are primarily by Level B harassment, as use of the acoustic sources (*i.e.,* vibratory pile driving and removal, impact pile driving) has the potential to result in disruption of behavioral patterns for individual marine mammals. There is also some potential for auditory injury (AUD INJ; Level A harassment) to result, primarily for VHF species, PW, and OW, because predicted AUD INJ zones are larger in comparison to the observability for some species. AUD INJ is unlikely to occur for mysticetes and high-frequency species. The mitigation and monitoring measures are expected to minimize the severity of the taking to the extent practicable.

As described previously, no serious injury or mortality is anticipated or authorized for this activity. Below we describe how the take numbers are estimated.

For acoustic impacts, generally speaking, we estimate take by considering: (1) acoustic criteria above which NMFS believes there is some reasonable potential for marine mammals to be behaviorally harassed or incur some degree of AUD INJ; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the take estimates.

*Acoustic Criteria*

NMFS recommends the use of acoustic criteria that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur AUD INJ of some degree (equated to Level A harassment).

Level B Harassment

Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source or exposure context (*e.g.,* frequency, predictability, duty cycle, duration of the exposure, signal-to-noise ratio, distance to the source), the environment (*e.g.,* bathymetry, other noises in the area, predators in the area), and the receiving animals (hearing, motivation, experience, demography, life stage, depth) and can be difficult to predict (*e.g.,* Southall *et al.,* 2007; Southall *et al.,* 2021; Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS generally predicts that marine mammals are likely to be behaviorally harassed in a manner considered to be Level B harassment when exposed to underwater anthropogenic noise above RMS Sound Pressure Level (SPL) of 120 dB re 1 µPa for continuous (*e.g.,* vibratory pile driving, drilling) and above RMS SPL 160 dB re 1 µPa for non-explosive impulsive (*e.g.,* seismic airguns) or intermittent (*e.g.,* scientific sonar) sources. Generally speaking, estimates

of take by Level B harassment based on these behavioral harassment thresholds are expected to include any likely takes by temporary threshold shift (TTS) as, in most cases, the likelihood of TTS occurs at distances from the source less than those at which behavioral harassment is likely. TTS of a sufficient degree can manifest as behavioral harassment, as reduced hearing sensitivity and the potential reduced opportunities to detect important signals (conspecific communication, predators, prey) may result in changes in behavior patterns that would not otherwise occur.

The Navy's 2026 MPR project includes the use of continuous (vibratory pile driving and removal) and impulsive (impact pile driving) sources, and therefore the RMS SPL thresholds of 120 and 160 dB re 1 µPa are applicable.

Level A Harassment

NMFS' Updated Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 3.0) (Updated Technical Guidance, 2024) identifies dual criteria to assess AUD INJ (Level A harassment) to five different underwater marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). The Navy's 2026 MPR project includes the use of impulsive (impact pile driving) and non-impulsive (vibratory pile driving and removal) sources.

The 2024 Updated Technical Guidance criteria include both updated thresholds and updated weighting functions for each hearing group. The thresholds are provided in the table below. The references, analysis, and methodology used in the development of the criteria are described in NMFS' 2024 Updated Technical Guidance, which may be accessed at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance-other-acoustic-tools.*

TABLE 4—THRESHOLDS IDENTIFYING THE ONSET OF AUDITORY INJURY

| Hearing group | AUD INJ onset acoustic thresholds * (received level) | |
|---|---|---|
| | Impulsive | Non-impulsive |
| Low-Frequency (LF) Cetaceans | *Cell 1:* $L_{pk,flat}$: 222 dB; $L_{E,LF,24h}$: 183 dB | *Cell 2:* $L_{E,LF,24h}$: 197 dB. |
| High-Frequency (HF) Cetaceans | *Cell 3:* $L_{pk,flat}$: 230 dB; $L_{E,HF,24h}$: 193 dB | *Cell 4:* $L_{E,HF,24h}$: 201 dB. |
| Very High-Frequency (VHF) Cetaceans | *Cell 5:* $L_{pk,flat}$: 202 dB; $L_{E,VHF,24h}$: 159 dB | *Cell 6:* $L_{E,VHF,24h}$: 181 dB. |
| Phocid Pinnipeds (PW)(Underwater) | *Cell 7:* $L_{pk,flat}$: 223 dB; $L_{E,PW,24h}$: 183 dB | *Cell 8:* $L_{E,PW,24h}$: 195 dB. |
| Otariid Pinnipeds (OW)(Underwater) | *Cell 9:* $L_{pk,flat}$: 230 dB; $L_{E,OW,24h}$: 185 dB | *Cell 10:* $L_{E,OW,24h}$: 199 dB. |

* Dual metric criteria for impulsive sounds: Use whichever criteria results in the larger isopleth for calculating AUD INJ onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level criteria associated with impulsive sounds, the PK SPL criteria are recommended for consideration for non-impulsive sources.

**Note:** Peak sound pressure level ($L_{p,0\text{-}pk}$) has a reference value of 1 µPa, and weighted cumulative sound exposure level ($L_{E,p}$) has a reference value of 1 $\mu Pa^2s$. In this table, criteria are abbreviated to be more reflective of International Organization for Standardization standards (ISO, 2017). The subscript "flat" is being included to indicate peak sound pressure are flat weighted or unweighted within the generalized hearing range of marine mammals underwater (*i.e.,* 7 Hz to 165 kHz). The subscript associated with cumulative sound exposure level criteria indicates the designated marine mammal auditory weighting function (LF, HF, and VHF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The weighted cumulative sound exposure level criteria could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these criteria will be exceeded.

*Ensonified Area*

Here, we describe operational and environmental parameters of the activity that are used in estimating the area ensonified above the acoustic thresholds, including source levels and transmission loss coefficient.

The sound field in the project area is the existing background noise plus additional construction noise from the project. Marine mammals are expected to be affected via sound generated by the primary components of the project (*i.e.,* vibratory pile driving and removal, and impact pile driving).

Source levels for these activities are based on reviews of measurements of the same or similar pile types and dimensions of piles available in literature. Source levels used for each pile size and activity are presented in table 5. Source levels for vibratory installation and removal of piles of the same diameter are assumed to be the same.

The Navy plans to use bubble curtains when impact driving steel piles. For the reasons described in the next paragraph, we assume here that use of the bubble curtain would result in a reduction of 8 dB from the assumed SPL (rms), SPL (peak) and Sound Exposure Level (SEL) source levels for these pile sizes, and reduce the applied source levels accordingly.

During the 2023 study at NBK Bremerton, the Navy conducted comparative measurements of source levels when impact driving steel piles with and without a bubble curtain. Underwater sound levels were measured at two locations during the installation of one 24-in diameter steel pile and four 36-in steel piles. The bubble curtain used during the measurements reduced median peak sound levels by between 8 and 12 dB, median RMS sound levels by 10 and 12 dB, and median single strike SEL sound levels by 7 and 8 dB. The analysis included in a proposed rule for regulations (83 FR 9366, March 5, 2018) preceding two consecutive IHAs (89 FR 47539, June 3, 2026) that preceded this project as well as results from the NBK Bangor Trident Support Facilities Explosive Handling Wharf study (Navy, 2013), are consistent with these findings. While proper set-up and operation of the system is critical, and variability in performance should be expected, we believe that in the circumstances evaluated here an effective attenuation performance of 8 dB is a reasonable assumption.

TABLE 5—ESTIMATES OF MEAN UNDERWATER SOUND LEVELS GENERATED DURING VIBRATORY AND IMPACT PILE INSTALLATION AND VIBRATORY PILE REMOVAL

[Unattenuated]

| Method | Type | Size (in) | RMS | Peak | SEL | Attenuation to be applied | Reference |
|---|---|---|---|---|---|---|---|
| Impact | Concrete | 24 | 174 | 188 | 164 | N/A | Navy, 2015. |
| | Steel | 18 | 185 | 200 | 175 | −8 dB [1] | Caltrans, 2020. |
| | | 20 | 193 | 210 | 181 | −8 dB [1] | Navy, 2015.[2] |
| | | 30 | 195 | 216 | 186 | −8 dB [1] | Navy, 2015. |
| Vibratory Installation and Removal | Steel | 12 | 155 | N/A | N/A | N/A | Caltrans, 2015. |
| | | 14 H | 150 | N/A | N/A | N/A | Caltrans, 2015. |
| | | 18 | 161 | N/A | N/A | N/A | Navy, 2015.[3] |
| | | 20 | 161 | N/A | N/A | N/A | Navy, 2015.[3] |
| | | 24 | 161 | N/A | N/A | N/A | Navy, 2015. |
| | | 30 | 166 | N/A | N/A | N/A | Navy, 2015. |
| | Concrete | 24 | 163 | N/A | N/A | N/A | NAVFAC SW [4] 2022. |
| | Casings | 36 | 167 | N/A | N/A | N/A | Navy, 2015. |
| | | [5] 42 | 170 | N/A | N/A | N/A | Navy, 2012; Navy 2013. |

**Note:** dB peak = peak sound Level; rms = root mean square; SEL = sound exposure level.

[1] Values modeled for impact driving of 18, 20 and 30-in steel piles will be reduced by 8 dB for noise exposure modeling to account for attenuation from a bubble curtain.

[2] The Navy uses sound levels estimated for impact pile driving of 24-in steel as proxy for this pile type.

[3] The Navy uses sound levels estimated for vibratory pile driving of 16 and 24-in steel as proxy for these pile types.

[4] The Navy uses sound levels estimated for vibratory pile driving of 20-in concrete as proxy for this pile type.

[5] NMFS and the Navy refer to measured sound levels for vibratory driving of 48-in steel pipe piles as proxy for this pile type and find that 170 dB RMS is a generally conservative value based on those measurements.

*TL* is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. *TL* parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition and topography. The general formula for underwater *TL* is:

$TL = B \times \mathrm{Log10}\ (R_1/R_2)$,

Where:

*TL* = transmission loss in dB

*B* = transmission loss coefficient

$R_1$ = the distance of the modeled SPL from the driven pile, and

$R_2$ = the distance from the driven pile of the initial measurement

Absent site-specific acoustical monitoring with differing measured *TL,* a practical spreading value of 15 is used as the *TL* coefficient in the above formula. Site-specific *TL* data for the Puget Sound and Hood Canal are not available; therefore, the default coefficient of 15 is used to determine the distances to the Level A harassment and Level B harassment thresholds.

The ensonified area associated with Level A harassment is more technically challenging to predict due to the need to account for a duration component. Therefore, NMFS developed an optional User Spreadsheet tool to accompany the 2024 Updated Technical Guidance that can be used to relatively simply predict an isopleth distance for use in conjunction with marine mammal density or occurrence to help predict potential takes. We note that because of some of the assumptions included in the methods underlying this optional tool, we anticipate that the resulting isopleth estimates are typically going to be overestimates of some degree, which may result in an overestimate of potential take by Level A harassment. However, this optional tool offers a practical, alternative way to estimate isopleth distances when more sophisticated modeling methods are not available or practical. For stationary sources such as pile driving, the optional User Spreadsheet tool predicts the distance at which, if a marine mammal remained at that distance for the duration of the activity, it would be expected to incur AUD INJ. Inputs used in the optional User Spreadsheet tool (table 6), and the resulting estimated isopleths (table 7), are reported below.

TABLE 6—USER SPREADSHEET INPUT PARAMETERS USED FOR CALCULATING LEVEL A HARASSMENT ISOPLETHS FOR PILE DRIVING AND REMOVAL BASED ON USER SPREADSHEET INPUTS PROVIDED BY THE NAVY

| Location | Pile size and type | Spreadsheet tab used | Weighting factor adjustment | Piles per day | Duration to drive a single pile (minutes) | Strikes |
|---|---|---|---|---|---|---|
| **Bangor** | | | | | | |
| Olympic Pier | 24-in Concrete | A.1. Vibratory pile driving | 2.5 | 2 | 10 | N/A |
| EHW–1 | | A.1. Vibratory pile driving | 2.5 | 3 | 10 | N/A |
| Olympic Pier | 20-in Steel | A.1. Vibratory pile driving | 2.5 | 2 | 10 | N/A |
| | | E.1. Impact pile driving | 2 | 2 | N/A | 500 |
| EHW–1 | 30-in Steel | A.1. Vibratory pile driving | 2.5 | 2 | 10 | N/A |
| | | E.1. Impact pile driving | 2 | 2 | 1,000 | N/A |
| **NS Everett** | | | | | | |
| Piers A, B, and South Wharf | 12-in Steel | A.1. Vibratory pile driving | 2.5 | 4 | 10 | N/A |
| | 18-in Steel | A.1. Vibratory pile driving | 2.5 | 4 | 10 | N/A |
| | | E.1. Impact pile driving | 2 | 4 | N/A | 400 |

TABLE 6—USER SPREADSHEET INPUT PARAMETERS USED FOR CALCULATING LEVEL A HARASSMENT ISOPLETHS FOR PILE DRIVING AND REMOVAL BASED ON USER SPREADSHEET INPUTS PROVIDED BY THE NAVY—Continued

| Location | Pile size and type | Spreadsheet tab used | Weighting factor adjustment | Piles per day | Duration to drive a single pile (minutes) | Strikes |
|---|---|---|---|---|---|---|
| **NBK Manchester** | | | | | | |
| Fuel Pier | 14-in H | A.1. Vibratory pile driving | 2.5 | 3 | 10 | N/A |
| | 36-in or 42-in casing (removal) | A.1. Vibratory pile driving | 2.5 | 3 | 30 | N/A |
| | 36-in or 42-in casing (install) | A.1. Vibratory pile driving | 2.5 | 2 | 30 | N/A |
| | 24-in concrete | E.1. Impact pile driving | 2 | 2 | N/A | 1,000 |
| | 24-in Steel | A.1. Vibratory pile driving | 2.5 | 4 | 15 | N/A |

TABLE 7—PROJECTED DISTANCES TO LEVEL A AND LEVEL B HARASSMENT ISOPLETHS (m) BY HEARING GROUP
[practical spreading]

| Pile size and type | Method | Location | Level A harassment isopleth (m) (attenuated as relevant) | | | | | Level B harassment zone m |
|---|---|---|---|---|---|---|---|---|
| | | | LF | HF | VHF | PW | OW | |
| **NBK Bangor** | | | | | | | | |
| 24-in Concrete | Vibratory Removal | Olympic Pier | 6.0 | 2.3 | 4.9 | 7.8 | 2.6 | 7,356 |
| | | EHW–1 | 7.9 | 3.0 | 6.5 | 10 | 3.4 | 7,356 |
| 20-in Steel | Vibratory Install | Olympic Pier | 4.4 | 1.7 | 3.6 | 5.7 | 1.9 | 5,412 |
| | Impact Install | | 214 | 27 | 332 | 190 | 71 | 464 |
| 30-in Steel | Vibratory Install | EHW–1 | 10 | 3.7 | 7.8 | 12 | 4.1 | 11,659 |
| | Impact Install | | 733 | 94 | 1,135 | 651 | 243 | 631 |
| **NS Everett** | | | | | | | | |
| 12-in Steel | Vibratory Removal | Piers A, B, and South Wharf | 2.8 | 1.1 | 2.3 | 3.6 | 1.2 | 2,154 |
| 18-in Steel | Vibratory Install | Piers A, B, and South Wharf | 7.0 | 2.7 | 5.7 | 9.1 | 3.0 | 5,412 |
| | Impact Install | | 117 | 15 | 181 | 104 | 39 | 136 |
| **NBK Manchester** | | | | | | | | |
| 14-in H Steel | Vibratory Removal | Fuel Pier | 1.1 | 0.4 | 0.9 | 1.4 | 0.5 | 1,000 |
| 36-in Steel | | | 30 | 12 | 25 | 39 | 13 | 13,594 |
| 42-in Steel | | | 37 | 14 | 30 | 47 | 16 | [1] 21,544 |
| 36-in Steel | Vibratory Install | Fuel Pier | 23 | 8.9 | 19 | 30 | 10 | 13,594 |
| 42-in Steel | | | 48 | 19 | 39 | 62 | 21 | [1] 21,544 |
| 24-in Concrete | Impact Install | | 86 | 11 | 132 | 76 | 28 | 86 |
| 24-in Steel | Vibratory Install and Removal. | Fuel Pier | 9.2 | 3.5 | 7.5 | 12 | 4.0 | 5,412 |

[1] Underwater noise would be truncated by land at approximately 13.9 km from Manchester Fuel Pier at its furthest distance.

*Marine Mammal Occurrence*

In this section we provide information about the occurrence of marine mammals, including density or other relevant information which will inform the take calculations.

Available information regarding marine mammal occurrence in the vicinity of the project area includes site-specific and nearby survey information from the Navy and the Washington State Department of Transportation (WSDOT). Specifically, data sources consulted included (1) the Navy's ''Summary of Weekly Marine Mammal Surveys at Navy Northwest Region Installations: 2008—2025'', and (2) PSO monitoring completed across (a) 156 monitoring days associated with four projects completed by the Navy at Bangor; (b) 11 monitoring days associated with one project completed by the Navy at Manchester, and (c) 169 monitoring days between 2015 and 2021, between the months of August and February, associated with the multi-year WSDOT Multimodal Construction Project completed by WSDOT, which was located near NS Everett. Species-specific data summaries of the above are included in the Description of Marine Mammals in the Area of Specified Activities section.

For large whales (humpback whales, minke whales, and gray whales), killer whales (transient and resident), Dall's porpoise, and elephant seals, NMFS considered the data sources identified above, as well as (1) data collected by The Whale Museum between August 2022 and July 2024 from Blake Island (approximately 3 km from NBK Manchester) provided by the Navy and, (2) The Orca Network archived sightings.

*Take Estimation*

Here we describe how the information provided above is synthesized to produce a quantitative estimate of the take that is reasonably likely to occur and authorized.

For species with rare or infrequent occurrence at a given installation during the in-water work window, the likelihood of occurrence was reviewed on the basis of past records of occurrence (described in Description of Marine Mammals in the Area of Specified Activities) and the potential maximum duration of work days at each installation, as well as total work days for all installations. In most cases, the occurrence of the species in this category (*i.e.,* large whales, killer whales, Dall's porpoise, and elephant seals (all installations)), is not anticipated to extend for multiple days. Except for gray whales, where increased strandings reports suggest individuals may occur in an area for a longer period of time, the probable duration of all rare, unpredictably occurring species is assumed to be 2 days, roughly equivalent to one transit in and out of

a project site (across all installations). The equation used to estimate take for species with rare or infrequent occurrence is:

Exposure estimate = Probable abundance during construction × probable duration

Where:

Probable abundance = expected group size or number based on data sources referenced above

Probable duration = probable duration of the animal(s) presence at construction sites during the entire in-water pile driving period.

For the remaining species, the Navy utilized density estimates or site-specific survey data to estimate the likelihood of occurrence. Specifically, the Navy proposed to use density estimates of harbor porpoise from the Navy's Marine Mammal Species Density Database (Navy, 2019) to estimate the likelihood of occurrence. However, NMFS finds it more appropriate to use local monitoring data to estimate the likelihood of occurrence for harbor porpoise. As such, for harbor porpoise and the other remaining species (California sea lion, Steller sea lion, and harbor seal), the Navy and NMFS predicted a daily occurrence, and estimated take by multiplying the estimated daily occurrence for each species by the number of in-water construction days, generally using the following equation;

Take by Level B harassment = marine mammal occurrence × days of pile driving activities.

Although certain species are not expected to occur at all at some facilities—for example, resident killer whales are not expected to occur in Hood Canal—an overall take estimate for these species has been developed across the entire project.

The Navy plans to implement a shutdown of pile driving activity if any large whale or killer whale is observed within or approaching any defined harassment zone (see Mitigation section). Additionally, the Navy plans at least daily coordination with the Orca Network to maintain situational awareness of large whales in the vicinity of the project sites and shut down should they be reported or observed by PSOs near the project site. As a result of this mitigation, we do not believe that Level A harassment is a likely outcome upon occurrence of any large whale or killer whale. Likewise, the Navy has not requested take by Level A harassment of large whales or killer whales, nor has NMFS authorized take by Level A harassment of these species.

In most cases where shutdown zones are greater than or equal to the calculated Level A harassment zones, take by Level A harassment is not authorized. However, there are scenarios for some pinniped species and installations (*i.e.,* California sea lions at NBK Bangor and NS Everett and harbor seals at NS Everett) where take by Level A harassment is authorized to account for the possibility that individuals could enter the shutdown zone and stay long enough to incur AUD INJ before PSOs are able to detect them and enact a shutdown.

Additionally, in cases where the Level A harassment zones are larger than the shutdown zones (*i.e.,* impact proofing of 30-inch steel for VHF and harbor seals at NBK Bangor), take by Level A harassment is authorized. The same general equation is used for take by Level A harassment that is used for take by Level B harassment: marine mammal occurrence multiplied by days of pile driving activities. In cases where the predicted Level A harassment zones exceed the shutdown zones for species that are occasionally or rarely expected to occur in the project area (*e.g.,* Dall's porpoise), it is assumed that takes could be by either Level A or Level B harassment.

We acknowledge that the number of estimated exposures above higher threshold criteria (*e.g.,* sound exposures exceeding Level A harassment criteria) also encompasses the potential for less impactful effects (*e.g.,* Level B harassment). An individual within the estimated Level A harassment isopleth may not incur auditory injury due to limited exposure duration; however, the individual may have experienced Level B harassment. This outcome is accounted for in our authorization of potential higher-level takes and in our analysis. Specifically, due to this approach for calculating Level A harassment and Level B harassment for Dall's porpoise, the number of takes by Level A harassment authorized may be applied to observations of Level B harassment. However, the total number of takes may not exceed the sum of the takes authorized by Level A and Level B harassment (table 8).

The Navy plans to shut down in-water pile driving upon observation of any large whale or killer whale approaching or within any estimated harassment zone. While the Navy plans to coordinate with the Orca Network to maintain situational awareness of the presence of large whales or killer whales near all three project areas, the Level B harassment zone is larger than is practicably observable by PSOs during most activities. As such, some take by Level B harassment is authorized for these species.

Humpback Whale

The Navy requested and NMFS concurred that one group of two humpback whales may occur in the Level B harassment zone during active pile driving on a total of 2 days over the course of the construction season. Therefore, NMFS has authorized four takes by Level B harassment of humpback whales.

No takes by Level A harassment of humpback whales are anticipated and none are authorized.

Gray Whale

The Navy initially assumed that one group of two gray whales may occur in the Level B harassment zone during active pile driving on a total of 2 days over the course of the construction season. However, given the recent reports of stranded gray whales in Puget Sound, the Navy requested and NMFS concurred that up to eight gray whales may be taken by Level B harassment during the project period. Therefore, NMFS has authorized eight takes by Level B harassment of gray whales.

No takes by Level A harassment of gray whales are anticipated and none are authorized.

Minke Whale

The Navy requested and NMFS concurred that one group of two minke whales may occur in a Level B harassment zone during active pile driving on a total of 2 days over the course of the construction season for a total of four takes by Level B harassment. Therefore, NMFS has authorized four takes by Level B harassment of minke whales.

No takes by Level A harassment of minke whales are anticipated and none are authorized.

Transient Killer Whale

The Navy requested and NMFS concurred that 1 group of 6 transient killer whales may occur in a Level B harassment zone during active pile driving on a total of 2 days over the course of the constructions season for a total of 12 takes by Level B harassment. Therefore, NMFS has authorized 12 takes by Level B harassment of transient killer whales.

No takes by Level A harassment of transient killer whales are anticipated and none are authorized.

Southern Resident Killer Whale

The Navy requested and NMFS concurred that 1 group of 10 SRKW may occur in the Level B harassment zone

during active pile driving on a total of 2 days over the course of the construction season for a total of 20 takes by Level B harassment. Therefore, NMFS has authorized 20 takes by Level B harassment of SRKWs.

No takes by Level A harassment of SRKW are anticipated and none are authorized.

Dall's Porpoise

The Navy requested and NMFS concurred that one group of two Dall's porpoise could occur within the project area during active pile driving on a total of 2 days over the course of the construction season for a total of four. Because exposure estimates are low and the Level A harassment zones are larger than are likely observable during impact pile driving, NMFS has authorized these four takes as Level A harassment, acknowledging that instead the takes could be by the less severe Level B harassment.

Harbor Porpoise

*NBK Bangor*—The Navy requested and NMFS concurred that 12 harbor porpoises could occur within the Level B harassment zone each construction day. This results in 264 takes by Level B harassment of harbor porpoises across the 22 construction days at this project site.

The calculated Level A harassment zone expected to occur during the 6 days of impact proofing of 30-in steel piles at Explosives Handling Wharf–1 (EHW–1) is 1,135 m, and the Navy plans to maintain a shutdown zone of 350 m (table 9). NMFS estimates that 12 harbor porpoises per day could occur within the calculated Level A harassment zone and remain for a sufficient period to accumulate enough energy to result in AUD INJ. As such, NMFS has authorized 72 takes by Level A harassment of harbor porpoises at this project site.

NMFS modified the calculated takes by Level B harassment to deduct the estimated amount of take by Level A harassment (*i.e.,* 264 takes by Level B harassment − 72 takes by Level A harassment = 192 takes by Level B harassment). Therefore, for harbor porpoises, NMFS has authorized 192 takes by Level B harassment and 72 takes by Level A harassment for a total of 264 takes across the 22 days of construction planned at this site.

*NS Everett*—The Navy requested and NMFS concurred that two harbor porpoises could occur within the Level B harassment zone each construction day. This results in 154 takes by Level B harassment of harbor porpoises across the 77 construction days at this project site.

No takes by Level A harassment of harbor porpoises are anticipated at this project site and none are authorized.

*NBK Manchester*—that the Navy requested and NMFS concurred that two harbor porpoises could occur within the Level B harassment zone each construction day. This results in 256 takes by Level B harassment of harbor porpoises across 128 construction days at this project site.

No takes by Level A harassment of harbor porpoises are anticipated at this project site and none are authorized.

Across all installations, NMFS has authorized 602 takes by Level B harassment of and 72 takes by Level A harassment of harbor porpoises for a total of 674 takes.

California Sea Lion

*NBK Bangor*—The Navy requested and NMFS concurred that 35 California sea lions could occur within the Level B harassment zone each construction day. This results in 770 takes by Level B harassment of California sea lions across the 22 construction days at this project site.

The Navy plans to shut down at distances slightly larger than the Level A harassment zones associated with this project site (see table 9). However, given the proximity of hauled out California sea lions to the project site, and the fact that on 6 construction days the calculated Level A harassment zone is 243 m (during impact proofing of 30-inch steel at EHW–1), NMFS predicts that it is possible that up to two California sea lions could go unobserved and remain within the calculated Level A harassment zone for a sufficient period to accumulate enough energy to result in AUD INJ. This results in two takes by Level A harassment of California sea lions at this project site.

Takes by Level B harassment were modified to deduct the amount of take by Level A harassment estimated (*i.e.,* 770 takes by Level B harassment − 2 takes by Level A harassment = 768 takes by Level B harassment). This results in 768 takes by Level B harassment and 2 takes by Level A harassment for a total of 770 takes across the 22 days of construction planned at this site.

*NS Everett*—The Navy requested and NMFS concurred that 35 California sea lions could occur within the Level B harassment zone each construction day. This results in 2,695 takes by Level B harassment across the 77 construction days at this project site.

The Navy plans to shut down at distances slightly larger than the Level A harassment zones associated with this project site (see table 9). However, given the proximity of hauled out California sea lions to the project site (the PSB at this location directly connects to the southwest end of Pier B and runs about 60 m along the southern end of both Piers A and B, and approximately 160 m along the southeastern extent of Pier A), and the fact that on 5 construction days the calculated Level A harassment zone is 38 m (during impact proofing of 18-inch steel fender piles at Piers A, B, and South Wharf), NMFS predicts that it is possible that up to one California sea lion per day could go unobserved and remain within the calculated Level A harassment zone for a sufficient period to accumulate enough energy to result in AUD INJ. This results in five takes by Level A harassment of California sea lions at this project site.

Takes by Level B harassment were modified to deduct the amount of take by Level A harassment estimated (*i.e.,* 2,695 takes by Level B harassment − 5 takes by Level A harassment = 2,690 takes by Level B harassment). This results in 2,690 takes by Level B harassment and 5 takes by Level A harassment for a total of 2,695 takes across the 77 days of construction planned at this site.

*NBK Manchester*—The Navy requested and NMFS concurred that six California sea lions could occur within the Level B harassment zone each construction day. This results in 768 takes by Level B harassment of California sea lions across 128 construction days at this project site.

No takes by Level A harassment of California sea lions are anticipated at this project site and none are authorized.

Across all installations, NMFS has authorized 4,226 takes by Level B harassment and 7 takes by Level A harassment of California sea lions for a total of 4,233 takes.

Steller Sea Lion

*NBK Bangor*—The Navy requested and NMFS concurred that four Steller sea lions could occur within the Level B harassment zone each construction day. This results in 88 takes by Level B harassment of Steller sea lions across the 22 construction days at this project site.

No takes by Level A harassment of Steller sea lions are anticipated at this project site and none are authorized.

*NS Everett*—The Navy requested and NMFS concurred that 0.25 Steller sea lions could occur within the Level B harassment zone every construction day, or one Steller sea lion could occur within the Level B harassment zone every 4 construction days. This results

in 19 takes by Level B harassment of Steller sea lions across the 77 days at this project site.

No takes by Level A harassment of Steller sea lions are anticipated at this project site and none are authorized.

*NBK Manchester*—The Navy requested and NMFS concurred that four Steller sea lions could occur within the Level B harassment zone each construction day. This results in 512 takes by Level B harassment across the 128 construction days at this project site.

No takes by Level A harassment of Steller sea lions are anticipated at this project site and none are authorized.

Across all installations, NMFS authorized 619 takes by Level B harassment of Steller sea lions. No takes by Level A harassment of Steller sea lions are requested and none are authorized.

Harbor Seal

*NBK Bangor*—The Navy requested and NMFS concurred that 16 harbor seals could occur within the Level B harassment zone each construction day. This results in 352 takes by Level B harassment across the 22 construction days at this project site.

The calculated Level A harassment zone expected to occur during 6 days of impact proofing of 30-inch steel piles at EHW–1 is 651 m. The calculated Level A harassment zone expected to occur during impact proofing of 20-inch steel fender piles at Olympic Pier is 190 m (planned on 2 construction days). The Navy plans to maintain a shutdown zone of 200 m (table 9) at this site during all impact pile driving activities. NMFS predicts that three harbor seals could be present in the project area during each of the 6 construction days where the calculated Level A harassment zone exceeds the planned shutdown zone. Additionally, given the regular occurrence of harbor seals at the project site, NMFS predicts that up to three harbor seals per day could go unobserved and remain within the calculated Level A harassment zone for a sufficient period to accumulate enough energy to result in AUD INJ during the 2 construction days where shutdown zone exceeds the calculated Level A harassment zone, but the Level A harassment zone is relatively large and more challenging for PSOs to effectively monitor. As such, NMFS has authorized 24 takes by Level A harassment of harbor seals at this project site.

Takes by Level B harassment were modified to deduct the amount of take by Level A harassment estimated (*i.e.,* 352 takes by Level B harassment − 24 takes by Level A harassment = 328 takes by Level B harassment). This results in 328 takes by Level B harassment and 24 takes by Level A harassment of harbor seals for a total of 352 takes across the 22 days of construction planned at this site.

*NS Everett*—The Navy requested and NMFS concurred that 54 harbor seals could occur within the Level B harassment zone each construction day. Fifty-four represents 25 percent of the harbor seals documented during the Navy's pinniped monitoring, because surveys were recently expanded to include the entire East Waterway. This results in 4,158 takes by Level B harassment across the 77 construction days planned at this site.

The Navy plans to shut down at distances slightly larger than the Level A harassment zones associated with this project site (see table 9). However, given the regular occurrence of harbor seals at the project site, and the fact that on 5 construction days the calculated Level A harassment zone is 104 m (during impact proofing of 18-inch steel fender piles at Piers A, B, and South Wharf), NMFS predicts that it is possible that up to one harbor seal per day could go unobserved and remain within the calculated Level A harassment zone for a sufficient period to accumulate enough energy to result in AUD INJ. As such, NMFS has authorized five takes by Level A harassment of harbor seals at this project site.

Takes by Level B harassment were modified to deduct the amount of take by Level A harassment estimated (*i.e.,* 4,158 takes by Level B harassment − 5 takes by Level A harassment = 4,153 takes by Level B harassment). This results in 4,153 takes by Level B harassment and 5 takes by Level A harassment for a total of 4,153 takes across the 77 days of construction planned at this site.

*NBK Manchester*—The Navy requested and NMFS concurred that 13 harbor seals could occur within the Level B harassment zone each construction day. This results in 1,664 takes by Level B harassment across the 128 construction days planned at this project site.

No takes by Level A harassment of California sea lions are requested at this project site and none are authorized.

Across all installations, we authorized 6,145 takes by Level B harassment of and 29 takes by Level A harassment of harbor seals for a total of 6,174 takes.

Northern Elephant Seal

Because the occurrence of northern elephant seals in Puget Sound is unpredictable and this species is known to linger, NMFS predicts that one northern elephant seal could occur within the project area on up to 4 days during the project period. This results in four takes by Level B harassment.

No takes by Level A harassment of northern elephant seals are anticipated and none are authorized.

TABLE 8—TAKE BY STOCK AND HARASSMENT TYPE AND AS A PERCENTAGE OF STOCK ABUNDANCE

| Species | Stock | Level A harassment | Level B harassment | Total harassment | Take as a percentage of stock abundance |
|---|---|---|---|---|---|
| Gray whale | Eastern N Pacific | 0 | 8 | 8 | <1 |
| Humpback whale [1] | Mainland Mexico—CA-OR-WA | 0 | 4 | 4 | <1 |
| | Hawai'i | | | | <1 |
| Minke whale | CA-OR-WA | 0 | 4 | 4 | <1 |
| Killer whale | West Coast Transient | 0 | 12 | 12 | 3.4 |
| | Southern Resident Killer Whale | 0 | 20 | 20 | 27 |
| Dall's Porpoise | CA-WA-OR | [2] 4 | 0 | 0 | <1 |
| Harbor Porpoise | Washington Inland | 72 | 602 | 674 | 6.0 |
| California Sea Lion | US | 7 | 4,226 | 4,233 | 1.6 |
| Steller sea lion | Eastern U.S | 0 | 619 | 619 | 1.7 |
| Harbor Seal [3] | Washington Inland Hood Canal | 24 | 328 | 352 | 12 |
| | Washington Inland Northern Puget Sound | 5 | 4,153 | 4,158 | 26 |
| | Washington Inland Southern Puget Sound | 0 | 1,664 | 1,664 | 66 |

TABLE 8—TAKE BY STOCK AND HARASSMENT TYPE AND AS A PERCENTAGE OF STOCK ABUNDANCE—Continued

| Species | Stock | Level A harassment | Level B harassment | Total harassment | Take as a percentage of stock abundance |
|---|---|---|---|---|---|
| Northern elephant seal | California Breeding | 0 | 4 | 4 | <1 |

[1] According to Curtis *et al.* (2025), the probability that whales encountered in the Salish sea are as follows: Central America DPS (Central America/Southern Mexico stock) (4.3 percent); Mexico DPS (Mainland Mexico—Oregon/California/Oregon stock) (45.7 percent); Hawaii DPS (Hawai'i stock) (50 percent). As such we estimate that 2 takes by Level B harassment would be from the Mainland Mexico—CA-OR-WA stock, and 2 takes by Level B harassment would be from the Hawai'i stock while 0 takes by Level B harassment would be from the Central America/Southern Mexico stock. Because PSOs would not be able to identify the stock of an observed humpback whale, all take is assumed to be from either stock where some occurrence is predicted.

[2] As described above, because exposure estimates are low and the Level A harassment zones are larger than are likely observable during impact pile driving, NMFS authorizes these four takes as Level A harassment, acknowledging that instead the takes could be by the less severe Level B harassment.

[3] The Washington Inland Hood Canal stock of harbor seal is the only harbor seal stock expected to occur at NBK Bangor. The Washington Inland Northern Puget Sound stock of harbor seal is the only stock of harbor seal expected to occur at NS Everett. The Washington Inland Southern Puget Sound stock of harbor seal is the only stock of harbor seal expected to occur at NBK Manchester.

## Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, NMFS considers two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned); and

(2) The practicability of the measures for applicant implementation, which may consider such things as cost, and impact on operations.

The mitigation requirements described in the following were proposed by the Navy in its adequate and complete application or are the result of subsequent coordination between NMFS and the Navy. The Navy has agreed that all of the mitigation measures are practicable. NMFS has fully reviewed the specified activities and the mitigation measures to determine if the mitigation measures would result in the least practicable adverse impact on marine mammals and their habitat, as required by the MMPA, and has determined the proposed measures are appropriate. NMFS describes these below as mitigation requirements, and has included them in the IHA.

### *Shutdown and Clearance Zones*

NMFS requires the establishment of both clearance and, where technically feasible, shutdown zones during project activities that have the potential to result in harassment of marine mammals. The purpose of ''clearance'' of a particular zone is to minimize potential instances of harassment and/or minimize the intensity of a harassment event by delaying the commencement of an activity if marine mammals are observed within the defined area. The purpose of a shutdown zone is to prevent or minimize a specific acute impact and/or minimize the intensity or duration of a harassment event by halting the activity that is already underway if a marine mammal is observed within the defined area (or in anticipation of an animal entering the defined area). For VHF, PR, and OW species, the clearance zone at all sites for all activities is equivalent to the shutdown zone and are not differentiated. For large whales and killer whales, a minimum clearance zone that is based on the distance that can be reliably observed by PSOs is established in addition to a shutdown zone.

For all large cetaceans and killer whales, the Navy plans to shut down at distances based on the largest estimated harassment zone for each activity. At Bangor, the largest shutdown zone for these hearing groups is 11. km, which corresponds to the maximum Level B harassment distance during a vibratory pile driving activity. At Everett, the largest shutdown zone for these hearing groups is 5.4 km, which corresponds to the maximum Level B harassment distance during a vibratory pile driving activity. At Manchester, the largest shutdown zone for these hearing groups is 13.9 km (revised from 13.6 from the notice of proposed IHA), which corresponds to the maximum Level B harassment distance during a vibratory pile driving activity (now based on vibratory removal and installation of 42-in casings rather than 36-in casings). If a large whale or killer whale is observed approaching the Level B harassment zone (*i.e.,* the shutdown zone) the Navy would implement shutdown measures.

Recognizing that the entirety of the Level B harassment zone cannot practicably be monitored by PSOs, the Orca Network will be consulted prior to commencing pile driving each day, and Navy biologists and lead PSOs will have access to text updates (See Monitoring and Reporting section for more details). If any large cetacean or killer whale is documented near or approaching the shutdown zone (equivalent to the Level B harassment zone during most activities), pile driving would be delayed or stopped until the whale or whales have moved away.

For all other hearing groups and activities, the shutdown zones are primarily based on the estimated Level A harassment isopleths. However, in

cases where it would be challenging to detect marine mammals at the Level A harassment isopleth, (*i.e.,* VHF cetaceans and PW species during impact pile driving of 30-in steel piles at NBK Bangor), smaller shutdown zones have been established (table 9).

TABLE 9—MINIMUM CLEARANCE AND SHUTDOWN ZONES (m)

| Install or remove | Pile size and type | Method | Location | Minimum clearance zone—LF and HF (m) [1] | Shutdown zones (m) | | | | | Level B harassment zone (m) |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | LF | HF | VHF | PW | OW | |
| **NBK Bangor** | | | | | | | | | | |
| Removal | 24-in Concrete | Vibratory | Olympic Pier | 2,500 | 7,356 | 7,356 | 10 | 10 | 10 | 7,356 |
| | | Vibratory | EHW–1 | 2,500 | 7,356 | 7,356 | 10 | 15 | 10 | 7,356 |
| Install | 20-in Steel | Vibratory | Olympic Pier | 2,500 | 5,412 | 5,412 | 10 | 10 | 10 | 5,412 |
| | | Impact | | 500 | 475 | 475 | 350 | 200 | 75 | 464 |
| | 30-in Steel | Vibratory | EHW–1 | 2,500 | 11,660 | 11,660 | 10 | 15 | 10 | 11,659 |
| | | Impact proofing | | 750 | 750 | 650 | 350 | 200 | 250 | 631 |
| **NS Everett** | | | | | | | | | | |
| Removal | 12-in Steel | Vibratory | Piers A, B, and South Wharf. | 2,200 | 2,200 | 2,200 | 10 | 10 | 10 | 2,154 |
| Install | 18-in Steel | Vibratory | Piers A, B, and South Wharf. | 2,500 | 5,412 | 5,412 | 10 | 10 | 10 | 5,412 |
| | | Impact | | 150 | 140 | 140 | 190 | 110 | 50 | 136 |
| **NBK Manchester** | | | | | | | | | | |
| Removal | 14-in H Steel | Vibratory | Fuel Pier | 1,000 | 1,000 | 1,000 | 10 | 10 | 10 | 1,000 |
| | 36-in Steel Casing | Vibratory | Fuel Pier | 2,500 | 13,600 | 13,600 | 30 | 50 | 15 | 13,594 |
| | 42-in Steel Casing | Vibratory | Fuel Pier | 2,500 | [2] 21,544 | [2] 21,544 | 30 | 50 | 20 | [2] 21,544 |
| Install | 36-in Steel Casing | Vibratory | Fuel Pier | 2,500 | 13,600 | 13,600 | 30 | 50 | 15 | 13,594 |
| | 42-in Steel Casing | Vibratory | Fuel Pier | 2,500 | [2] 21,544 | [2] 21,544 | 40 | 70 | 30 | [2] 21,544 |
| | 24-in Concrete | Impact | Fuel Pier | 100 | 90 | 90 | 140 | 80 | 35 | 86 |
| Install and Removal. | 24-in Steel | Vibratory | Fuel Pier | 2,500 | 5,412 | 5,412 | 10 | 20 | 10 | 5,412 |

[1] For low frequency and high frequency cetaceans, a clearance zone is established based on the distance that can practicably be observed by PSOs. For VHF cetaceans, PW, and OW species, the clearance zones are equivalent to the shutdown zones and are not differentiated. Prior to commencing pile driving, PSOs must, at minimum, be able to determine that the clearance zones are clear of marine mammals. Shutdowns must be implemented should a marine mammal be observed entering or within a relevant shutdown zone.

[2] Underwater noise would be truncated by land at approximately 13.9 km from Manchester Fuel Pier at its furthest distance.

*Pre-Clearance Monitoring Through Post-Activity Monitoring*

Prior to the start of daily in-water construction activities (*i.e.,* pile driving), or whenever a break in pile driving of 30 minutes or longer occurs, PSOs will observe the clearance zones (at minimum) (LF and HF) and shutdown zones and beyond to the extent that PSOs can see for a period of 30 minutes. Pre-start clearance monitoring must be conducted during periods of visibility sufficient for the lead PSO to determine that the clearance zones (at minimum) (LF and HF) and shutdown zones are clear of marine mammals.

Pile driving may commence following 30 minutes of observation when the determination is made that the clearance zones (at minimum) (LF and HF) and shutdown zones are clear of marine mammals. Monitoring of the clearance zone, shutdown zone, and beyond to the extent that PSOs can see, will continue for the duration of pile driving through 30 minutes post completion of pile driving activity. Monitoring beyond the shutdown zones enables observers to be aware of and communicate the presence of marine mammals in the project areas outside the shutdown zones and thus prepare for a potential delay or cessation of activity should the animal enter the zone.

If any marine mammal is observed entering or within the shutdown zones, pile driving activity must be delayed or halted. If pile driving is delayed or halted due to the presence of a marine mammal, the activity may not commence or resume until either the animal has voluntarily exited and been visually confirmed beyond the relevant zone, (at minimum), or 15 minutes have passed without re-detection of the animal. If work ceases for more than 30 minutes, the pre-activity monitoring of the clearance zone (at minimum) (LF and HF) and shutdown zones, and beyond to the extent that PSOs can see, would commence.

Construction supervisors and crews, PSOs, and relevant Navy staff must avoid direct physical interaction with marine mammals during all construction activities. If a marine mammal comes within 10 m of such activity, operations must cease and vessels must reduce speed to the minimum level required to maintain steerage and safe working conditions, as necessary to avoid direct physical interaction.

*PSOs*

The number and placement of PSOs (described in the Monitoring and Reporting section) would ensure that the clearance zone (at minimum) (LF and HF) and shutdown zones are visible, such that PSOs are confident of their ability to observe marine mammals at relevant distances. For VHF cetaceans, PW, and OW species, the clearance zones are equivalent to the shutdown zones and are not differentiated. For low frequency and high frequency cetaceans, the clearance zones are based on the distances that can be reliably observed by PSOs. However, PSOs would conduct monitoring beyond the clearance zones to the extent that they can see.

*Soft Start*

The use of soft-start procedures is believed to provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the hammer operating at full

capacity. For impact pile driving, contractors would be required to provide an initial set of three strikes from the hammer at reduced energy, with each strike followed by a 30-second waiting period. This procedure would be conducted a total of three times before impact pile driving begins. Soft start would be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of 30 minutes or longer. Soft start is not required during vibratory pile driving activities.

*Bubble Curtain*

A bubble curtain will be employed during impact installation or proofing of steel piles. Bubble curtains are not required during vibratory pile driving. If a bubble curtain is used, it would distribute air bubbles around 100 percent of the piling perimeter for the full depth of the water column. The lowest bubble ring would be in contact with the mudline for the full circumference of the ring. The weights attached to the bottom ring would ensure 100 percent mudline contact. No parts of the ring or other objects would prevent full mudline contact.

NMFS conducted an independent evaluation of the measures, and has determined that the mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

**Monitoring and Reporting**

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present while conducting the activities. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the activity; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and
- Mitigation and monitoring effectiveness.

The monitoring and reporting requirements described in the following were proposed by the Navy in its adequate and complete application and/or are the result of subsequent coordination between NMFS and the Navy. The Navy has agreed to the requirements. NMFS describes these below as requirements and has included them in the IHA.

*Visual Monitoring*

Visual monitoring will be conducted by trained PSOs positioned at suitable vantage points to be able to observe the entirety of the clearance zones (at minimum) (LF and HF), the shutdown zones, and the surrounding area to the maximum extent possible based on the required number of PSOs, required monitoring locations, and environmental conditions.

During all pile driving activities at all installations the Navy intends to employ three PSOs per location (for a total of nine PSOs on days with work at all three locations), to monitor the clearance zones (at minimum) (LF and HF), the shutdown zones, and the surrounding area. At least one PSO will be placed near the pile driving site during all pile driving and removal activities.

Monitoring will be conducted 30 minutes before, during, and 30 minutes after all in-water construction activities. In addition, PSOs would record all incidents of marine mammal occurrence, regardless of distance from activity, and would document any behavioral reactions in concert with distance from piles being driven or removed. Pile driving activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than 30 minutes.

*Coordination With Local Marine Mammal Research Network*

The Orca Network receives sighting information from citizen scientists, vessel captains, and researchers throughout the Puget Sound area. Navy biologists and the lead PSO will have access to the Orca Network notification texts, and they can call into the notification system. Prior to pile driving each day, the lead PSO will contact the Orca Network and monitor social media to review updated sighting locations of large whales, including ESA-listed SRKWs and humpback whales. If any large whale or killer whale species are reported approaching, or within the shutdown zone, pile driving would be delayed until the whale or whales have moved away.

*Acoustic Monitoring*

The Navy may implement hydroacoustic monitoring during impact pile driving of sheet piles with a bubble curtain to verify the sound source levels associated with the use of this attenuation device with this pile type. If hydroacoustic monitoring is planned, Navy would submit a hydroacoustic monitoring plan to NMFS for review and approval no less than 90 days prior to implementation of sound source verification activities. The Navy would conduct its activities consistent with the NMFS-approved plan.

*Reporting*

The Navy will submit a draft marine mammal monitoring report within 90 calendar days after the completion of pile driving activities, or 60 days prior to a requested date of issuance of any future IHAs for projects at the same location, whichever comes first. The report will include an overall description of the construction work completed, a narrative regarding marine mammal sightings, and associated PSO data sheets (in a queryable electronic format). Specifically, the report will include:

- Dates and times (begin and end) of all marine mammal monitoring;
- Construction activities occurring during each daily observation period, including: (1) number of and type of

piles that were driven and the method (*e.g.,* impact or vibratory); and (2) Total duration of driving time for each pile (vibratory driving) and number of strikes for each pile (impact driving);

- PSO locations during marine mammal monitoring;
- Environmental conditions during monitoring periods (at beginning and end of PSO shift and whenever conditions change significantly), including Beaufort sea state and other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon, and estimated observable distance;
- Upon observation of a marine mammal, the following information: (1) name of PSO who sighted the animal(s) and PSO location and activity at time of sighting; (2) time of sighting; (3) identification of the animal(s) (*e.g.,* genus/species, lowest possible taxonomic level, or unidentified), PSO confidence in identification, and the composition of the group if there is a mix of species; (4) distance from activities to marine mammals and distance from the marine mammals to the observation point; (5) estimated number of animals (min/max/best estimate); (6) estimated number of animals by cohort (adults, juveniles, neonates, group composition, *etc.*); (7) animal's closest point of approach and estimated time spent within the estimated harassment zone; (8) description of any marine mammal behavioral observations (*e.g.,* observed behaviors such as feeding or traveling), including an assessment of behavioral responses thought to have resulted from the activity (*e.g.,* no response or changes in behavioral state such as ceasing feeding, changing direction, flushing, or breaching);
- Number of marine mammals detected within the estimated harassment zones, by species; and,
- Detailed information about implementation of any mitigation (*e.g.,* shutdowns and delays), a description of specific actions that ensued, and resulting changes in behavior of the animal(s), if any.

Should acoustic monitoring be conducted, an acoustic monitoring report(s) must be submitted, at minimum, on the same schedule as visual monitoring reports (*i.e.,* within 90 days following the completion of activity). The estimated harassment and clearance/shutdown zones may be modified with NMFS' approval following NMFS' acceptance of an acoustic monitoring report. The acoustic monitoring report(s) would need to be submitted to NMFS for review and approval prior to any adjustments to the harassment zones. The acoustic monitoring report must contain the informational elements described in the acoustic monitoring plan.

A final report must be prepared and submitted within 30 calendar days following receipt of any NMFS comments on the draft report. If no comments are received from NMFS within 30 calendar days of receipt of the draft report, the report will be considered final. All PSO data will be submitted electronically in a format that can be queried such as a spreadsheet or database and will be submitted with the draft marine mammal report.

In the event that personnel involved in the construction activities discover an injured or dead marine mammal, the Navy must report the incident to the NMFS OPR (*PR.ITP.MonitoringReports@noaa.gov* and *itp.fleming@noaa.gov*) and the West Coast Region Stranding Hotline as soon as possible. If the death or injury was clearly caused by the specified activity, the Navy must immediately cease the activities until NMFS OPR is able to review the circumstances of the incident and determine what, if any, additional measures are appropriate to ensure compliance with the terms of this IHA. The Navy must not resume their activities until notified by NMFS. The report must include the following information:

- Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);
- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animals(s), if alive;
- Photographs or video footage of the animal(s), if available; and
- The general circumstances under which the animal was discovered.

**Negligible Impact Analysis and Determination**

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.,* intensity, duration), the context of any impacts or responses (*e.g.,* critical reproductive time or location, foraging impacts affecting energetics), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, the majority of our analysis applies to all the species listed in table 2, given that many of the anticipated effects of this project on different marine mammal stocks are expected to be relatively similar in nature. Where there are meaningful differences between species or stocks, or groups of species, in anticipated individual responses to activities, impact of expected take on the population due to differences in population status, or impacts on habitat, they are described independently in the analysis below.

Pile driving and removal associated with this project, as outlined previously, have the potential to disturb or displace marine mammals. Specifically, the specified activities may result in take, in the form of Level B harassment and, for Dall's porpoise, harbor porpoise, California sea lions and harbor seals, Level A harassment, from underwater sounds generated by pile installation and removal. Potential takes could occur if individuals are present in the ensonified zone when these activities are underway.

No serious injury or mortality is expected, even in the absence of required mitigation measures, given the nature of the activities. Further, for six species of marine mammals (all low frequency and high frequency cetaceans, Steller sea lions, and northern elephant seals), no take by Level A harassment is anticipated, due to the rarity of these species in the project areas (Steller sea lions and northern elephant seals), or due to the relatively small Level A harassment zones (low and high frequency cetaceans). The likelihood of

take by Level A harassment occurring is further reduced by Navy's plans to implement mitigation measures such as shutdown zones that encompass all or a portion of the Level A harassment zones (see Mitigation section).

Level A harassment is authorized for VHF cetaceans (Dall's porpoise and harbor porpoise) and the pinniped species that commonly occur in the project areas (California sea lions, and two out of three stocks of harbor seals). Any take by Level A harassment is expected to arise from, at most, a small degree of AUD INJ (*i.e.,* minor degradation of hearing capabilities within regions of hearing that align most completely with the energy produced by impact pile driving such as the low-frequency region below 2 kHz), not severe hearing impairment or impairment within the ranges of greatest hearing sensitivity. Animals would need to be exposed to higher levels and/or longer duration than are expected to occur here in order to incur any more than a small degree of AUD INJ.

Additionally, the amount of take by Level A harassment authorized for these four species is very low. NMFS expects no more than 4 takes by Level A harassment for Dall's porpoise, 72 takes by Level A harassment for harbor porpoise, 7 takes by Level A harassment for California sea lions, and 29 takes by Level A harassment for harbor seals (across 2 out of 3 stocks). For all hearing groups, if hearing impairment occurs, it is most likely that the affected animal would lose only a few dB in its hearing sensitivity. Due to the small degree anticipated, any AUD INJ potentially incurred would not be expected to affect the reproductive success or survival of any individuals, much less result in adverse impacts on the species or stock.

Additionally, some subset of the individuals that are behaviorally harassed could also simultaneously incur some small degree of TTS for a short duration of time. However, since the hearing sensitivity of individuals that incur TTS is expected to recover completely within minutes to hours, it is unlikely that the brief hearing impairment would affect the individual's long-term ability to forage and communicate with conspecifics, and would therefore not likely impact reproduction or survival of any individual marine mammal, let alone adversely affect rates of recruitment or survival of the species or stock.

Effects on individuals that are taken by Level B harassment in the form of behavioral disruption, on the basis of reports in the literature as well as monitoring from other similar activities, would likely be limited to reactions such as avoidance, increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring) (*e.g.,* Thorson and Reyff, 2006). The Navy has conducted multi-year activities potentially affecting marine mammals at some of the installations considered herein (NBK Bangor and NBK Manchester). Reporting from these activities has similarly reported no apparently consequential behavioral reactions or long-term effects on marine mammal populations (Callaghan *et al.,* 2024; Hamer Environmental, 2021; Sandoval and Johnson, 2022; DoN, 2022; DoN, 2021). Most likely, individuals would simply move away from the sound source and temporarily avoid the area where pile driving is occurring.

If sound produced by project activities is sufficiently disturbing, animals are likely to simply avoid the area while the activities are occurring. We expect that any avoidance of the project areas by marine mammals would be temporary in nature and that any marine mammals that avoid the project areas during construction would not be permanently displaced. Short-term avoidance of the project areas and energetic impacts of interrupted foraging or other important behaviors is unlikely to affect the reproduction or survival of individual marine mammals, and the effects of behavioral disturbance on individuals is not likely to accrue in a manner that would affect the rates of recruitment or survival of any affected stock.

Some individual marine mammals in the project areas, such as California sea lions, harbor seals, or harbor porpoises, may be present and be subject to repeated exposure to sound from pile driving activities on multiple days. Repeated exposures of individuals to relatively low levels of sound outside of preferred habitat areas are unlikely to significantly disrupt critical behaviors. Thus, even repeated Level B harassment of some small subset of an overall stock is unlikely to result in any effects on rates of reproduction and survival of the stock.

Additionally, pile driving and extraction would not likely occur every day at each installation, and these individuals would likely return to normal behavior during gaps in pile driving activity within each day of construction and in between work days. As discussed above, individuals could temporarily relocate during construction activities to reduce exposure to elevated sound levels from the project. While vibratory driving associated with some project components may produce sound at distances of many kms from the pile driving site, thus intruding on higher-quality habitat, the project sites themselves and the majority of sound fields produced by the specified activities are within industrialized areas. Therefore, we expect that animals displaced by project sound would simply avoid the area.

The project is also not expected to have significant adverse effects on affected marine mammals' habitats. The project activities would not modify existing marine mammal habitat for a significant amount of time. The activities may cause a low level of turbidity in the water column and some fish may leave the area of disturbance, thus temporarily impacting marine mammals' foraging opportunities in a limited portion of the foraging range; but, because of the short duration of the activities and the relatively small area of the habitat that may be affected (with the exception of gray whales and SRKWs, there are no habitats of known particular importance to marine mammals), the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences.

There is a BIA for feeding gray whales that intersects with the project area associated with NS Everett, but it is active between February and May (Calambokidis *et al.,* 2024), which does not intersect with the majority of the time period when the project activities are planned (mid-July through mid-February at NS Everett). This suggests that impacts from the project would have minimal to no impact on foraging gray whales and would therefore be unlikely to affect reproduction and survival.

ESA critical habitat for SRKW occurs in Puget Sound (see the Description of Marine Mammals in the Area of Specified Activities section of this notice) but excludes the areas around military installations which would be most impacted by pile driving sound. NMFS did not identify in-water sound levels as a separate essential feature of critical habitat, though anthropogenic sound is recognized as one of the primary threats to SRKW (NMFS, 2019). The exposure of SRKW to sound from the planned activities would be minimized by the required mitigation measures (*e.g.,* shutdown zones equivalent to the Level B harassment zones). The effects of the activities on SRKW habitat generally, such as sedimentation and impacts to availability of prey species, are expected to be limited both spatially and temporally, constrained to the immediate area around the pile driver(s) at each pier and returning to baseline

levels quickly. Additionally, the timing of the in-water work window for the projects is intended to limit impacts to ESA-listed fishes, which would accordingly reduce potential impacts to SRKW prey.

As described above, increased sightings of gray whale strandings have been reported in Puget Sound. We do not expect authorized takes to exacerbate or compound upon these increased strandings. As discussed above, no injury, serious injury or mortality is expected or authorized, and the impact of Level B harassment takes of these species will be minimized through the incorporation of mitigation measures. The strandings do not provide cause for concern regarding population-level impacts. Despite the strandings, the Eastern North Pacific population of gray whales remains healthy.

Finally, it is unlikely that minor noise effects in a small, localized area of habitat would have any effect on the reproduction or survival of any individuals, much less these stocks' annual rates of recruitment or survival. In combination, we believe that these factors, as well as the available body of evidence from other similar activities, demonstrate that the potential effects of the specified activities would have only minor, short-term effects on individuals. The specified activities are not expected to impact rates of recruitment or survival and would therefore not result in population-level impacts.

In summary and as described above, the following factors primarily support our determination that the impacts resulting from this activity are not expected to adversely affect any of the species or stocks through effects on annual rates of recruitment or survival:

- No serious injury or mortality is anticipated authorized;
- Any Level A harassment is anticipated to cause only slight auditory injury, including PTS of a few decibels within the lower frequencies associated with impact pile driving of 18-in steel at Everett and 30-in steel at Bangor, and not encompassing a species' full hearing range;
- At worst, the anticipated incidents of Level B harassment would result in temporary behavior modifications or a small degree of TTS that would resume to baseline at the cessation of activities or as animals move away from the source;
- The project areas at all three installations are industrialized; therefore, individuals taken are likely habituated to anthropogenic activities and behavioral reactions are expected to be minor and temporary;
- The project areas at all three installations are small relative to the overall habitat range of each species, and overlap with known habitats of particular importance is minimal;
- Effects on marine mammal prey species from the activities are primarily expected to be short-term, and any associated impacts on marine mammal feeding are not expected to result in significant or long-term consequences for individuals, or to accrue to adverse impacts on their populations; and
- The mitigation measures are expected to minimize the severity of the effects of the specified activity.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the monitoring and mitigation measures, NMFS finds that the total marine mammal take from the activity will have a negligible impact on all affected marine mammal species or stocks.

**Small Numbers**

As noted previously, only take of small numbers of marine mammals may be authorized under section 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers (see 86 FR 5322, January 19, 2021). Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

We authorize incidental take of 15 marine mammal stocks (table 8). The total amount of taking authorized is less than 33.3 percent for 14 stocks, which meets the definition stated above.

Though the most recent SAR includes an unreliable population estimate for the Washington Inland Southern Puget Sound stock of harbor seal because it is more than 8 years old, Pearson *et al.* (2024) reports that the peak population estimate for this stock is 2,832. The total number of authorized takes for the Washington Inland Southern Puget Sound stock of harbor seals, if assumed to accrue solely to new individuals, is 66 percent of the total stock abundance. However, these numbers represent the estimated incidents of take, not the number of individuals taken. Harbor seals in the Puget Sound region are known to exhibit site fidelity and generally remain close to their primary haulout location; those that move further from their primary haulout tend to stay at a new location for several weeks (Peterson *et al.,* 2012). Given the relatively short duration of the projects at each site, NMFS believes that it is highly unlikely that each exposure would affect a new individual. Rather, NMFS predicts that a relatively small subset of this population will be harassed by project activities.

Given that the specified activity will be stationary within an area not recognized as being of any special significance that would serve to attract or harbor seals, we therefore believe that the estimated numbers of takes, were they to occur, likely represent repeated exposures of a much smaller number of individual harbor seals and that these estimated incidents of take represent small numbers of harbor seals.

Based on the analysis contained herein of the activity (including the mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals would be taken relative to the population size of the affected species or stocks.

**Unmitigable Adverse Impact Analysis and Determination**

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

**Endangered Species Act**

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*) requires that each Federal agency ensures that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take of endangered or threatened species.

NMFS authorized take of SRKW, as well as one stock of humpback whales (Mainland Mexico—CA-OR-WA), which are listed under the ESA.

The NMFS OPR requested initiation of section 7 consultation with the NMFS West Coast Region (WCR) for the issuance of this IHA. On September 18, 2026, WCR concluded that NMFS' current action remains covered by the programmatic Biological Opinion (WCRO–2016–00018) completed for the issuance of regulations preceding this IHA (83 FR 9366, March 5, 2018), and that reinitiation of the consultation is not required. WCR specified that the new IHA is consistent with the original effects analysis included in the original programmatic opinion, and OPR's action would not change the conclusions nor the effects of the proposed action as written in the Biological Opinion.

**National Environmental Policy Act**

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an IHA) and alternatives with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NAO 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has determined that the issuance of this IHA qualifies to be categorically excluded from further NEPA review.

**Authorization**

NMFS has issued an IHA to the Navy for the potential harassment of small numbers of 10 marine mammal species incidental to conducting the 2026 MPR Project in Puget Sound, Washington, Washington, that includes previously explained mitigation,

Dated: September 25, 2026.

**Kimberly Damon-Randall,**

*Director, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2026–20222 Filed 10–1–26; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[RTID 0648–XG059]**

### New England Fishery Management Council; Public Meeting

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

**ACTION:** Notice of public meeting.

**SUMMARY:** The New England Fishery Management Council (Council) is scheduling a public meeting of its United States/Canada Steering Committee to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

**DATES:** This meeting will be held on Friday, October 16, 2026 at 8:30 a.m. EDT Webinar registration URL information:

https://nefmc-org.zoom.us/meeting/register/dd_-yj3kR5OpaDUwCwJrkQ.

**ADDRESSES:** This meeting will be held at the Marriott Boston Downtown/North Station, 107 Beverly Street, Boston, MA 02114; Phone (617) 725–0003.

*Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

**FOR FURTHER INFORMATION CONTACT:** Cate O'Keefe, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

**SUPPLEMENTARY INFORMATION:**

**Agenda**

The United States/Canada Steering Committee will meet to review information presented by the Species at Risk Working Group and the Transboundary Management Guidance Committee (TMGC). The Committee will also plan for 2027 TMGC and Steering Committee meetings and review plans for the TMGC process review. Other business will be discussed as necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

**Special Accommodations**

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Cate O'Keefe, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: September 30, 2026.

**Rey Israel Marquez,**

*Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2026–20268 Filed 10–1–26; 8:45 am]

**BILLING CODE 3510–22–P**

## COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

### Determination Under the Textile and Apparel Commercial Availability Provision of the Dominican Republic-Central America-United States Free Trade Agreement (''CAFTA–DR'')

**AGENCY:** The Committee for the Implementation of Textile Agreements.

**ACTION:** Determination to add a product in unrestricted quantities to Annex 3.25 of the CAFTA–DR.

**SUMMARY:** The Committee for the Implementation of Textile Agreements (''CITA'') has determined that certain faux leather fabric bonded to a pile fabric, as specified below, is not available in commercial quantities in a timely manner in the CAFTA–DR countries. The product is added to the list in Annex 3.25 of the CAFTA–DR in unrestricted quantities.

**DATES:** *Applicable Date:* October 2, 2026.

**ADDRESSES:** *https://otexaprod.trade.gov/otexacapublicsite/requests/cafta* under ''Approved Requests,'' File Number: CA2026008.

**FOR FURTHER INFORMATION CONTACT:** Kayla Johnson, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–2532 or *Kayla.Johnson@trade.gov.*

**SUPPLEMENTARY INFORMATION:**

*Authority:* The CAFTA–DR; Section 203(o)(4) of the Dominican Republic-Central America-United States Free Trade Agreement Implementation Act (''CAFTA–DR Implementation Act''), Public Law 109–53; the Statement of

Administrative Action accompanying the CAFTA–DR Implementation Act; and Presidential Proclamation 7987 (February 28, 2006).

*Background:* The CAFTA–DR provides a list in Annex 3.25 for fabrics, yarns, and fibers that the Parties to the CAFTA–DR have determined are not available in commercial quantities in a timely manner in the territory of any Party. The CAFTA–DR provides that this list may be modified pursuant to Article 3.25.4, when the United States determines that a fabric, yarn, or fiber is not available in commercial quantities in a timely manner in the territory of any Party. *See* Annex 3.25 of the CAFTA–DR; *see also* section 203(o)(4)(C) of the CAFTA–DR Implementation Act.

The CAFTA–DR Implementation Act requires the President to establish procedures governing the submission of a request and providing opportunity for interested entities to submit comments and supporting evidence before a commercial availability determination is made. In Presidential Proclamation 7987, the President delegated to CITA the authority under section 203(o)(4) of CAFTA–DR Implementation Act for modifying the Annex 3.25 list. Pursuant to this authority, on September 15, 2008, CITA published modified procedures it would follow in considering requests to modify the Annex 3.25 list of products determined to be not commercially available in the territory of any Party to the CAFTA–DR (*Modifications to Procedures for Considering Requests Under the Commercial Availability Provision of the Dominican Republic-Central America-United States Free Trade Agreement,* 73 FR 53200) (''CITA's Procedures'').

On August 28, 2026, CITA received a Commercial Availability Request (''Request'') from Youngone (El Salvador) S.A. de C.V. (''Youngone'') for certain faux leather fabric bonded to a pile fabric, as specified below. On September 1, 2026, in accordance with CITA's Procedures, CITA notified interested parties of the Request, which was posted on the dedicated website for CAFTA–DR Commercial Availability proceedings. In its notification, CITA advised that any Response with an Offer to Supply (''Response'') must be submitted by September 14, 2026, and any Rebuttal to a Response (''Rebuttal'') must be submitted by September 18, 2026, in accordance with sections 6 and 7 of CITA's Procedures. No interested entity submitted a Response to the Request advising CITA of its objection to the Request with an offer to supply the subject product.

In accordance with section 203(o)(4)(C) of the CAFTA–DR Implementation Act, and section 8(c)(2) of CITA's Procedures, as no interested entity submitted a Response objecting to the Request and providing an offer to supply the subject product, CITA has determined to add the specified fabric to the list in Annex 3.25 of the CAFTA–DR.

The subject product has been added to the list in Annex 3.25 of the CAFTA–DR Agreement in unrestricted quantities. A revised list has been posted on the dedicated website for CAFTA–DR Commercial Availability proceedings, at *https://otexaprod.trade.gov/otexacapublicsite/shortsupply/cafta.*

**Specifications: Certain Faux Leather Fabric Bonded to a Pile Fabric**

*HTS:* 6001.10; 6001.92.00.

*Fabric Type:* Knit fabric, faux leather bonded to a pile fabric.

*Fiber Content:*

*Face:* Faux leather fabric constructed from a 100% polyester knit fabric.

*Back:* Sherpa knit pile fabric 60–64% polyester, 36–40% acrylic.

*Yarn Size:*

*Face:* 75 Denier sea-island filament 100% polyester used for both warp and weft.

*Back:* Binding polyester 150 denier polyester combined with tops acrylic fiber, weighing between 8 to 18 grams.

*Thread Count:*

*Face:* Wales/cm 32, Course/cm 32.

*Back:* Wales/cm 7, Course/cm 8.

*Weight:* 442–488 grams per square meter.

*Width:* 137 to 143 centimeters (equivalent to 53.9 inches to 56.30 inches).

*Weave:* Knit in both, face and back.

*Coloration:*

*Face:* Roll dyed, colors: black, brown and green and overprinted;

*Back side:* fiber Dyed in colors black, brown and green.

*Finishing:* Bonded using the Moltopren heat process, which involves a flame lamination technique that fuses the layers through controlled heat and pressure.

The finished sherpa hair has a height of approximately 4 to 7 mm in the back.

*Additional Information:* Sea island fiber is also known as super-conjugate fiber or butterfly polyester yarn, is formed by a core component dispersed in another polymer in a longitudinally continuous way. Polymer material forms the core part, which is also called the island phase or dispersed phase. Another polymer is called sea component, sea phase, or continuous phase. Because original dispersed phase fiber presents as an island state in the fiber section, it is called sea-island fiber.

**Joshua Kroon,**

*Chairman, Committee for the Implementation of Textile Agreements.*

[FR Doc. 2026–20244 Filed 10–1–26; 8:45 am]

**BILLING CODE 3510–DR–P**

## COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

### Public Meeting

**AGENCY:** Committee for Purchase From People Who Are Blind or Severely Disabled.

**ACTION:** Notice of public meeting.

**DATES:** October 28, 2026, from 2 p.m. to 4 p.m. ET.

**ADDRESSES:** The meeting will be accessible to the public virtually via Zoom webinar.

**FOR FURTHER INFORMATION CONTACT:** Angela Phifer, 250 E Street SW, Suite 3100, Washington, DC 20024; (703) 798–5873; *CMTEFedReg@AbilityOne.gov.*

**SUPPLEMENTARY INFORMATION:**

*Background:* The Committee for Purchase From People Who Are Blind or Severely Disabled is an independent Federal agency operating as the U.S. AbilityOne Commission. It oversees the AbilityOne Program, which provides employment opportunities through Federal contracts for people who are blind or have significant disabilities in the manufacture and delivery of products and services to the Federal Government. The Javits-Wagner-O'Day Act (41 U.S.C. chapter 85) authorizes the contracts.

*Registration:* Attendees *not* requesting speaking time should register not later than October 27, 2026. Attendees requesting speaking time must register not later than October 20, 2026, and use the comment fields in the registration form to specify the intended speaking topic(s). The registration link will be available on the Commission's home page, *www.abilityone.gov,* under News and Events.

*Commission Statement:* This regular quarterly public meeting will include updates from the Commission Chairperson, Executive Director, and Acting Inspector General.

*Public Participation:* The public engagement session topic is ''Strategies to Reduce Employment Barriers Faced by Americans Who Are Blind or Have Disabilities.'' The Commission looks forward to receiving comments and suggestions related to this topic.

During registration, you may choose to submit comments, or you may request speaking time at the meeting. The Commission may invite some attendees who submit advance comments to discuss their comments during the meeting. Comments submitted will be reviewed by staff and the Commission members before the meeting. Comments posted in the chat box during the meeting will be shared with the Commission members after the meeting. The Commission is not subject to the requirements of 5 U.S.C. 552(b); however, the Commission published this notice to encourage the broadest possible participation in its meeting.

*Personal Information:* Speakers should not include any information that they do not want publicly disclosed.

**Michael R. Jurkowski,**

*Director, Business Operations.*

[FR Doc. 2026–20252 Filed 10–1–26; 8:45 am]

**BILLING CODE 6353–01–P**

## DEPARTMENT OF EDUCATION

**[Docket No.: ED–2026–SCC–2641]**

### Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Eligible Career Pathway Program

**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 November 2, 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:* Eligible Career Pathway Program.

*OMB Control Number:* 1845–0175.

*Type of Review:* Extension without change of a currently approved ICR.

*Respondents/Affected Public:* State, Local, and Tribal Governments; Private Sector.

*Total Estimated Number of Annual Responses:* 5,000.

*Total Estimated Number of Annual Burden Hours:* 50,000.

*Abstract:* Section 668.157, under the authority of section 484 of the HEA, specifies the documentation requirements for eligible career pathway programs for submission by institutions to the Department for approval as a Title IV eligible program. Enrollment in an eligible career pathways program is one of the three Ability to Benefit (ATB) alternatives that an individual who is not a high school graduate could fulfill to receive Title IV, HEA, Federal student aid.

**Ross Santy,**

*Chief Data Officer, Office of Planning, Evaluation and Policy Development.*

[FR Doc. 2026–20279 Filed 10–1–26; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF ENERGY

### 21st Century Energy Workforce Advisory Board

**AGENCY:** Office of Policy, Department of Energy.

**ACTION:** Notice of open meeting.

**SUMMARY:** This notice announces a virtual, open meeting of the 21st Century Energy Workforce Advisory Board (EWAB). The Federal Advisory Committee Act requires that public notice of these meetings be announced in the **Federal Register**.

**DATES:** Monday, November 2, 2026, from 2 to 3 p.m. Eastern Time (ET).

**ADDRESSES:** Virtual meeting.

*Register to attend at: https://events.gcc.teams.microsoft.com/event/625684d3-34b1-4fe6-b433-98a46b4ef2d8@6b183ecc-4b55-4ed5-b3f8-7f64be1c4138.*

*The meeting information will be posted on the EWAB website at: https://www.energy.gov/policy/21st-century-energy-workforce-advisory-board-ewab* and can also be obtained by emailing *EWAB@hq.doe.gov.*

**FOR FURTHER INFORMATION CONTACT:** Angela Dayton, Designated Federal Officer (DFO), EWAB; Telephone: (240) 449–0652; or Email: *EWAB@hq.doe.gov.*

**SUPPLEMENTARY INFORMATION:**

*Purpose of the Board:* EWAB advises the Secretary of Energy in developing a strategy for the Department of Energy to support and develop a skilled energy workforce to meet the changing needs of the U.S. energy system. It was established pursuant to Section 40211 of the Infrastructure Investment and Jobs Act (IIJA), Public Law 117–58 (42 U.S.C. 18744) in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. 1001 *et seq.* This is the eleventh meeting of the EWAB.

*Tentative Agenda:* The preliminary agenda for the meeting includes a roll call of the Board, a presentation on the history of the EWAB, deliberation of topics for the biennial report, and an opportunity for public comments.

*Public Participation:* The meeting is open to the public via a virtual meeting option. Individuals who would like to attend must register for the meeting here: *https://events.gcc.teams.microsoft.com/event/625684d3-34b1-4fe6-b433-98a46b4ef2d8@6b183ecc-4b55-4ed5-b3f8-7f64be1c4138.*

It is the policy of the EWAB to accept written public comments up to five (5) pages and to accommodate oral public comments, whenever possible. The EWAB expects that public statements presented at its meetings will not be repetitive of previously provided oral or submitted written statements. The public comment period for this meeting will take place on November 2, 2026, at a time specified in the meeting agenda. This public comment period is designed only for substantive commentary on the EWAB's work, not for business marketing purposes. The DFO will

conduct the meeting to facilitate the orderly conduct of business.

*Oral Comments:* To be considered for the meeting's public speaker list, interested parties must register to speak by emailing *EWAB@hq.doe.gov* no later than 3 p.m. ET on October 27, 2026. To accommodate as many speakers as possible, the time for public comments will be limited to three (3) minutes per person, with a total public comment period of up to 15 minutes. If more speakers register than there is space available on the agenda, the EWAB will select speakers on a first-come, first-served basis from those who registered. Those not able to present oral comments may always file written comments with the EWAB.

*Written Comments:* Although written comments are accepted continuously, written comments relevant to the subjects of the meeting should be submitted to *EWAB@hq.doe.gov* no later than 3 p.m. ET on October 27, 2026, so that the comments can be made available to the EWAB members prior to this meeting for their consideration. Please note that because EWAB operates under the provisions of FACA, all public comments and related materials will be treated as public documents and will be made available for public inspection, including being posted on the EWAB website.

*Minutes:* The minutes of this meeting will be available on the EWAB website at: *https://www.energy.gov/policy/21st-century-energy-workforce-advisory-board-ewab* or by contacting the DFO at *EWAB@hq.doe.gov.*

*Signing Authority:* This document of the Department of Energy was signed on September 29, 2026, by David Borak, Committee Management Officer, pursuant to delegated authority from the Secretary of Energy. The 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 U.S. 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 September 30, 2026.

**Jennifer Hartzell,**

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

[FR Doc. 2026–20231 Filed 10–1–26; 8:45 am]

**BILLING CODE 6450–01–P**

## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

**[Project No. 2731–046]**

## Green Mountain Power Corporation; Notice of Intent To File License Application, Filing of Pre-Application Document (Pad), Commencement of Pre-Filing Process and Scoping, Request for Comments on the Pad and Scoping Document, and Identification of Issues and Associated Study Requests

a. *Type of Filing:* Notice of Intent to File License Application for a New License and Commencing Pre-filing Licensing Process.

b. *Project No.:* 2731–046.

c. *Dated Filed:* July 31, 2026.

d. *Submitted By:* Green Mountain Power Corporation (GMP).

e. *Name of Project:* Weybridge Hydroelectric Project.

f. *Location:* The project is located on Otter Creek in Addison County, Vermont.

g. *Filed Pursuant to:* 18 CFR part 5 of the Commission's regulations.

h. *Potential Applicant Contact:* Mr. John Tedesco, Generation Project Coordinator, Green Mountain Power Corporation, 163 Acorn Lane, Colchester, VT 05446; (802) 655–8753 or email at *John.Tedesco@greenmountainpower.com.*

i. *FERC Contact:* Erin Mocko, Project Coordinator, Great Lakes Branch, Division of Hydropower Licensing; telephone at (202) 502–8107; email at *Erin.Mocko@FERC.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item o below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See* 94 FERC ¶ 61,076 (2001).

k. *With this notice, we are initiating informal consultation with:* (a) the U.S. Fish and Wildlife Service and the National Oceanic and Atmospheric Administration—Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR, part 402; and (b) the Vermont State Historic Preservation Officer, as required by section 106, National Historic Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. With this notice, we are designating GMP as the Commission's non-federal representative for carrying out informal consultation pursuant to section 7 of the Endangered Species Act and section 106 of the National Historic Preservation Act.

m. GMP filed with the Commission a Pre-Application Document (PAD), including a proposed process plan and schedule, pursuant to 18 CFR 5.6 of the Commission's regulations.

n. A copy of the PAD is available for review on the Commission's website (*http://www.ferc.gov*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits of the sub-docket in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). A copy is also available via the contact in paragraph h.

You may register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

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.*

o. With this notice, we are soliciting comments on the PAD and Commission staff's Scoping Document 1 (SD1), as well as study requests. All comments on the PAD and SD1, and study requests should be sent to the address above in paragraph h. In addition, all comments on the PAD and SD1, study requests, requests for cooperating agency status, and all communications to and from Commission staff related to the merits of the potential application must be filed with the Commission.

The Commission strongly encourages electronic filing. Please file documents using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 10,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory

Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. All filings must clearly identify the project name and docket number on the first page: *Weybridge Hydroelectric Project (P–2731–046).*

All filings with the Commission must bear the appropriate heading: ''Comments on Pre-Application Document,'' ''Study Requests,'' ''Comments on Scoping Document 1,'' ''Request for Cooperating Agency Status,'' or ''Communications to and from Commission Staff.'' Any individual or entity interested in submitting study requests, commenting on the PAD or SD1, and any agency requesting cooperating status must do so by 5:00 p.m. Eastern Standard Time, November 30, 2026.

p. Scoping Process: In accordance with the National Environmental Policy Act (NEPA), Commission staff will prepare either an environmental assessment (EA) or an environmental impact statement (EIS) (collectively referred to as the ''NEPA document''). The NEPA document will consider the environmental effects of the proposed action and reasonable alternatives to the proposed action. The Commission's scoping process will help determine the required level of analysis and satisfy the NEPA scoping requirements, irrespective of whether the Commission prepares an EA or EIS.

**Scoping Sessions**

Commission staff will hold two scoping session for the project to receive input on the scope of the NEPA document. A daytime session will focus on concerns of resource agencies, Indian Tribes, and non-governmental organizations (NGO); and an evening session will focus on input from the public. We invite all interested agencies, Indian Tribes, NGOs, and the public to attend one or both sessions to assist staff in identifying the scope of environmental issues that should be analyzed in the NEPA document. The dates and times of the scoping sessions are listed below.

**Morning Scoping Session**

*Date:* Tuesday, October 27, 2026.

*Time:* 8:30 a.m. to 10:30 p.m.

*Location:* Green Mountain Power Corporation, 121 Cady Rd., Middlebury, VT 05753.

**Evening Scoping Session**

*Date:* Tuesday, October 27, 2026.

*Time:* 5:30 p.m. to 7:30 p.m.

*Location:* Green Mountain Power Corporation, 121 Cady Rd., Middlebury, VT 05753.

Copies of SD1, outlining the subject areas to be addressed in the environmental document, were mailed to the individuals and entities on the Commission's mailing list. Copies of SD1 may be viewed on the web at *http://www.ferc.gov,* using the ''eLibrary'' link. Follow the directions for accessing information in paragraph n. Based on all oral and written comments, a Scoping Document 2 (SD2) may be issued. SD2 may include a revised process plan and schedule, as well as a list of issues, identified through the scoping process.

**Site Visit**

A site visit of the project will be conducted at 19 Water St., Weybridge, VT 05753, on Tuesday, October 27, 2026, from 2:30 p.m. to 3:30 p.m.

All interested individuals, agencies, Indian Tribes, and NGOs are invited to attend. Participants should meet at 2:30 p.m. at 19 Water St., Weybridge, VT 05753. Please contact John Tedesco at (803) 324–7318 or via email at *john.tedesco@greenmountainpower.com* on or before October 23, 2026, if you plan to attend.

**Scoping Session Procedures**

Agencies, Indian Tribes, NGOs, and individuals with environmental expertise and concerns are encouraged to attend the sessions and to assist the staff in defining and clarifying the issues to be addressed in the NEPA document. Individual oral comments will be taken on a one-on-one basis with a court reporter (with Commission staff present). This format is designed to receive the maximum number of oral comments in a convenient way during the timeframe allotted. If you wish to speak, Commission staff will hand out numbers in the order of your arrival. If all individuals who wish to provide comments have had an opportunity to do so, Commission staff may conclude the session a half hour earlier than the scheduled time. Please see appendix A of the SD1 for additional information on the session format and conduct.

Scoping comments will be recorded by the court reporter and become part of the public record for this proceeding. Transcripts will be publicly available on FERC's eLibrary system. If a significant number of people are interested in providing oral comments in the one-on-one settings, a time limit may be implemented for each commentor.

It is important to note that the Commission provides equal consideration to all comments received, whether filed in writing or provided orally at a scoping session. Although there will not be a formal presentation, Commission staff will be available throughout the scoping sessions to answer your questions about the environmental review process. Representatives from GMP will also be present to answer project-specific questions.

(Authority: 18 CFR 2.1)

Dated: September 29, 2026.

**Debbie-Anne A. Reese,**

*Secretary.*

[FR Doc. 2026–20239 Filed 10–1–26; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

**[Project No. 2737–029]**

## Green Mountain Power Company; Notice of Intent To File License Application, Filing of Pre-Application Document (Pad), Commencement of Pre-Filing Process and Scoping, Request for Comments on the Pad and Scoping Document, and Identification of Issues and Associated Study Requests

a. *Type of Filing:* Notice of Intent to File License Application for a New License and Commencing Pre-filing Licensing Process.

b. *Project No.:* 2737–029.

c. *Dated Filed:* July 31, 2026.

d. *Submitted By:* Green Mountain Power Corporation (GMP).

e. *Name of Project:* Middlebury Lower Hydroelectric Project.

f. *Location:* The project is located on Otter Creek in Addison County, Vermont.

g. *Filed Pursuant to:* 18 CFR part 5 of the Commission's regulations.

h. *Potential Applicant Contact:* Mr. John Tedesco, Generation Project Coordinator, Green Mountain Power Corporation, 163 Acorn Lane, Colchester, VT 05446; (802) 655–8753 or email at *John.Tedesco@greenmountainpower.com.*

i. *FERC Contact:* Erin Mocko, Project Coordinator, Great Lakes Branch, Division of Hydropower Licensing; telephone at (202) 502–8107; email at *Erin.Mocko@FERC.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental

document should follow the instructions for filing such requests described in item o below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See* 94 FERC ¶ 61,076 (2001).

k. With this notice, we are initiating informal consultation with: (a) the U.S. Fish and Wildlife Service and the National Oceanic and Atmospheric Administration—Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR, part 402; and (b) the Vermont State Historic Preservation Officer, as required by section 106, National Historic Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. With this notice, we are designating GMP as the Commission's non-federal representative for carrying out informal consultation pursuant to section 7 of the Endangered Species Act and section 106 of the National Historic Preservation Act.

m. GMP filed with the Commission a Pre-Application Document (PAD), including a proposed process plan and schedule, pursuant to 18 CFR 5.6 of the Commission's regulations.

n. A copy of the PAD is available for review on the Commission's website (*http://www.ferc.gov*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits of the sub-docket in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). A copy is also available via the contact in paragraph h.

You may register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

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.*

o. With this notice, we are soliciting comments on the PAD and Commission staff's Scoping Document 1 (SD1), as well as study requests. All comments on the PAD and SD1, and study requests should be sent to the address above in paragraph h. In addition, all comments on the PAD and SD1, study requests, requests for cooperating agency status, and all communications to and from Commission staff related to the merits of the potential application must be filed with the Commission.

The Commission strongly encourages electronic filing. Please file documents using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 10,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. All filings must clearly identify the project name and docket number on the first page: *Middlebury Lower Hydroelectric Project (P–2737–029).*

All filings with the Commission must bear the appropriate heading: ''Comments on Pre-Application Document,'' ''Study Requests,'' ''Comments on Scoping Document 1,'' ''Request for Cooperating Agency Status,'' or ''Communications to and from Commission Staff.'' Any individual or entity interested in submitting study requests, commenting on the PAD or SD1, and any agency requesting cooperating status must do so by 5:00 p.m. Eastern Standard Time, November 30, 2026.

p. *Scoping Process:* In accordance with the National Environmental Policy Act (NEPA), Commission staff will prepare either an environmental assessment (EA) or an environmental impact statement (EIS) (collectively referred to as the ''NEPA document''). The NEPA document will consider the environmental effects of the proposed action and reasonable alternatives to the proposed action. The Commission's scoping process will help determine the required level of analysis and satisfy the NEPA scoping requirements, irrespective of whether the Commission prepares an EA or EIS.

**Scoping Sessions**

Commission staff will hold two scoping sessions for the project to receive input on the scope of the NEPA document. A daytime session will focus on concerns of resource agencies, Tribes, and non-governmental organizations (NGO); and an evening session will focus on input from the public. We invite all interested agencies, Indian Tribes, NGOs, and the public to attend one or both sessions to assist staff in identifying the scope of environmental issues that should be analyzed in the NEPA document. The dates and times of the scoping sessions are listed below.

**Morning Scoping Session**

*Date:* Tuesday, October 27, 2026
*Time:* 8:30 a.m. to 10:30 p.m.
*Location:* Green Mountain Power Corporation, 121 Cady Rd., Middlebury VT 05753.

**Evening Scoping Session**

*Date:* Tuesday, October 27, 2026.
*Time:* 5:30 p.m. to 7:30 p.m.
*Location:* Green Mountain Power Corporation, 121 Cady Rd., Middlebury VT 05753.

Copies of SD1, outlining the subject areas to be addressed in the environmental document, were mailed to the individuals and entities on the Commission's mailing list. Copies of SD1 may be viewed on the web at *http://www.ferc.gov,* using the ''eLibrary'' link. Follow the directions for accessing information in paragraph n. Based on all oral and written comments, a Scoping Document 2 (SD2) may be issued. SD2 may include a revised process plan and schedule, as well as a list of issues, identified through the scoping process.

**Site Visit**

A site visit of the project will be conducted at 81 Seymour St Ext, Middlebury, VT 05753, on Tuesday, October 27, 2026, from 12:30 p.m. to 1:30 p.m.

All interested individuals, agencies, Tribes, and NGOs are invited to attend. Participants should meet at 2:30 p.m. at 19 Water St, Weybridge VT 05753. Please contact John Tedesco at (803) 324–7318 or via email at *john.tedesco@greenmountainpower.com* on or before October 23, 2026, if you plan to attend.

**Scoping Session Procedures**

Agencies, Indian Tribes, NGOs, and individuals with environmental expertise and concerns are encouraged to attend the sessions and to assist the staff in defining and clarifying the issues to be addressed in the NEPA document. Individual oral comments will be taken on a one-on-one basis with a court reporter (with Commission staff present). This format is designed to receive the maximum number of oral comments in a convenient way during the timeframe allotted. If you wish to

speak, Commission staff will hand out numbers in the order of your arrival. If all individuals who wish to provide comments have had an opportunity to do so, Commission staff may conclude the session a half hour earlier than the scheduled time. Please see appendix A of the SD1 for additional information on the session format and conduct.

Scoping comments will be recorded by the court reporter and become part of the public record for this proceeding. Transcripts will be publicly available on FERC's eLibrary system. If a significant number of people are interested in providing oral comments in the one-on-one settings, a time limit may be implemented for each commentor.

It is important to note that the Commission provides equal consideration to all comments received, whether filed in writing or provided orally at a scoping session. Although there will not be a formal presentation, Commission staff will be available throughout the scoping sessions to answer your questions about the environmental review process. Representatives from GMP will also be present to answer project-specific questions.

(Authority: 18 CFR 2.1.)

Dated: September 29, 2026.

**Debbie-Anne A. Reese,**

*Secretary.*

[FR Doc. 2026–20241 Filed 10–1–26; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings

Take notice that the Commission received the following Natural Gas Pipeline Rate and Refund Report filings:

**Filings Instituting Proceedings**

*Docket Numbers:* RP26–1288–000.
*Applicants:* Transcontinental Gas Pipe Line Company, LLC.
*Description:* § 4(d) Rate Filing: Non-Conforming—Gillis West to be effective 11/1/2026.
*Filed Date:* 9/28/26.
*Accession Number:* 20260928–5124.
*Comment Date:* 5 p.m. ET 10/13/26.

*Docket Numbers:* RP26–1289–000.
*Applicants:* Enerplus Resources (USA) Corporation, Appalachian USA LLC.
*Description:* Joint Petition for Limited Waiver of Capacity Release Regulations, et al. of Enerplus Resources (USA) Corporation, et al.
*Filed Date:* 9/28/26.
*Accession Number:* 20260928–5181.
*Comment Date:* 5 p.m. ET 10/13/26.

*Docket Numbers:* RP26–1290–000.
*Applicants:* Transcontinental Gas Pipe Line Company, LLC.
*Description:* Compliance filing: Annual Cash-Out Report Ending July 31, 2026 to be effective N/A.
*Filed Date:* 9/29/26.
*Accession Number:* 20260929–5003.
*Comment Date:* 5 p.m. ET 10/13/26.

*Docket Numbers:* RP26–1291–000.
*Applicants:* Algonquin Gas Transmission, LLC.
*Description:* Compliance filing: AGT September 2026 OFO Penalty Disbursement Report to be effective N/A.
*Filed Date:* 9/29/26.
*Accession Number:* 20260929–5016.
*Comment Date:* 5 p.m. ET 10/13/26.

*Docket Numbers:* RP26–1292–000.
*Applicants:* Iroquois Gas Transmission System, L.P.
*Description:* § 4(d) Rate Filing: 9.29.26 Negotiated Rates—Trafigura Trading LLC R–8150–03 to be effective 11/1/2026.
*Filed Date:* 9/29/26.
*Accession Number:* 20260929–5019.
*Comment Date:* 5 p.m. ET 10/13/26.

*Docket Numbers:* RP26–1293–000.
*Applicants:* Iroquois Gas Transmission System, L.P.
*Description:* § 4(d) Rate Filing: 9.29.26 Negotiated Rates—Trafigura Trading LLC R–8150–04 to be effective 11/1/2026.
*Filed Date:* 9/29/26.
*Accession Number:* 20260929–5023.
*Comment Date:* 5 p.m. ET 10/13/26.

*Docket Numbers:* RP26–1294–000.
*Applicants:* Iroquois Gas Transmission System, L.P.
*Description:* § 4(d) Rate Filing: 9.29.26 Negotiated Rates—NRG Business Marketing LLC R–7465–13 to be effective 11/1/2026.
*Filed Date:* 9/29/26.
*Accession Number:* 20260929–5024.
*Comment Date:* 5 p.m. ET 10/13/26.

*Docket Numbers:* RP26–1295–000.
*Applicants:* Iroquois Gas Transmission System, L.P.
*Description:* § 4(d) Rate Filing: 9.29.26 Negotiated Rates—NRG Business Marketing LLC R–7465–14 to be effective 11/1/2026.
*Filed Date:* 9/29/26.
*Accession Number:* 20260929–5027.
*Comment Date:* 5 p.m. ET 10/13/26.

*Docket Numbers:* RP26–1296–000.
*Applicants:* Guardian Pipeline, L.L.C.
*Description:* § 4(d) Rate Filing: Semi-Annual Electric Power Cost Recovery Surcharge—Winter 2026 Rate to be effective 11/1/2026.
*Filed Date:* 9/29/26.
*Accession Number:* 20260929–5032.
*Comment Date:* 5 p.m. ET 10/13/26.

*Docket Numbers:* RP26–1297–000.
*Applicants:* Midwestern Gas Transmission Company.
*Description:* § 4(d) Rate Filing: Annual Load Management Service Cost—2026 Rate to be effective 11/1/2026.
*Filed Date:* 9/29/26.
*Accession Number:* 20260929–5034.
*Comment Date:* 5 p.m. ET 10/13/26.

*Docket Numbers:* RP26–1298–000.
*Applicants:* Viking Gas Transmission Company.
*Description:* § 4(d) Rate Filing: Semi-Annual Fuel and Loss Retention Percentages—Winter 2026 Rates to be effective 11/1/2026.
*Filed Date:* 9/29/26.
*Accession Number:* 20260929–5037.
*Comment Date:* 5 p.m. ET 10/13/26.

*Docket Numbers:* RP26–1299–000.
*Applicants:* Guardian Pipeline, L.L.C.
*Description:* § 4(d) Rate Filing: Annual Transporter's Use Gas Percentage—Winter 2026 Rate to be effective 11/1/2026.
*Filed Date:* 9/29/26.
*Accession Number:* 20260929–5040.
*Comment Date:* 5 p.m. ET 10/13/26.

*Docket Numbers:* RP26–1300–000.
*Applicants:* Texas Eastern Transmission, LP.
*Description:* § 4(d) Rate Filing: Negotiated Rates—Various Releases October 2026 to be effective 10/1/2026.
*Filed Date:* 9/29/26.
*Accession Number:* 20260929–5041.
*Comment Date:* 5 p.m. ET 10/13/26.

*Docket Numbers:* RP26–1301–000.
*Applicants:* Cenovus Energy Marketing Services LTD., Cenovus Trading & Supply Company, Husky Marketing and Supply Company.
*Description:* Joint Petition for Temporary Waiver of Capacity Release Regulations, et al. of Cenovus Energy Marketing Services Ltd., et al.
*Filed Date:* 9/29/26.
*Accession Number:* 20260929–5048.
*Comment Date:* 5 p.m. ET 10/13/26.

*Docket Numbers:* RP26–1302–000.
*Applicants:* Alliance Pipeline L.P.
*Description:* § 4(d) Rate Filing: Negotiated Rates—Releases 2026–10–01 and Housekeeping to be effective 10/1/2026.
*Filed Date:* 9/29/26.
*Accession Number:* 20260929–5056.
*Comment Date:* 5 p.m. ET 10/13/26.

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/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

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: September 29, 2026.

**Carlos D. Clay,**

*Deputy Secretary.*

[FR Doc. 2026–20217 Filed 10–1–26; 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 Electric Corporate filings:

*Docket Numbers:* EC26–176–000.

*Applicants:* Shell Energy North America (US), L.P., Hunlock Creek Generating LLC, Hunlock Energy, LLC.

*Description:* Joint Application for Authorization Under Section 203 of the Federal Power Act of Hunlock Creek Generating LLC, et al.

*Filed Date:* 9/25/26.

*Accession Number:* 20260925–5229.

*Comment Date:* 5 p.m. ET 10/16/26.

*Docket Numbers:* EC26–177–000.

*Applicants:* West Camp Wind Farm, LLC, Arizona Public Service Company.

*Description:* Joint Application for Authorization Under Section 203 of the Federal Power Act of West Camp Wind Farm, LLC, et al.

*Filed Date:* 9/25/26.

*Accession Number:* 20260925–5232.

*Comment Date:* 5 p.m. ET 10/16/26.

*Docket Numbers:* EC26–178–000.

*Applicants:* Viridon Wisconsin LLC, NGV US Transmission Inc.

*Description:* Joint Application for Authorization Under Section 203 of the Federal Power Act of Viridon Wisconsin LLC, et al.

*Filed Date:* 9/28/26.

*Accession Number:* 20260928–5177.

*Comment Date:* 5 p.m. ET 10/19/26.

*Docket Numbers:* EC26–179–000.

*Applicants:* Switched On, LLC.

*Description:* Application for Authorization Under Section 203 of the Federal Power Act of Switched On, LLC.

*Filed Date:* 9/25/26.

*Accession Number:* 20260925–5234.

*Comment Date:* 5 p.m. ET 10/16/26.

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

*Docket Numbers:* EL26–111–000.

*Applicants:* Base Power, Inc.

*Description:* Petition for Declaratory Order of Base Power, Inc.

*Filed Date:* 9/18/26.

*Accession Number:* 20260918–5444.

*Comment Date:* 5 p.m. ET 10/19/26.

Take notice that the Commission received the following Electric Rate filings:

*Docket Numbers:* ER16–1530–005.

*Applicants:* BIF III Holtwood LLC.

*Description:* Refund Report: Refund Report to be effective N/A.

*Filed Date:* 9/29/26.

*Accession Number:* 20260929–5112.

*Comment Date:* 5 p.m. ET 10/20/26.

*Docket Numbers:* ER21–887–004.

*Applicants:* Brookfield Power Piney & Deep Creek LLC.

*Description:* Refund Report: Refund Report to be effective N/A.

*Filed Date:* 9/29/26.

*Accession Number:* 20260929–5114.

*Comment Date:* 5 p.m. ET 10/20/26.

*Docket Numbers:* ER24–2394–000; ER24–2396–000; ER24–2399–000.

*Applicants:* Aurora Trading Company, LLC, Venturi Asset Management, LLC, Cataract Coast, LLC, Aurora Trading Company, LLC, Venturi Asset Management, LLC.

*Description:* Notice of Cancellation of Market Based Rate Tariff of Cataract Coast, LLC, et al.

*Filed Date:* 9/28/26.

*Accession Number:* 20260928–5170.

*Comment Date:* 5 p.m. ET 10/19/26.

*Docket Numbers:* ER25–3555–001.

*Applicants:* Mayes Solar, LLC.

*Description:* Notice of Change in Status of Mayes Solar, LLC.

*Filed Date:* 9/28/26.

*Accession Number:* 20260928–5174.

*Comment Date:* 5 p.m. ET 10/19/26.

*Docket Numbers:* ER26–2998–001.

*Applicants:* Jackpot Holdings, LLC.

*Description:* Tariff Amendment: Response to Deficiency Letter and Revised Market-Based Rate Tariff to be effective 7/1/2026.

*Filed Date:* 9/28/26.

*Accession Number:* 20260928–5163.

*Comment Date:* 5 p.m. ET 10/19/26.

*Docket Numbers:* ER26–2999–001.

*Applicants:* Jones Farm Lane Solar, LLC.

*Description:* Tariff Amendment: Response to Deficiency Letter and Revised Market-Based Rate Tariff to be effective 7/1/2026.

*Filed Date:* 9/28/26.

*Accession Number:* 20260928–5168.

*Comment Date:* 5 p.m. ET 10/19/26.

*Docket Numbers:* ER26–3000–001.

*Applicants:* Mesa Wind Power LLC.

*Description:* Tariff Amendment: Response to Deficiency Letter and Revised Market-Based Rate Tariff to be effective 7/1/2026.

*Filed Date:* 9/28/26.

*Accession Number:* 20260928–5169.

*Comment Date:* 5 p.m. ET 10/19/26.

*Docket Numbers:* ER26–3003–001.

*Applicants:* North Rosamond Solar, LLC.

*Description:* Tariff Amendment: Response to Deficiency Letter and Revised Market-Based Rate Tariff to be effective 7/1/2026.

*Filed Date:* 9/28/26.

*Accession Number:* 20260928–5142.

*Comment Date:* 5 p.m. ET 10/19/26.

*Docket Numbers:* ER26–3004–001.

*Applicants:* Pike Solar LLC.

*Description:* Tariff Amendment: Response to Deficiency Letter and Revised Market-Based Rate Tariff to be effective 7/1/2026.

*Filed Date:* 9/28/26.

*Accession Number:* 20260928–5144.

*Comment Date:* 5 p.m. ET 10/19/26.

*Docket Numbers:* ER26–3005–001.

*Applicants:* Spanish Peaks Solar LLC.

*Description:* Tariff Amendment: Response to Deficiency Letter and Revised Market-Based Rate Tariff to be effective 7/1/2026.

*Filed Date:* 9/28/26.

*Accession Number:* 20260928–5145.

*Comment Date:* 5 p.m. ET 10/19/26.

*Docket Numbers:* ER26–3006–001.

*Applicants:* Sweetland Wind Farm, LLC.

*Description:* Tariff Amendment: Response to Deficiency Letter and Revised Market-Based Rate Tariff to be effective 7/1/2026.

*Filed Date:* 9/28/26.

*Accession Number:* 20260928–5147.

*Comment Date:* 5 p.m. ET 10/19/26.

*Docket Numbers:* ER26–3008–001.

*Applicants:* Wildflower Solar LLC.

*Description:* Tariff Amendment: Response to Deficiency Letter and Revised Market-Based Rate Tariff to be effective 7/1/2026.

*Filed Date:* 9/28/26.

*Accession Number:* 20260928–5149.

*Comment Date:* 5 p.m. ET 10/19/26.

*Docket Numbers:* ER26–3012–001.
*Applicants:* Foxglove Solar Project, LLC.
*Description:* Tariff Amendment: Response to Deficiency Letter and Revised Market-Based Rate Tariff to be effective 7/1/2026.
*Filed Date:* 9/28/26.
*Accession Number:* 20260928–5150.
*Comment Date:* 5 p.m. ET 10/19/26.
*Docket Numbers:* ER26–3014–001.
*Applicants:* Franklin Solar LLC.
*Description:* Tariff Amendment: Response to Deficiency Letter and Revised Market-Based Rate Tariff to be effective 7/1/2026.
*Filed Date:* 9/28/26.
*Accession Number:* 20260928–5152.
*Comment Date:* 5 p.m. ET 10/19/26.
*Docket Numbers:* ER26–3015–001.
*Applicants:* Goose Prairie Solar LLC.
*Description:* Tariff Amendment: Response to Deficiency Letter and Revised Market-Based Rate Tariff to be effective 7/1/2026.
*Filed Date:* 9/28/26.
*Accession Number:* 20260928–5159.
*Comment Date:* 5 p.m. ET 10/19/26.
*Docket Numbers:* ER26–3017–001.
*Applicants:* Bitter Ridge Wind Farm, LLC.
*Description:* Tariff Amendment: Response to Deficiency Letter and Revised Market-Based Rate Tariff to be effective 7/1/2026.
*Filed Date:* 9/28/26.
*Accession Number:* 20260928–5143.
*Comment Date:* 5 p.m. ET 10/19/26.
*Docket Numbers:* ER26–3019–001.
*Applicants:* Black Mesa Energy, LLC.
*Description:* Tariff Amendment: Response to Deficiency Letter and Revised Market-Based Rate Tariff to be effective 7/1/2026.
*Filed Date:* 9/28/26.
*Accession Number:* 20260928–5146.
*Comment Date:* 5 p.m. ET 10/19/26.
*Docket Numbers:* ER26–3020–001.
*Applicants:* Crystal Hill Solar, LLC.
*Description:* Tariff Amendment: Response to Deficiency Letter and Revised Market-Based Rate Tariff to be effective 7/1/2026.
*Filed Date:* 9/28/26.
*Accession Number:* 20260928–5154.
*Comment Date:* 5 p.m. ET 10/19/26.
*Docket Numbers:* ER26–3458–001.
*Applicants:* Midcontinent Independent System Operator, Inc., Ameren Illinois Company.
*Description:* Tariff Amendment: Ameren Illinois Company submits tariff filing per 35.17(b): 2026–09–29_SA 3064 Ameren IL–RECC Sub 1st Rev UCA to be effective 10/7/2026.
*Filed Date:* 9/29/26.
*Accession Number:* 20260929–5094.
*Comment Date:* 5 p.m. ET 10/20/26.
*Docket Numbers:* ER26–3832–000.
*Applicants:* Pacific Gas and Electric Company.
*Description:* Notice of Termination of Service Agreement No. 330 under Pacific Gas and Electric Company's FERC Electric Tariff Volume No. 4.
*Filed Date:* 9/18/26.
*Accession Number:* 20260918–5445.
*Comment Date:* 5 p.m. ET 10/20/26.
*Docket Numbers:* ER26–3876–000.
*Applicants:* Southwest Power Pool, Inc.
*Description:* § 205(d) Rate Filing: 1148R40 American Electric Power NITSA and NOA to be effective 9/1/2026.
*Filed Date:* 9/29/26.
*Accession Number:* 20260929–5004.
*Comment Date:* 5 p.m. ET 10/20/26.
*Docket Numbers:* ER26–3877–000.
*Applicants:* Southwest Power Pool, Inc.
*Description:* § 205(d) Rate Filing: 5006 Bullfrog Energy GIA to be effective 9/14/2026.
*Filed Date:* 9/29/26.
*Accession Number:* 20260929–5015.
*Comment Date:* 5 p.m. ET 10/20/26.
*Docket Numbers:* ER26–3878–000.
*Applicants:* Midcontinent Independent System Operator, Inc., Northern States Power Company, a Minnesota corporation.
*Description:* § 205(d) Rate Filing: Northern States Power Company, a Minnesota corporation submits tariff filing per 35.13(a)(2)(iii: 2026–09–29_SA 2473 NSP–GRE 1st Rev T–T (Brownton) to be effective 9/30/2026.
*Filed Date:* 9/29/26.
*Accession Number:* 20260929–5028.
*Comment Date:* 5 p.m. ET 10/20/26.
*Docket Numbers:* ER26–3879–000.
*Applicants:* Midcontinent Independent System Operator, Inc.
*Description:* § 205(d) Rate Filing: 2026–09–29_SA 4867 Ameren Illinois-Northwest Solar GIA (S1057) to be effective 9/22/2026.
*Filed Date:* 9/29/26.
*Accession Number:* 20260929–5082.
*Comment Date:* 5 p.m. ET 10/20/26.

Take notice that the Commission received the following Qualifying Facility filings:
*Docket Numbers:* QF26–1442–000.
*Applicants:* DUO001, LLC.
*Description:* Form 556 of DUO001, LLC.
*Filed Date:* 9/28/26.
*Accession Number:* 20260928–5185.
*Comment Date:* 5 p.m. ET 10/19/26.

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: September 29, 2026.

**Carlos D. Clay,**

*Deputy Secretary.*

[FR Doc. 2026–20216 Filed 10–1–26; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Project No. 15429–000]**

### RamaFlux Sierra PSH, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On April 30, 2026, RamaFlux Sierra PSH LLC, filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Fish Creek Pumped Storage Project (Fish Creek Project or project). The proposed facility would be a 750-megawatt (MW) closed-loop pumped storage hydroelectric facility located near the town of Nevada City in Nevada County, California. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following new facilities: (1) an

upper reservoir created by a new embankment at an approximate elevation of 4,200 feet above mean sea level to serve as the upper pool; (2) a lower reservoir created by a new embankment with at an approximate elevation of 2,600 feet above mean sea level to be located on the eastern slope of the Fish Creek drainage basin to serve as the lower pool; (3) a conduit system of steel-lined penstocks with a concrete and steel-lined pressure shaft to connect the upper and lower reservoirs to the powerhouse; (4) an underground powerhouse with reversible pump-turbine units with a generation capacity of 750 MWs located adjacent to the lower reservoir on its western side; (5) an intake structure at the lower reservoir; (6) a new single-circuit 230 kilovolt (kV) transmission line to connect the powerhouse to the existing 230 kV transmission infrastructure at the vicinity of the proposed project; (7) construction access routes; and (8) appurtenant facilities.

*Applicant Contact:* Bin Li, RamaFlux Sierra PSH, LLC, 2261 Market Street, Suite 78891, San Francisco, California 94114; phone: (650) 460–4696; email: *contact@ramafluxsierrapsh.com*.

*FERC Contact:* Khatoon Melick, (202) 502–8433, *khatoon.melick@ferc.gov*.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: on or before 5:00 p.m. Eastern Time on November 30, 2026. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

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*.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at *https://ferconline.ferc.gov/eFiling.aspx*. Commenters can submit brief comments up to 10,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx*. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–15429–000.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's website at *http://www.ferc.gov/docs-filing/elibrary.asp*. Enter the docket number (P–15429) in the docket number field to access the document. For assistance, contact FERC Online Support.

(Authority: 18 CFR 2.1)

Dated: September 29, 2026.

**Debbie-Anne A. Reese,**

*Secretary.*

[FR Doc. 2026–20238 Filed 10–1–26; 8:45 am]

**BILLING CODE 6717–01–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL OPRM–FAD–242]**

### Environmental Impact Statements; Notice of Availability

*Responsible Agency:* Office of Federal Activities, General Information 202–993–3272 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed September 21, 2026 10 a.m. EST Through September 28, 2026 10 a.m. EST

Pursuant to CEQ Guidance on 42 U.S.C. 4332.

*Notice:* Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxapps.epa.gov/cdx-enepa-II/public/action/eis/search.*

*EIS No. 20260129, Final, FERC, TX,* Sabine Pass Stage 5 Expansion Project, Contact: Office of External Affairs 866–208–3372.

*EIS No. 20260130, Final Supplement, NHTSA, REG,* Final Supplemental Environmental Impact Statement Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule III for Model Years 2022 to 2031 Passenger Cars and Light Trucks, Contact: Joseph Bayer 888–327–4236.

**Amended Notice**

*EIS No. 20260122, Final, EPA, CA,* ADOPTION—FEIS for Dam Retrofit and Surrender of the Anderson Dam Hydroelectric Project Exemption, Review Period Ends: 10/19/2026, Contact: Alaina McCurdy 202–564–6996.

Revision to FR Notice Published 9/18/2026; Correction to Comment Period Due Date from October 9, 2026 to October 19, 2026.

Dated: September 30, 2026.

**Nancy Abrams,**

*Deputy Director, Federal Activities Division.*

[FR Doc. 2026–20240 Filed 10–1–26; 8:45 am]

**BILLING CODE 6560–50–P**

## FEDERAL RESERVE SYSTEM

### Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company; Withdrawal

Notice FR Doc. 2026–19900 published at 91 FR 61406 on September 29, 2026. is hereby withdrawn.

Board of Governors of the Federal Reserve System.

**Michele Taylor Fennell,**

*Associate Secretary of the Board.*

[FR Doc. 2026–20242 Filed 10–1–26; 8:45 am]

**BILLING CODE 6210–01–P**

## FEDERAL RESERVE SYSTEM

### Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm*. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as

confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than October 19, 2026.

*A. Federal Reserve Bank of Cleveland* (Jenni M. Frazer, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101–2566. Comments can also be sent electronically to *Comments.applications@clev.frb.org*:

1. *Barbara J. Mouser, Jason L. Mouser, Denise E. Mouser, and Anita K. Mouser, all of Ridgeway, Ohio; and Ronald E. Mouser and Melissia J. Mouser, West Mansfield, Ohio;* as individuals and as members of the Mouser Family Control Group, a group acting in concert, to retain voting shares of Victory Bancshares, Inc., and thereby indirectly retain voting shares of Mt. Victory State Bank, both of Mt. Victory, Ohio.

*B. 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. *Robert D. Cook, individually, and as trustee of The Trust for Brad Cook under the Bobby & Anita Cook Living Trust, all of Watkinsville, Georgia;* to retain voting shares of TCB Bancshares, Inc., and thereby indirectly retain voting shares of The Commercial Bank, both of Crawford, Georgia.

Board of Governors of the Federal Reserve System.

**Michele Taylor Fennell,**

*Associate Secretary of the Board.*

[FR Doc. 2026–20243 Filed 10–1–26; 8:45 am]

**BILLING CODE;P**

## FEDERAL RESERVE SYSTEM

**[Docket No. OP–1882]**

## Request for Comment on Model Changes for the Board's 2027 Supervisory Stress Test

**AGENCY:** Board of Governors of the Federal Reserve System.

**ACTION:** Notice, request for comment.

**SUMMARY:** The Board of Governors of the Federal Reserve System (Board) invites public input on proposed model changes for the Board's 2027 supervisory stress test, and invites comment on proposed changes to the FR Y–14A/Q/M reports that would facilitate future model development and improve the risk capture of the stress test.

**DATES:** Comments must be received on or before December 1, 2026.

**ADDRESSES:** You may submit comments, identified by Docket No. OP–1882, 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, 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 not be 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:** Doriana Ruffino, Associate Director (202) 452–5235, Hillel Kipnis, Assistant Director, (202) 452–2924, John Simone, Manager, (202) 245–4256, Alice Moore, Senior Financial Institution Policy Analyst II, (202) 360–0155, and Theo Pistner, Financial Institution and Policy Analyst III, (202) 941–1825, Division of Supervision and Regulation; Asad Kudiya, Associate General Counsel, (202) 360–6887, Julie Anthony, Senior Special Counsel, (202) 658–9400, Jonah Kind, Senior Counsel, (202) 452–2045, Brian Kesten, Senior Counsel (202) 843–4079, Tara Hofbauer, Senior Attorney (202) 680–2503, Rye Salerno, Attorney (240) 374–7788, Legal Division. Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551. For users of TDD–TYY, please call 711 from any telephone, anywhere in the United States.

**SUPPLEMENTARY INFORMATION:**

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I. Introduction
II. Proposed Model Change
III. Revisions to the FR Y–14A/Q/M
IV. Administrative Law Matters
A. Paperwork Reduction Act Analysis

### I. Introduction

Stress testing is a core element of the Board's regulatory framework and supervisory program for large firms. The stress test enables the Board to assess whether large bank holding companies, savings and loan holding companies, U.S. intermediate holding companies of foreign banking organizations, and nonbank financial companies supervised by the Board (collectively, firms) have sufficient capital to absorb potential losses under hypothetical stress scenarios and continue lending under severely adverse conditions, although it is not designed or intended to be predictive of future economic conditions. The stress tests evaluate the financial resilience of large banks by estimating bank losses, revenues, expenses, and resulting capital levels—which provide a cushion against losses—under hypothetical recession scenarios.[1] The Board uses the results of a stress test, in part, to set large bank capital requirements. This proposal seeks public input on revisions to the models used to conduct the analysis for the 2027 stress test and targeted revisions to reporting forms to facilitate future model development and improve the risk capture of the stress test.

### II. Proposed Model Change

To enhance the transparency and public accountability of the annual stress tests, the Board is issuing a separate final rule under which it would establish a process by which the Board would publish for public input any material model changes before implementing them in the annual supervisory stress test.[2] While this

[1] U.S. bank holding companies (BHCs), covered savings and loan holding companies (SLHCs), and intermediate holding companies of foreign banking organizations (IHCs) with $100 billion or more in assets are subject to the Board's supervisory stress test rule (12 CFR part 238, subpart O; 12 CFR part 252, subpart E) and capital planning requirements (12 CFR 225.8; 12 CFR 238.170). In addition, certain BHCs, SLHCs, IHCs, and state member banks must comply with the Board's company-run stress test rules (12 CFR part 238, subpart P; and 12 CFR part 252, subparts B and F).

[2] A material model change is a model change that could have, in the Board's estimation, an impact on the post-stress common equity tier 1 regulatory capital ratio of any firm, or on the average post-stress common equity tier 1 capital ratios of all firms with total consolidated assets of $100 billion or more subject to the stress test, equal to (i) a change of 20 basis points or more in the projected common equity tier 1 ratio of any such firm; or (ii)

Continued

aspect of the final rule is not yet effective, consistent with the purposes and features of this enhanced disclosure process, the Board is inviting comment on proposed adjustments to the models for the 2027 stress test. The proposed changes were informed by comments received on the models proposed for the 2026 stress test and would better capture heterogeneity across firms in the noninterest income model.[3]

A detailed description of the proposed model, as well as analysis of these proposed changes, are available on the Board's website: *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2027.htm.*

## III. Revisions to the FR Y–14A/Q/M

To facilitate potential future model development or to improve risk capture of the stress test, the Board is proposing several revisions to the FR Y–14A/Q/M. For example, to assess whether a future model change is appropriate, the Board is proposing to reimplement FR Y–14Q, Schedule I (Mortgage Servicing Rights Valuation), with limited adjustments, to capture data on serviced mortgages. This information could enable the Board to develop a model for mortgage servicing rights that better captures the risks associated with a firm's servicing portfolio. Similarly, the Board is proposing to add a limited number of items to FR Y–14Q, Schedule G (PPNR) and Schedule H (Wholesale) that could be informative in determining whether future model changes are appropriate, such as additional collateral and guarantor information on corporate loans. Many of these revisions were suggested by commenters in response to the models proposed by the Board in October 2025.[4] Finally, the Board is proposing several revisions to FR Y–14Q, Schedule A (Retail), Schedule B (Securities), Schedule F (Trading), Schedule L (Counterparty), and Schedule M (Balances), as well as FR Y–14M, Schedule A (First Lien) and Schedule B (Home Equity) to improve the instructions and consistency of reporting. These proposed revisions do not indicate that the Board will propose a related model change. The proposed revisions are described in Section IV.A of this Supplementary Information.

## IV. Administrative Law Matters

### *A. Paperwork Reduction Act Analysis*

In accordance with the requirements of the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), the Board 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 Board is proposing to revise the FR Y–14A/Q/M to collect additional information to support the supervisory stress test models and improve the reporting instructions.

The Board invites public comment on the following information collection:

(a) Whether the collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

(b) The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the information 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.

Proposal Under OMB Delegated Authority to Extend for Three Years, With Revision, the Following Information Collection

*Collection title:* Capital Assessments and Stress Testing Reports.

*Collection identifier:* FR Y–14A/Q/M.

*OMB control number:* 7100–0341.

*General description of collection:* The FR Y–14 reports collect stress test and capital plan data from the largest holding companies, which are those with $100 billion or more in total consolidated assets. The data collected through the FR Y–14 reports provide the Board with the information needed to help ensure that large holding companies have strong, firm-wide risk measurement and management processes supporting their internal assessments of capital adequacy and that their capital resources are sufficient given their business focus, activities, and resulting risk exposures. Information gathered in this data collection is also used in the supervision and regulation of these financial institutions.

*Current Actions:* The proposal would modify the FR Y–14A/Q/M to collect additional information to potentially inform supervisory model developments and improve reporting instructions. All proposed revisions would be effective for the December 31, 2027, report date.

1. Mortgage Servicing Rights

Prior to 2019, FR Y–14Q, Schedule I (MSR Valuation) collected valuation data on mortgage servicing rights (MSR). The schedule was retired, as the data was immaterial for most firms that submitted the FR Y–14Q. However, this data could allow the Board to develop a model for MSRs that better captures the risks of loans in a firm's servicing portfolio, as discussed in questions in the proposed noninterest income model documentation associated with this notice. Therefore, to help assess whether such a model would be appropriate, the Board is proposing to reimplement Schedule I with a small number of changes, primarily to delete fields that are not necessary and update others to reflect current industry practices. This schedule would collect data on a firm's MSR portfolio such as the volume of loans serviced, capitalization rates, prepayment information, and other characteristics of the portfolio.

*Question #1:* The Board seeks comment on the proposed fields and definitions in FR Y–14Q, Schedule I. Are there any alternative fields, or definitions of fields, that would better capture the risks associated with a firm's servicing portfolio, such as different industry credit scores, delinquency buckets, or product types?

2. Wholesale

a. Revisions Suggested by Commenters

In response to the Wholesale models proposed in October 2025, commenters provided several modeling suggestions that would require the collection of additional data. For example, commenters suggested that corporate loans that qualify for securitization be treated as available-for-sale/held-to-maturity securities, that facility-level rating information be accounted for in corporate credit losses, and that the corporate model account for loan guarantees, including partial guarantees. Similarly, commenters suggested that the Board identify commercial real estate (CRE) loans collateralized by affordable housing and collect

a change of 10 basis points or more in the average of the absolute value of each firm's change in projected common equity tier 1 ratio. The analysis is based on the prior year's severely adverse scenario and prior year's input data. A model change is the introduction of a new model or a conceptual change to an existing model.

[3] *See* 90 FR 51856 (Nov. 18, 2025), available at *https://www.federalregister.gov/d/2025-20211.*

[4] *See* Board, Review of Comments and Summary of Changes to the Proposed 2026 Stress Test Models, available at *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2027.htm.*

information on construction and development projects that are in a transitional phase. Commenters also suggested allowing alternative measurements for the reporting of CRE current occupancy. Per the commenters, these revisions would better enable the Board to capture heterogeneity across firms, thereby improving the risk capture of the models, or would clarify the instructions.

As discussed in the Board's review of comments, it is not adopting modeling changes related to these suggestions at this time.[5] However, to further assess the commenters' suggestions, the Board is proposing to revise existing items or add new ones to FR Y–14Q, Schedule H.1 (Corporate) and Schedule H.2 (CRE) to collect this information. Specifically, to capture data on loan guarantees, securitizations, and internal risk ratings for corporate exposures, the Board is proposing to add item 124 (''Guarantee Amount''), item 125 (''Securitization Flag''), and item 126 (''Facility Internal Risk Rating'') to Schedule H.1. The Board is also proposing to add item 78 (''Affordable Housing Flag'') and item 79 (''Current Development Status'') to Schedule H.2 to gather data on affordable housing and the development status associated with CRE exposures. Further, to clarify the reporting of affordable housing, the Board is also proposing to revise Schedule H.2, item 9 (''Property Type''). Finally, to enable the use of alternative measurements for Schedule H.2, item 23 (''Current Occupancy'') the Board proposes to revise Schedule H.2, item 39 (''Property Size'') to further clarify property types and measurement units.

To further assess the commenters' suggestions and align with the Board's capital rule, the Board is proposing to revise the definition of an eligible guarantor in Schedule H.1 to be consistent with the corresponding definition in 12 CFR 217.2. For consistency with Schedule H.1, the Board is similarly proposing to revise Schedule H.2, item 21 (''Recourse'') and add item 77 (''Recourse Amount'') to capture the amount of a loan covered by recourse and align the definition of guarantor with the corresponding definition in 12 CFR 217.2.

Obligor Internal Risk Ratings

Firms are currently required to report obligor internal risk ratings in Schedule H.1, item 10 (''Obligor Internal Risk Rating''). The Board is not proposing any revisions to this item. However, as described above, the Board is proposing to collect facility internal risk ratings for corporate exposures. The Board is seeking feedback on the proposed revisions to capture facility internal risk rating information, as well as potentially collecting related, supplemental data items, and has provided specific questions below.

*Question #2:* The Board seeks comment on whether the proposed facility internal risk rating field on Schedule H.1 should explicitly capture loss severity in the event of default rating or instead capture a blended expected loss rating that considers both the probability of default and loss severity. What would be the advantages and disadvantages of each approach?

*Question #3:* The Board seeks comment on adding an item to Schedule H.1 that would map the proposed Facility Internal Risk Rating field to an external equivalent. As an alternative, the Board also seeks comment on collecting each firm's universe of internal facility risk ratings in a manner similar to Schedule H.4 (Internal Risk Rating Schedule). What would be the advantages and disadvantages of each approach?

b. Covenants

On May 20, 2026, the Board published in the **Federal Register** a notice announcing the finalization of revisions to the FR Y–14 reports, including the addition of item 119 (''Covenant Violation'') on Schedule H.1 to capture information on loan covenants.[6] The adopted item provides several options for reporting whether a covenant exists, whether a covenant has been violated, and, if so, whether the agreement has been amended or waived. However, these options do not capture a scenario in which a covenant violation occurs and is cured, without amendment or waiver, within a reporting quarter. To capture this scenario, the Board is proposing to add a new option for a covenant violation that is cured. This revision would enable the Board to better assess the structure and risks of reported covenants.

3. Retail

a. Margin Loans

In December 2025, the Board adopted changes to the FR Y–9C that require margin loans, whether purpose or non-purpose, primarily collateralized by securities with readily determinable fair value to be reported on Schedule HC–C, item 9.b.(1).[7] Prior to this reporting change, retail non-purpose loans were reported in Schedule HC–C, items 6.b or 6.d, which are also reported on FR Y–14Q, Schedule M.1 (Quarter-end Balances), item 4.c (''Non purpose lending''). As a result of this reporting change, Schedule M.1, item 4.c collects a smaller number of balances, as loans reported on Schedule HC–C, item 9.b.(1) are reported on Schedule M.1, item 5.c (''Securities lending''). To simplify the reporting and modeling of these exposures, the Board is proposing to retire item 4.c, which would result in all loans currently reported in item 4.c to be reported in item 4.e (''Other consumer loans''), which is more appropriate given the composition of these loans. For consistency, the Board is also proposing to revise the reportable categories of FR Y–14Q, Schedule A.6 (International Other Consumer) and Schedule A.7 (U.S. Other Consumer) to capture these exposures.

b. Property Valuation Methods

Currently, FR Y–14M, Schedule A.1 (First Lien Loan Level Table) and Schedule B.1 (Home Equity Loan Level Table) collects data on first lien and home equity portfolios, including property valuation methods. However, the options provided to report property valuation methods are not always consistent between the corresponding Schedule A.1 and Schedule B.1 items, which could lead to a valuation method not being captured consistently across schedules. Specifically, Schedule B.1, item 88 (''Property Valuation Method at Origination (appraisal method)'') includes 'TAV—tax assessed value,' 'purchase price,' and 'other' which are not options on the corresponding item on Schedule A.1 (item 111). To ensure that all valuation methods are captured on Schedule A.1, the Board is proposing to add 'TAV—tax assessed value,' 'purchase price,' and 'other' as reportable values to item 111.

Further, Schedule A.1, item 69 and Schedule B.1, item 80 both collect data on the refreshed property valuation method and provide known valuation methods as reportable options. However, both item 69 and item 80 lack an 'other' option for instances when the valuation method does not fall under one of the options provided. For comprehensiveness, the Board is proposing to add 'other' as a reportable value to item 69 and item 80, as well as definitions for these three reporting options to the applicable fields in Schedule A.1 and B.1.

c. Workout Type

In the FR Y–14 revisions finalized on May 20, 2026, the Board adopted

[5] The documentation is available on the Board's website. See *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2027.htm.*

[6] *See* 91 FR 29485 (May 20, 2026).

[7] *See* 90 FR 56756 (December 8, 2025).

revisions to FR Y–14M, Schedule A.1, item 143 (''Workout Type Started'') and Schedule B.1, item 120 (''Workout Type Started'') to clarify that these fields should be left blank if the loan has never been in loss mitigation or in the months following completion of a workout plan. However, a loan may enter loss mitigation but not have an active workout plan, which would be reported as blank under the current instructions. To better capture loans that have entered loss mitigation, the Board is proposing to revise item 43 and item 120 to indicate '0' should be reported for a loan in loss mitigation but no workout plan has been established.

4. Pre-Provision Net Revenue

In response to the pre-provision net revenue (PPNR) models proposed in October 2025, commenters provided several modeling suggestions that would require the collection of additional data.

Specifically, to better enable the Board to capture heterogeneity in across firms, thereby improving the risk capture of the models, commenters suggested that the Board collect data on deposit beta segmentation by wholesale and retail deposits, transfer pricing, and mark-to-market and fair value adjustments in noninterest revenue. The Board has determined that these data are not necessary for the PPNR models finalized for the 2027 stress test; however, it is proposing to add items to FR Y–14Q, Schedule G (PPNR) and revise existing items to collect this information to potentially inform future model development. For consistency, the Board is proposing corresponding changes to FR Y–14A, Schedule A.7.a (PPNR Projections) and A.7.b (PPNR Net Interest Income), as applicable.

In addition, one commenter suggested that the Board add an item to FR Y–14Q, Schedule B.1 (Securities 1—Main Schedule) to capture coupon rates for all securities, to support the projection of interest income on securities for which vendor data is unavailable. In response to the comment, the Board is proposing revisions to Schedule B.1 to collect coupon rate data for each security, as this information would enable the Board to better evaluate interest income associated with reported securities.

5. Market Risk

The Board has identified several areas of FR Y–14Q, Schedule B (Securities), Schedule F (Trading), and Schedule L (Counterparty) where revisions would improve the instructions, increase consistency in reporting, or support the supervisory models.

a. Securities

The Board considered comments suggesting that reporting requirements for equities on FR Y–14Q, Schedule B.1 could be reduced to exclude debt-security focused data items. Upon review, the Board determined that certain data fields collected on Schedule B.1 with respect to equities can be removed without impacting stress test projections. Accordingly, the Board is proposing to remove the requirement to report amortized cost, current face amount, original face amount, price and pricing date for equities on Schedule B.1.

b. Trading

Currently, FR Y–14Q, Schedule F.18 (Corporate Credit—Advanced) and Schedule F.19 (Corporate Credit—Emerging Markets) indicate that credit baskets should be reported under the single name credit default swaps (SN CDS) category. However, as these exposures can contain multiple underlying assets, it is more appropriate that they be reported according to the associated risks to be more accurately modeled. Therefore, the Board is proposing to clarify the Schedule F.18 and Schedule F.19 instructions to indicate that credit baskets should be reported according to the risks related to the underlying assets.

c. Counterparty

The Board is also proposing several changes to Schedule L to improve the instructions or facilitate supervisory modeling. Currently, FR Y–14Q, Schedule L.5 (Derivatives and Securities Financing Transactions Profile) allows for eligible credit derivatives such as single-name CDS hedges to be reported. As a result, single-name CDS hedges provided by counterparties within the firm (internal hedges) may be reported and thus included in the largest counterparty default (LCPD) calculation. As both parties are within the firm, internal hedges should not offset a firm's projected LCPD losses. Therefore, the Board is proposing to revise the Schedule L.5 instructions to exclude internal hedges.

The Board also received several comments on the Schedule L instructions based on the models proposed in October 2025. One commenter requested that the Board clarify the reporting of client-cleared derivatives (CCDs) and inter-affiliate transactions in the CVA schedules. Currently, Schedule L.5 requires CCD exposures to be reported when the firm guarantees client performance to the central clearing counterparty (CCP) or has offsetting transactions with the CCP. However, CCD exposures are only reported in Schedule L.1–L.4 if the firm either guarantees the performance of the CCP to the client or when it enters into an offsetting (or back-to-back) transaction with the CCP. For consistency, the Board is proposing to revise Schedule L.1–L.4 for CCDs such that they are reported if the firm guarantees client performance to the CCP or when it enters into an offsetting transaction with the CCP.

Further, inter-affiliate transactions are reported inconsistently across sub-schedules due to ambiguity in the instructions, particularly in terms of how these transactions are reported on Schedules L.1–L.4. Therefore, the Board is proposing to clarify that all inter-affiliate transactions, including IHC inter-affiliate transactions, should be included in the counterparty population for Schedules L.1–L.4. IHC inter-affiliate transactions would continue to only be reported according to the current Schedule L.5 instructions given the materiality of these exposures, even though affiliate exposures are excluded from the LCPD Model. Non-IHC inter-affiliate transactions would continue to be excluded from Schedule L.5.

Additionally, commenters provided feedback on ways they believe that Schedule L could be streamlined, including removing both sub-schedules containing residual CVA exposure data and columns containing redundant metadata. After considering these comments, the Board has determined that Schedule L.1.f, which collects the bottom 5 percent of CVA, is no longer beneficial for supervisory monitoring. Similarly, the Board has determined that certain counterparty metadata fields (country and sector) on Schedule L.2 and L.3 are not necessary as they are also collected on Schedule L.1. Therefore, the Board is proposing to retire Schedule L.1.f and the applicable metadata items from Schedules L.2 and L.3.

d. Additional Revisions

FR Y–14A, Schedule A.3.f (Expected Credit Loss and Provision for Credit Loss—HTM Securities) and Schedule A.3.g (Expected Credit Loss and Provision for Credit Loss—AFS Securities) collect data on projected allowances and provisions for credit losses for HTM and AFS securities, respectively, across various classes of securities. Commenters asserted that reporting and cross-referencing this information across schedules imposes a significant burden on firms. Given that the detailed disaggregation of credit loss projections by security type collected in

these schedules is of ancillary value and the low materiality of total securities portfolio credit loss provisions, the Board is proposing to retire Schedule A.3.f and Schedule A.3.g.

*Frequency:* Annually, quarterly, and monthly.

*Respondents:* Holding companies with $100 billion or more in total consolidated assets, as based on (1) the average of the firm's total consolidated assets in the four most recent quarters as reported quarterly on the firm's Consolidated Financial Statements for Holding Companies (FR Y–9C; OMB No. 7100–0128) or (2) the average of the firm's total consolidated assets in the most recent consecutive quarters as reported quarterly on the firm's FR Y–9Cs, if the firm has not filed an FR Y–9C for each of the most recent four quarters.

*Total estimated number of respondents:* 35.

*Estimated change in burden:*

- *FR Y–14A:* −280 hours.
- *FR Y–14Q:* +3,780 hours.
- *FR Y–14M:* 0 hours.
- *Total estimated change in burden:* +3,500.

*Total estimated annual burden hours:* 763,928.

By order of the Board of Governors of the Federal Reserve System.

**Michele Taylor Fennell,**

*Associate Secretary of the Board.*

[FR Doc. 2026–20245 Filed 10–1–26; 8:45 am]

**BILLING CODE 6210–01–P**

## OFFICE OF MANAGEMENT AND BUDGET

### Office of Federal Procurement Policy

## DEPARTMENT OF DEFENSE

## GENERAL SERVICES ADMINISTRATION

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

**[OMB Control No. 9000–0153; Docket No. 2026–0332; Sequence No. 1]**

### Information Collection; Federal Acquisition Regulation Part 11 Requirements

**AGENCY:** Office of Federal Procurement Policy (OFPP), Office of Management and Budget (OMB); Department of Defense (DOD); General Services Administration (GSA); and National Aeronautics and Space Administration (NASA).

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 and OMB regulations, OFPP, DoD, GSA, and NASA invite the public to comment on an extension concerning certain Federal Acquisition Regulation (FAR) part 11 requirements. OFPP, DoD, GSA, and NASA invite comments on: whether the proposed collection of information is necessary for the proper performance of the functions of Federal Government acquisitions, including whether the information will have practical utility; the accuracy of the estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. OMB has approved this information collection for use through January 31, 2027. OFPP, DoD, GSA, and NASA propose that OMB extend its approval for use for three additional years beyond the current expiration date.

**DATES:** OFPP, DoD, GSA, and NASA will consider all comments received by December 1, 2026.

**ADDRESSES:** OFPP, DoD, GSA, and NASA invite interested persons to submit comments on this collection through *https://www.regulations.gov* and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.*

*Instructions:* All items submitted must cite OMB Control No. 9000–0153, Federal Acquisition Regulation Part 11 Requirements. Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two-to-three days after submission to verify posting.

**FOR FURTHER INFORMATION CONTACT:** *FARPolicy@gsa.gov* or call 202–969–4075.

**SUPPLEMENTARY INFORMATION:**

### A. OMB Control Number, Title, and Any Associated Form(s)

OMB Control No. 9000–0153, Federal Acquisition Regulation Part 11 Requirements

### B. Need and Uses

This clearance covers the information that offerors or contractors must submit to comply with the following FAR requirements:

- FAR 52.211–7, Alternatives to Government-Unique Standards. This solicitation provision permits offerors to propose alternatives to Government-unique standards in response to Government solicitations. When an offeror proposes a voluntary consensus standard as an alternative to a Government-unique standard included in a solicitation, the offeror must furnish data and/or information regarding the alternative in sufficient detail for the Government to determine if it meets the Government's requirements. This provision is prescribed in FAR 11.107 for use when a solicitation uses Government-unique standards and the agency uses the transaction-based reporting method to report its use of voluntary consensus standards to the National Institutes of Standards and Technology (NIST). This provision is optional for use if an agency uses the categorical method to report to NIST. In accordance with OMB Circular A–119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, and section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113, 15 U.S.C. 272 note), agencies must use voluntary consensus standards, when they exist, in lieu of Government-unique standards, except where inconsistent with law or otherwise impractical. The information collected from offerors will be used by Federal agencies to determine if voluntary consensus standards will satisfy the Government's needs for a particular solicitation.
- FAR 52.211–8, Time of Delivery; and 52.211–9, Desired and Required Time of Delivery. These time of delivery clauses may be used by contracting officers to set forth a required delivery schedule and to allow offerors to propose an alternative delivery schedule. Contracting officers use the collected information to ensure supplies or services are obtained in a timely manner.

### C. Annual Burden

*Respondents:* 1,377.

*Total Annual Responses:* 1,377.

*Total Burden Hours:* 739.

*Obtaining Copies:* 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 OMB Control No. 9000–0153, Federal Acquisition Regulation Part 11 Requirements.

**Janet Fry,**

*Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.*

[FR Doc. 2026–20271 Filed 10–1–26; 8:45 am]

**BILLING CODE 6820–EP–P**

## OFFICE OF MANAGEMENT AND BUDGET

## Office of Federal Procurement Policy

## DEPARTMENT OF DEFENSE

## GENERAL SERVICES ADMINISTRATION

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

**[OMB Control No. 9000–0037; Docket No. 2026–0331; Sequence No. 1]**

### Information Collection; Presolicitation Notice and Response

**AGENCY:** Office of Federal Procurement Policy (OFPP), Office of Management and Budget (OMB); Department of Defense (DOD); General Services Administration (GSA); and National Aeronautics and Space Administration (NASA).

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 and OMB regulations, OFPP, DoD, GSA, and NASA invite the public to comment on an extension concerning presolicitation notice and response. OFPP, DoD, GSA, and NASA invite comments on: whether the proposed collection of information is necessary for the proper performance of the functions of Federal Government acquisitions, including whether the information will have practical utility; the accuracy of the estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. OMB has approved this information collection for use through January 31, 2027. OFPP, DoD, GSA, and NASA propose that OMB extend its approval for use for three additional years beyond the current expiration date.

**DATES:** OFPP, DoD, GSA, and NASA will consider all comments received by December 1, 2026.

**ADDRESSES:** OFPP, DoD, GSA, and NASA invite interested persons to submit comments on this collection through *https://www.regulations.gov* and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.*

*Instructions:* All items submitted must cite OMB Control No. 9000–0037, Presolicitation Notice and Response. Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two-to-three days after submission to verify posting.

**FOR FURTHER INFORMATION CONTACT:** *FARPolicy@gsa.gov* or call 202–969–4075.

**SUPPLEMENTARY INFORMATION:**

#### A. OMB Control Number, Title, and Any Associated Form(s)

9000–0037, Presolicitation Notice and Response.

#### B. Need and Uses

This clearance covers the information that offerors must submit to comply with the following Federal Acquisition Regulation (FAR) requirements:

- *FAR 14.205.* For sealed bidding, presolicitation notices briefly describe requirements and provide other essential information to enable potential bidders to determine whether they have an interest in the invitation and if appropriate, respond by communicating their interest in receiving the invitation for bid.
- *FAR 15.201(c).* For contracting by negotiation, presolicitation notices provide a means of early exchanges of information about future acquisitions between Government and industry, to which potential offerors may respond with feedback concerning acquisition strategy, terms and conditions, and any other concerns or questions.
- *FAR 36.213–2.* For construction contracts, presolicitation notices are required for construction requirements in excess of the simplified acquisition threshold to communicate essential information on the requirements, to which potential bidders may respond by communicating their interest in receiving the invitation for bid.

Presolicitation notices are used by the Government to inform, and, where specified, solicit a response from potential offerors or bidders. The primary purposes of the notices are to improve small business access to acquisition information and enhance competition by identifying contracting and subcontracting opportunities.

The contracting officer will use the information as follows:

- For sealed bidding, to include interested bidders in the distribution of the invitations for bids; and
- For contracting by negotiation, to consider the industry feedback in shaping the acquisition strategy.

#### C. Annual Burden

*Respondents:* 143,218.
*Total Annual Responses:* 429,654.
*Total Burden Hours:* 34,372.
*Obtaining Copies:* 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 OMB Control No. 9000–0037, Presolicitation Notice and Response.

**Janet Fry,**

*Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.*

[FR Doc. 2026–20270 Filed 10–1–26; 8:45 am]

**BILLING CODE 6820–EP–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Agency for Healthcare Research and Quality

### Patient Safety Organizations: Delisting for Cause for the Hospital Rep Safety Solutions Corp. PSO

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

**ACTION:** Notice of Delisting.

**SUMMARY:** The Patient Safety and Quality Improvement Final Rule (Patient Safety Rule) authorizes AHRQ, on behalf of the Secretary of HHS, to list as a patient safety organization (PSO) an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' by the Secretary if it is found to no longer meet the requirements of the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) and Patient Safety Rule, when a PSO chooses to

voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. AHRQ delisted the Hospital Rep Safety Solutions Corp., PSO number P0264, of its status as a PSO, when it failed to correct a finding of deficiency, and has delisted the PSO accordingly.

**DATES:** The delisting was effective at 12:00 Midnight ET (2400) on September 9, 2026.

**ADDRESSES:** The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. Both directories can be accessed electronically at the following HHS website: *https://www.pso.ahrq.gov/listed.*

**FOR FURTHER INFORMATION CONTACT:** Cathryn Bach, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, MS 07E01D, Rockville, MD 20857; Telephone (toll free): (866) 403–3697; Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: *pso@ahrq.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

**Background**

The Patient Safety Act, 42 U.S.C. 299b-21 to 299b-26, and the related Patient Safety Rule, 42 CFR part 3, published in the **Federal Register** on November 21, 2008 (73 FR 70732–70814), establish a framework by which individuals and entities that meet the definition of provider in the Patient Safety Rule may voluntarily report information to PSOs listed by AHRQ, on a privileged and confidential basis, for the aggregation and analysis of patient safety work product.

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of PSOs.

AHRQ has delisted the Hospital Rep Safety Solutions Corp. for cause. Accordingly, the Hospital Rep Safety Solutions Corp., P0264, was delisted effective at 12:00 Midnight ET (2400) on September 9, 2026.

More information on PSOs can be obtained through AHRQ's PSO website at *http://www.pso.ahrq.gov.*

**Roger D. Klein,**

*Director.*

[FR Doc. 2026–20212 Filed 10–1–26; 8:45 am]

**BILLING CODE 4160–90–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

**[Office of Management and Budget #:0970–0474]**

### Proposed Information Collection Activity; U.S. Repatriation Forms

**AGENCY:** Office of Human Services Emergency Preparedness and Response, Administration for Children and Families, U.S. Department of Health and Human Services.

**ACTION:** Request for public comments.

**SUMMARY:** The Administration for Children and Families (ACF) is requesting a 3-year extension of the U.S. Repatriation Program forms (OMB #0970–0474, expiration 1/31/2027). There are several changes requested to the thirteen forms. Burden estimates have also been updated.

**DATES:** *Comments due December 1, 2026.*

**ADDRESSES:** In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above. You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* The purpose of the U.S. Repatriation Program (Program) is to provide temporary assistance to eligible U.S. citizens and their dependents (repatriates) returned by the Department of State from a foreign country because of destitution, illness, war, threat of war, or a similar crisis, and who are without available resources, or (2) mental illness. Temporary assistance is provided upon their arrival in the United States and is available initially for up to 90 days from a repatriate's date of arrival in the United States. Temporary assistance is provided in the form of a service loan and is repayable to the U.S. Government.

Temporary assistance is defined in 42 U.S.C. 1313(c) as money payments, medical care, temporary lodging, transportation, and other goods and services necessary for the health or welfare of individuals, including guidance, counseling, and other welfare services provided to them within the United States upon their arrival in the United States. Other goods and services may include clothes, food, assistance with obtaining identification (driver's license, birth certificate), child care, and translation services.

The ACF Office of Human Services Emergency Preparedness and Response (OHSEPR), at the U.S. Department of Health and Human Services (HHS), administers the Program.

OHSEPR made changes to all thirteen forms to ensure the information collected aligns with Program statutes and regulations as well as the purpose and use of the form. Revisions include clarifying statutory authority and aligning data collection with policy. Forms were also simplified. These changes reduced the burden hours.

The following is a description of the proposed revisions:

**Emergency Repatriation Eligibility Application (Form RR–01)**

The purpose of this form is for U.S. citizens and their dependents to request temporary assistance during an emergency repatriation incident. To reduce the burden of reviewing numerous forms to receive assistance, proposed revisions include the following:

- Adding information about privacy and loan repayment

**Emergency Repatriation Reimbursement Request (Form RR–02)**

The purpose of this form is for states to request reimbursement for emergency repatriation expenditures. Proposed revisions include the following to align with deregulatory priorities:

- Changing reference 45 CFR part 75 to 2 CFR part 200
- Removing references to 45 CFR part 211 and 45 CFR part 212

**Loan Waiver and Deferral Application (Form RR–03)**

The purpose of this form is for repatriates to request a waiver or deferral of their loan for temporary assistance received through the U.S. Repatriation Program. Proposed

revisions include the following to align with deregulation changes:

- Removing references to 45 CFR part 211 and 45 CFR part 212

**Routine Repatriation Reimbursement Request (Form RR–04)**

The purpose of this form is for state and local service providers to submit reimbursement requests for providing temporary assistance to repatriates under the U.S. Repatriation Program. Proposed revisions include the following to align with deregulatory priorities and decrease fraud, waste, and abuse:

- Changing reference 45 CFR part 75 to 2 CFR part 200
- Removing references to 45 CFR part 211 and 45 CFR part 212
- Adding information on supporting documentation for administrative costs
- Updating information on where to submit form

**Repatriation Repayment and Privacy Agreement (Form RR–05)**

The purpose of this form is for repatriates to agree to accept temporary assistance under the U.S. Repatriation Program, to agree to repay HHS for temporary assistance, and to allow HHS to share personal information for benefits purposes. Proposed revisions include the following to align with deregulatory priorities and ACF priorities:

- Removing references to 45 CFR part 211 and 45 CFR part 212
- Adding information about automatic waivers for wrongful detainees and kin taking custody of unaccompanied minors

**Refusal of Temporary Assistance (Form RR–06)**

The purpose of this form is for repatriates to refuse to accept temporary assistance under the U.S. Repatriation Program after receiving information about the Program. Proposed revisions include adding the following to align with deregulation:

- Removing references to 45 CFR part 211 and 45 CFR part 212

**Temporary Assistance Extension Request (Form RR–07)**

The purpose of this form is for repatriates to request an extension of temporary assistance beyond the initial 90-day eligibility period. Proposed revisions include the following to align with deregulatory priorities:

- Removing references to 45 CFR part 211 and 45 CFR part 212
- Removing collection of dependent information
- Removing questions on lawsuits, assets, fixed monthly expenses, and loans and liabilities

**Needs Assessment Form (Form RR–09)**

The purpose of this form is for repatriation case workers to collect information on the needs of repatriates. This is a new form. Information collected includes repatriation program case information, repatriate arrival information, repatriate background information, dependent information, contact information, engagement information, valid identification information, information on need for medical care and accessibility and functional assistance, information on need for temporary lodging, information on need for local transportation, information on need for cash assistance, information on need for food assistance, information on need for translation assistance, information on need for legal aid, information on need for vocational training assistance, information on need for childcare assistance, information on need for other assistance.

**State Contact List**

The purpose is to ensure current and accurate points-of-contact within states and territories for the U.S. Repatriation Program routine and emergency operations.

Proposed revisions include the following to reduce burden to the states:

- Separately asking for the names of contacts by role and the state departments and agencies involved in repatriation

**Repatriation Training and Technical Assistance Request**

States, territories, counties, and local service providers may use this form to request training and technical assistance on the U.S. Repatriation Program via a web portal account. Proposed revisions include the following to reduce burden on the states:

- Combining categories for ''Emergency Repatriation—Financial Reimbursement'' and ''Routine Repatriation—Financial Reimbursement''
- Combining categories for ''Emergency Repatriation—Unaccompanied Minors'' and ''Routine Repatriation—Unaccompanied Minors''
- Adding question on delivery preference

**Post-Training Survey**

The purpose of this survey is to receive feedback on trainings to improve the support for and customer experience of states, territories, and local service providers supporting the U.S. Repatriation Program. Proposed revisions include the following to reduce burden for respondents and focus on program improvement:

- Removing questions on number of years in position
- Changing training evaluation from questions to statements
- Changing reference to ''your position'' to ''your role'' in regards to relevance of training
- Changing question on training engagement from ''interactive and engaging'' to ''engaging and supported my learning''
- Changing question on material from ''easy to understand'' to ''clear and easy to understand''
- Changing question asking respondent to rate the quality of the multimedia to asking respondent whether the multimedia ''supported my learning''
- Removing question on training meeting expectations
- Removing question on asking respondent to rate the quality of the training session
- Removing question on how multimedia could be improved
- Adding question on how prepared respondent feels to apply what they have learned

**Emergency Repatriation Cooperative Agreement Reporting Template**

The purpose of this reporting template is for states to report whether they conducted any emergency repatriation operations over the reporting period, and if so, to report on emergency repatriation center operations, immediate support services and resources offered, coordination and information sharing, demobilization, and lessons learned. This is a new form.

*Respondents:* States, territories, local social service providers, administrative staff, repatriates, and authorized representatives of repatriates.

*Annual Burden Estimates:*

| Instrument | Total number of respondents | Total number of responses per respondent | Average burden hours per response | Annual burden hours |
|---|---|---|---|---|
| Emergency Repatriation Eligibility Application | 250 | 1 | 0.5 | 125 |
| Emergency Repatriation Reimbursement Request | 10 | 1 | 0.3 | 3 |
| Loan Waiver and Deferral Application | 25 | 1 | 0.5 | 12.5 |
| Routine Repatriation Reimbursement Request | 55 | 2 | 0.3 | 33 |
| Repatriation Repayment and Privacy Agreement | 800 | 1 | 0.17 | 136 |
| Refusal of Temporary Assistance | 50 | 1 | 0.05 | 2.5 |
| Temporary Assistance Extension Request | 125 | 1 | 0.3 | 37.5 |
| Emergency Repatriation Request for Cost Approval and Federal Support | 5 | 10 | 0.3 | 15 |
| Repatriation State Contact List | 55 | 1 | 0.17 | 9.35 |
| Repatriation Training and Technical Assistance Request Form | 55 | 1 | 0.25 | 13.75 |
| Repatriation Post-Training Survey | 55 | 2 | 0.17 | 18.7 |
| Needs Assessment | 800 | 1 | 0.75 | 600 |
| Emergency Repatriation Cooperative Agreement Reporting Template | 13 | 1 | 0.4 | 5.2 |
| Estimated Total Annual Burden Hours: | 1,011.5 | | | |

*Comments:* The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

*Authority:* 42 U.S.C. 1313, 24 U.S.C. 321–329.

**Samantha L. Illangasekare,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2026–20265 Filed 10–1–26; 8:45 am]

**BILLING CODE 4184–PL–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Skeletal Structure, Physiology and Disease Study Section.

*Date:* October 27–28, 2026.

*Time:* 9:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Amber Taylor Collins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827–5245, *amber.collins@nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Medical Imaging Research.

*Date:* October 27–28, 2026.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Debanjan Goswami, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Office 810–G, Bethesda, MD 20892, (301) 451–1587, *debanjan.goswami@nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; RFA–TR–25–002: Review of R21 applications for Concept Studies for Rare Diseases.

*Date:* October 27, 2026.

*Time:* 9:30 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Lee Warren Slice, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 867–5309, *slicelw@mail.nih.gov.*

*Name of Committee:* Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Chemical Biology and Probes Study Section.

*Date:* October 27–28, 2026.

*Time:* 9:30 a.m. to 8:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Prema Chandrasekhar Iyer, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–1821, *prema.iyer@nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowships: Neurobiology of Development, Aging, and Cognition.

*Date:* October 27–28, 2026.

*Time:* 9:30 a.m. to 7:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* John Drake Morgan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Room 1015A, Bethesda, MD 20892, (301) 827–9283, *morganjod@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Special: Integrative Myocardial Physiology.

*Date:* October 27–28, 2026.

*Time:* 9:30 a.m. to 6:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Sara Ahlgren, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 4136,

Bethesda, MD 20892, 301–435–0904, *sara.ahlgren@nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Translational Auditory Neuroscience and Hearing Loss Mechanisms and Technologies Recurring SEP.

*Date:* October 27, 2026.

*Time:* 9:30 a.m. to 6:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Kausik Ray, Ph.D. Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rockville, MD 20852, (301) 402–3587, *rayk@mail.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Drug and Therapy Development in Neurological Disorders.

*Date:* October 27–28, 2026.

*Time:* 9:30 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Milene Lara Brownlow, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (984) 287–3209, *milene.brownlow@nih.gov.*

*Name of Committee:* Oncology 1—Basic Translational Integrated Review Group; Basic Cancer Immunobiology Study Section.

*Date:* October 27–28, 2026.

*Time:* 9:30 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Sarita Kandula Sastry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20782, 301–402–4788, *sarita.sastry@nih.gov.*

*Name of Committee:* Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Learning, Memory and Decision Neuroscience Study Section.

*Date:* October 27–28, 2026.

*Time:* 10:00 a.m. to 9:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Ana Olariu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496–9223, *Ana.Olariu@nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Immune Mechanisms of Rheumatology.

*Date:* October 27–28, 2026.

*Time:* 10:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Lindsey M. Pujanandez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (240) 627–3206, *lindsey.pujanandez@nih.gov.*

*Name of Committee:* Cell Biology Integrated Review Group; Maximizing Investigators' Research Award—D Study Section.

*Date:* October 27–28, 2026.

*Time:* 10:00 a.m. to 6:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Anne Marie Strohecker, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (202) 924–4186, *stroheckeram@csr.nih.gov.*

*Name of Committee:* Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Cell Signaling and Molecular Endocrinology Study Section.

*Date:* October 27–28, 2026.

*Time:* 10:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Andrew M. Wolfe, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Room 6214, Bethesda, MD 20892, 301–402–3019, *andrew.wolfe@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 30, 2026.

**Rosalind M. Niamke,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2026–20248 Filed 10–1–26; 8:45 am]

**BILLING CODE 4167–05–P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

**[OMB Control Number 1651–0NEW]**

### Agency Information Collection Activities; New Collection of Information; Client Representative Technical Assistance Portal (CR–TAP)

**AGENCY:** U.S. Customs and Border Protection (CBP), Department of Homeland Security.

**ACTION:** 30-Day notice and request for comments.

**SUMMARY:** The Department of Homeland Security, U.S. Customs and Border Protection (CBP) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

**DATES:** Comments are encouraged and must be submitted (no later than November 2, 2026) to be assured of consideration.

**ADDRESSES:** Written comments and/or suggestions regarding the item(s) contained in this notice should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Please submit written comments and/or suggestions in English. 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:** Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

**SUPPLEMENTARY INFORMATION:** CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork

Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (91 FR 24898) on May 7, 2026, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (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) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

**Overview of This Information Collection**

*Title:* Client Representative Technical Assistance Portal (CR–TAP).

*OMB Number:* 1651–0NEW.

*Form Number:* N/A.

*Current Actions:* New Collection.

*Type of Review:* New Collection.

*Affected Public:* Individuals.

*Abstract:* The Client Representative Technical Assistance Portal (CRTAP) provides the public with a method to inform CBP on technical issues impacting Automated Broker Interface (ABI) and Automated Commercial Environment electronic cargo systems transactions. The web-based application provides the trade with the capability to notify, identify, track, and communicate technical issues impacting operations with select CBP personnel. Trade participants will access the application via the ACE Portal or through a separate link at: *https://clientservicesportal.cbp.gov.*

CBP personnel will monitor, process and manage inquiries to streamline operations, enhance communications and improve processes: better security and privacy, and improved documentation of technical issues in a central location.

The Automated Commercial Environment (ACE) is a trade data processing system that is the current import system for U.S. Customs and Border Protection (CBP) operations. ACE is authorized by Executive Order 13659 which mandates implementation of a Single Window through which businesses will transmit data required by participating agencies for the importation or exportation of cargo ACE supports government agencies and the trade community with border-related missions with respect to moving goods across the border efficiently and securely.

To establish an ACE Portal account, participants submit information such as their name, their employer identification number (EIN) or social security number (SSN), and if applicable, a statement certifying their capability to connect to the internet. This information is submitted through the ACE Secure Data Portal which is accessible at: *https://www.cbp.gov/trade/automated.*

*Type of Information Collection:* CR–TAP.

*Estimated Number of Respondents:* 18,000.

*Estimated Number of Annual Responses per Respondent:* 3.

*Estimated Number of Total Annual Responses:* 54,000.

*Estimated Time per Response:* 5 minutes.

*Estimated Total Annual Burden Hours:* 4,500.

**Seth D. Renkema,**

*Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.*

[FR Doc. 2026–20229 Filed 10–1–26; 8:45 am]

**BILLING CODE 9111–14–P**

## DEPARTMENT OF HOMELAND SECURITY

### Office of the Secretary

### Determination Pursuant to Section 102 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, as Amended

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

**ACTION:** Notice of determination.

**SUMMARY:** The Secretary of Homeland Security has determined, pursuant to law, that it is necessary to waive certain laws, regulations, and other legal requirements in order to ensure the expeditious construction of barriers and roads in the vicinity of the international land border in the state of New Mexico.

**DATES:** This determination takes effect on October 2, 2026.

**SUPPLEMENTARY INFORMATION:** Important mission requirements of the Department of Homeland Security (''DHS'') include border security and the detection and prevention of illegal entry into the United States. Border security is critical to the nation's national security. Recognizing the critical importance of border security, Congress has mandated DHS to achieve and maintain operational control of the international land border. Secure Fence Act of 2006, Public Law 109–367, section 2, 120 Stat. 2638 (Oct. 26, 2006) (8 U.S.C. 1701 note). Congress defined ''operational control'' as the prevention of all unlawful entries into the United States, including entries by terrorists, other unlawful aliens, instruments of terrorism, narcotics, and other contraband. *Id.* Consistent with that mandate, the President's Executive Order on Securing Our Borders directs that I take all appropriate action to deploy and construct physical barriers to ensure complete operational control of the southern border of the United States. Executive Order 14165, section 3 (Jan. 20, 2025).

Congress has provided to the Secretary of Homeland Security a number of authorities necessary to carry out DHS's border security mission. One of those authorities is found at section 102 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, as amended (''IIRIRA''). Public Law 104–208, Div. C, 110 Stat. 3009–546, 3009–554 (Sept. 30, 1996) (8 U.S.C 1103 note), as amended by the REAL ID Act of 2005, Public Law 109–13, Div. B, 119 Stat. 231, 302, 306 (May 11, 2005) (8 U.S.C. 1103 note), as amended by the Secure Fence Act of 2006, Public Law 109–367, section 3, 120 Stat. 2638 (Oct. 26, 2006) (8 U.S.C. 1103 note), as amended by the Department of Homeland Security Appropriations Act, 2008, Public Law 110–161, Div. E, Title V, section 564, 121 Stat. 2090 (Dec. 26, 2007). In section 102(a) of IIRIRA, Congress provided that the Secretary of Homeland Security shall take such actions as may be necessary to install additional physical barriers and roads (including the removal of obstacles to detection of illegal entrants) in the vicinity of the United States border to deter illegal crossings in areas of high illegal entry into the United States. In section 102(b) of IIRIRA, Congress mandated that in carrying out the authority of section 102(a), I provide for the installation of additional fencing, barriers, roads, lighting, cameras, and sensors to achieve and maintain

operational control of the border. Finally, in section 102(c) of IIRIRA, Congress granted to the Secretary of Homeland Security the authority to waive all legal requirements that I, in my sole discretion, determine necessary to ensure the expeditious construction of barriers and roads authorized by section 102 of IIRIRA.

**Determination and Waiver**

*Section 1*

The U.S. Border Patrol El Paso Sector is an area of high illegal entry. Between fiscal year 2021 and August 30, 2026, Border Patrol apprehended over 1,248,000 illegal aliens attempting to enter the United States between border crossings in the El Paso Sector. In that same time period, Border Patrol seized over 1,580 pounds of marijuana, over 2890 pounds of cocaine, over 3,450 pounds of methamphetamine, over 40 pounds of heroin, and over 285 pounds of fentanyl.

Since the President took office, DHS has delivered the most secure border in history. More can and must be done, however. As the statistics cited above demonstrate, the El Paso Sector is an area of high illegal entry where illegal aliens regularly attempt to enter the United States and smuggle illicit drugs, and given my mandate to achieve and maintain operational control of the border, I must use my authority under section 102 of IIRIRA to install additional barriers and roads in the El Paso Sector. Therefore, DHS will take immediate action to construct additional barriers and roads in a segment of the border in the El Paso Sector. The segment where such construction will occur is referred to herein as the ''project area,'' which is more specifically described in Section 2 below.

*Section 2*

I determine that the following area in the vicinity of the United States border, located in the state of New Mexico within the U. S. Border Patrol El Paso Sector, is an area of high illegal entry (the ''project area''): Starting at Border Monument 71 and extending east to Border Monument 53, then extending north to Border Monument 40, then extending east to Border Monument 1.

There is presently an acute and immediate need to construct additional physical barriers and roads in the vicinity of the border of the United States in order to prevent unlawful entries into the United States in the project area pursuant to section 102(a) and 102(b) of IIRIRA. In order to ensure the expeditious construction of additional physical barriers and roads in the project area, I have determined that it is necessary that I exercise the authority that is vested in me by section 102(c) of IIRIRA.

Accordingly, pursuant to section 102(c) of IIRIRA, I hereby waive in their entirety, with respect to the construction of physical barriers and roads (including, but not limited to, accessing the project areas, creating and using staging areas, the conduct of earthwork, excavation, fill, and site preparation, designing, drilling, constructing, operating, maintaining, repairing, and plugging of wells, and installation and upkeep of physical barriers, roads, supporting elements, drainage, erosion controls, safety features, lighting, cameras, and sensors) in the project area, all of the following statutes, including all federal, state, or other laws, regulations, and legal requirements of, deriving from, or related to the subject of, the following statutes, as amended: Public Law 82–495, section 208, 66 Stat. 549, 560 (July 10, 1952) (43 U.S.C. 666); the New Mexico Water Code (NMSA 1978, 72–1–1 through 72–20–103); and the New Mexico Administrative Code Title 19, Chapter 27, Part 1 (19.27.1.1 through 19.27.1.39) and Part 4 (19.27.4.1 through 19.27.4.39).

This waiver does not revoke or supersede any other waiver determination made pursuant to section 102(c) of IIRIRA. Such waivers shall remain in full force and effect in accordance with their terms. I reserve the authority to execute further waivers from time to time as I may determine to be necessary under section 102 of IIRIRA.

**Markwayne Mullin,**

*Secretary of Homeland Security.*

[FR Doc. 2026–20233 Filed 10–1–26; 8:45 am]

**BILLING CODE 9111–14–P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–7094–N–10; OMB Control No. 2506–0199]**

## 60-Day Notice of Proposed Information Collection: Recordkeeping for HUD's Continuum of Care Program

**AGENCY:** Office of the Assistant Secretary for Community Planning and Development, HUD.

**ACTION:** Notice of proposed information collection.

**SUMMARY:** HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

**DATES:** Comments due December 1, 2026.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to *www.regulations.gov.* Interested persons are also invited to submit comments regarding this proposal and comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Urnell Johnson, PRA Supervisor, Correspondence Unit, Department of Housing and Urban Development, 451 7th Street SW, Room 7232, Washington, DC 20410.

**FOR FURTHER INFORMATION CONTACT:** Karen DeBlasio, Director, Office of Special Needs Assistance Programs, Office of Community Planning and Development, Department of Housing and Urban Development, 451 7th Street SW, Room 7262, Washington, DC 20410; telephone (202) 402–4773 (This is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Copies of available supporting documents for the proposed collection may be obtained from Ms. DeBlasio.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

**A. Overview of Information Collection**

*Title of Information Collection:* Recordkeeping for HUD's Continuum of Care Program.

*OMB Approval Number:* 2506–0199.

*Type of Request:* Revision.

*Form Number:* N/A.

*Description of the need for the information and proposed use:* This submission is to request an extension of an Existing Collection in use without an OMB Control Number for the Recordkeeping for HUD's Continuum of Care Program (CoC). Continuum of Care program recipients will be expected to implement and retain the information

collection for the recordkeeping requirements. The statutory provisions and implementing interim regulations govern the Continuum of Care Program recordkeeping requirements for recipient and subrecipients and the standard operating procedures for ensuring that Continuum of Care Program funds are used in accordance with the program requirements. To see the regulations for the new CoC program and applicable supplementary documents, visit HUD's Homeless Resource Exchange at *https://www.onecpd.info/resource/2033/hearth-coc-program-interim-rule/.*

*Respondents:* Continuum of Care program recipients and subrecipients.

*Estimated Number of Respondents:* The CoC recordkeeping requirements include 45 distinct activities. Each activity requires a different number of respondents ranging from 10 to 350,000. There are 366,500 unique respondents.

*Estimated Number of Responses:* 2,485,300.

*Frequency of Response:* Each activity has a unique frequency of response, ranging from once to 200 times annually.

*Average Hours per Response:* Each activity also has a unique associated number of hours of response, ranging from 15 minutes to 180 hours.

*Total Estimated Burdens:* The total number of hours needed for all reporting is 1,600,385.50 hours.

| Information collection | Number of respondents | Response frequency (average) | Total annual responses | Burden hours per response | Total annual hours | Hourly rate | Burden cost per instrument |
|---|---|---|---|---|---|---|---|
| A | B | C | D | E | F | | |
| § 578.5(a) Establishing the CoC | 395 | 1 | 395 | 8 | 3,160.00 | 49.07 | 155061.2 |
| § 578.5(b) Establishing the Board | 395 | 1 | 395 | 5 | 1975.00 | 49.07 | 96913.25 |
| § 578.7(a)(1) Hold CoC Meetings | 395 | 2 | 790 | 4 | 3,160.00 | 49.07 | 155061.2 |
| § 578.7(a)(2) Invitation for New Members | 395 | 1 | 395 | 1 | 395 | 49.07 | 19382.65 |
| § 578.7(a)(4) Appoint Committees | 395 | 2 | 790 | 0.5 | 395 | 49.07 | 19382.65 |
| § 578.7(a)(5) Governance Charter | 395 | 1 | 395 | 7 | 2765.00 | 49.07 | 135678.6 |
| § 578.7(a)(6) and (7) Monitor Performance and Evaluation | 395 | 1 | 395 | 9 | 3555.00 | 49.07 | 174443.9 |
| § 578.7(a)(8) Centralized or Coordinated Assessment System | 395 | 1 | 395 | 8 | 3160.00 | 49.07 | 155061.2 |
| § 578.7(a)(9) Written Standards | 395 | 1 | 395 | 5 | 1975.00 | 49.07 | 96913.25 |
| § 578.7(b) Designate HMIS | 395 | 1 | 395 | 10 | 3950.00 | 49.07 | 193826.5 |
| § 578.9 Application for Funds | 395 | 1 | 395 | 180 | 71100.00 | 49.07 | 3488877 |
| § 578.11(c) Develop CoC Plan | 395 | 1 | 395 | 9 | 3555 | 49.07 | 174443.9 |
| § 578.21(c) Satisfying Conditions | 7000 | 1 | 7000 | 4 | 28000.00 | 49.07 | 1373960 |
| § 578.23 Executing Grant Agreements | 7000 | 1 | 7000 | 1 | 7000.00 | 49.07 | 343490 |
| § 578.35(b) Appeal—solo | 10 | 1 | 10 | 4 | 40 | 49.07 | 1962.8 |
| § 578.35(c) Appeal—denied or Decreased Funding | 15 | 1 | 15 | 1 | 15 | 49.07 | 736.05 |
| § 578.35(d) Appeal—competing CoC | 10 | 1 | 10 | 5 | 50 | 49.07 | 2453.5 |
| § 578.35(e) Appeal—Consolidated Plan Certification | 5 | 1 | 5 | 2 | 10 | 49.07 | 490.7 |
| § 578.49(a) Leasing Exceptions | 5 | 1 | 5 | 1.5 | 7.5 | 49.07 | 368.025 |
| § 578.65 HPC Standards | 20 | 1 | 20 | 10 | 200 | 49.07 | 9814 |
| § 578.75(a)(1) State and local Requirements—Appropriate Service Provision | 7,000.00 | 1 | 7,000.00 | 0.5 | 3,500.00 | 49.07 | 171745 |
| § 578.75(a)(1) State and Local Requirements—Housing Codes | 20 | 1 | 20 | 3 | 60 | 49.07 | 2944.2 |
| § 578.75(b) Housing Quality Standards | 72,800.00 | 2 | 145,600.00 | 1 | 145,600.00 | 49.07 | 7144592 |
| § 578.75(b) Suitable Dwelling Size | 72,800.00 | 2 | 145,600.00 | 0.08 | 11,648.00 | 49.07 | 571567.4 |
| § 578.75(c) Meals | 70,720.00 | 1 | 70,720.00 | 0.5 | 35,360.00 | 49.07 | 1735115 |
| § 578.75(e) Ongoing Assessment of Supportive Services | 8,000.00 | 1 | 8,000.00 | 1.5 | 12,000.00 | 49.07 | 588840 |
| § 578.75(f) Residential Supervision | 6,600.00 | 3 | 19,800.00 | 0.75 | 14,850.00 | 49.07 | 728689.5 |
| § 578.75(g) Participation of Homeless Individuals | 11,500.00 | 1 | 11,500.00 | 1 | 11,500.00 | 49.07 | 564305 |
| § 578.75(h) Supportive Service Agreements | 3,000.00 | 100 | 300,000.00 | 0.5 | 150,000.00 | 49.07 | 7360500 |
| § 578.77(a) Signed Leases/Occupancy Agreements | 104,000.00 | 2 | 208,000.00 | 1 | 208,000.00 | 49.07 | 10206560 |
| § 578.77(b) Calculating Occupancy Charges | 1,840.00 | 200 | 368,000.00 | 0.75 | 276,000.00 | 49.07 | 13543320 |
| § 578.77(c) Calculating Rent | 2,000.00 | 200 | 400,000.00 | 0.75 | 300,000.00 | 49.07 | 14721000 |
| § 578.81(a) Use Restriction | 20 | 1 | 20 | 0.5 | 10 | 49.07 | 490.7 |
| § 578.91(a) Termination of Assistance | 395 | 1 | 395 | 4 | 1580 | 49.07 | 77530.6 |
| § 578.91(b) Due Process for Termination of Assistance | 4,500.00 | 1 | 4,500.00 | 3 | 13,500.00 | 49.07 | 662445 |
| § 578.95(d) Conflict-of-Interest Exceptions | 10 | 1 | 10 | 3 | 30 | 49.07 | 1472.1 |
| § 578.103(a)(3) Documenting Homelessness | 300,000.00 | 1 | 300,000.00 | 0.25 | 75,000.00 | 49.07 | 3680250 |
| § 578.103(a)(4) Documenting at Risk of Homelessness | 10,000.00 | 1 | 10,000.00 | 0.25 | 2,500.00 | 49.07 | 122675 |
| § 578.103(a)(5) Documenting Imminent Threat of Harm | 200 | 1 | 200 | 0.5 | 100 | 49.07 | 4907 |
| § 578.103(a)(7) Documenting Program Participant Records | 350,000.00 | 6 | 350,000 | 0.25 | 87,500 | 49.07 | 4293625 |
| § 578.103(a)(7) Documenting Case Management | 8,000.00 | 12 | 96,000.00 | 1 | 96,000.00 | 49.07 | 4710720 |
| § 578.103(a)(13) Documenting Faith-Based Activities | 8,000.00 | 1 | 8,000.00 | 1 | 8,000.00 | 49.07 | 392560 |
| § 578.103(b) Confidentiality Procedures | 11,500.00 | 1 | 11,500.00 | 1 | 11,500.00 | 49.07 | 564305 |
| § 578.105(a) Grant/Project Changes—UFAs | 20 | 2 | 40 | 2 | 80 | 49.07 | 3925.6 |
| § 578.105(b) Grant/Project Changes—Multiple Project Applicants | 800 | 1 | 800 | 2 | 1,600.00 | 49.07 | 78512 |
| Total | 1,072,530 | | 2,485,300 | | 1,600,385.50 | | 78,530,916.49 |

## B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

**C. Authority**

44 U.S.C. 3507.

**Ronald J. Kurtz,**

*Assistant Secretary for Community Planning and Development.*

[FR Doc. 2026–20183 Filed 10–1–26; 8:45 am]

**BILLING CODE 4210–67–P**

## DEPARTMENT OF THE INTERIOR

### Office of the Secretary

**[DOI–2026–0199; 26XD4523WS/DS67010000/DWSN00000.000000/DP67012]**

### Privacy Act of 1974; Matching Program

**AGENCY:** Office of the Secretary, Interior.

**ACTION:** Notice of a new matching program.

**SUMMARY:** In accordance with the Privacy Act of 1974, as amended, and Office of Management and Budget guidance on computer matching, the U.S. Department of the Interior (DOI) is providing notice of the establishment of a new matching program. The matching program will enable the 20 DOI programs listed in the appendix to compare records maintained in applicable DOI systems of records, including INTERIOR/DOI–85, Payroll, Attendance, Retirement, and Leave Records; INTERIOR/DOI–86, Accounts Receivable: FBMS; INTERIOR/DOI–87, Acquisition of Goods and Services: FBMS; and INTERIOR/DOI–89, Grants and Cooperative Agreements: FBMS, with records maintained in the U.S. Department of the Treasury's Do Not Pay Working System. DOI will use the matching program to verify prepayment or pre-award eligibility, identify and prevent improper payments, and conduct related recovery activities.

**DATES:** Submit comments on or before November 2, 2026. This matching program will be effective November 2, 2026 through September 10, 2029.

**ADDRESSES:** You may send comments identified by docket number DOI–2026–0199 by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for sending comments.
- *Email: DOI_Privacy@ios.doi.gov.* Include docket number DOI–2026–0199 in the subject line of the message.
- *U.S. Mail or Hand Delivery:* Walter Clay, Departmental Privacy Officer (Acting), U.S. Department of the Interior, 1849 C Street NW, Room 7112, Washington, DC 20240.

All submissions received must include the agency name and docket number DOI–2026–0199. All comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

**FOR FURTHER INFORMATION CONTACT:** Walter Clay, Departmental Privacy Officer (Acting), U.S. Department of the Interior, 1849 C Street NW, Room 7112, Washington, DC 20240, *DOI_Privacy@ios.doi.gov* or (202) 208–1605.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Computer Matching and Privacy Protection Act of 1988 amended the Privacy Act to establish procedural protections for certain computerized comparisons. The Payment Integrity Information Act of 2019 established the Do Not Pay Initiative.

Pursuant to the Payment Integrity Information Act of 2019, the Secretary of the Treasury, after consultation with the Director of the Office of Management and Budget, authorized a four-year waiver of the matching-agreement requirement under 5 U.S.C. 552a(o) for the class of Do Not Pay matching programs that meet the criteria established in OMB Memorandum M–25–32. The waiver is effective from September 10, 2025, through September 10, 2029.

DOI, in consultation with the U.S. Department of the Treasury, Bureau of the Fiscal Service, determined that the Do Not Pay matching program described in this notice is eligible for the waiver described in OMB Memorandum M–25–32. For purposes of this notice, the matching activities conducted between the Federal benefit programs listed in the appendix to this document and the Do Not Pay Working System constitute a single agency-wide DOI matching program implementing Do Not Pay for DOI's listed programs.[1]

**II. Participating Agencies**

The U.S. Department of the Interior programs listed in the appendix, administered by the Bureau of Indian Affairs and the U.S. Fish and Wildlife Service, will compare records with the Do Not Pay Working System, which is administered by the U.S. Department of the Treasury, Bureau of the Fiscal Service.

**III. Authority for Conducting the Matching Program**

The Payment Integrity Information Act of 2019, 31 U.S.C. 3351 *et seq.;* Executive Order 13520, Reducing Improper Payments (74 FR 62201); Executive Order 14249, Protecting America's Bank Account Against Fraud, Waste, and Abuse (90 FR 14011); and OMB Memorandum M–25–32, Preventing Improper Payments and Protecting Privacy Through Do Not Pay. Additional information regarding the authorities for the collection and maintenance of information for each of the DOI programs that will conduct matches with the Do Not Pay Working System are contained within the systems of records notices listed in the appendix below.

**IV. Purpose(s)**

The purpose of the matching program is to identify and prevent improper payments and support related recovery activities by verifying prepayment or pre-award eligibility through the Do Not Pay Working System. Data elements that are necessary for eligibility determinations for a relevant DOI program that are contained in records from DOI systems of records will be compared with records in Do Not Pay Working System.

When the Do Not Pay Working System identifies a potential match, it will notify the submitting DOI program and identify the database or data source containing the potential match. The DOI program will independently verify the information before taking any action that could affect an individual, applicant, awardee, recipient, vendor, or payee. If the Do Not Pay Working System identifies no match, it will return a no-match response.

**V. Categories of Individuals**

Applicants for or recipients of Federal funds administered through the DOI programs listed in the appendix, including individual awardees, vendors, payees, and sole proprietors whose records are submitted to the Do Not Pay

[1] The statutory definition of the term ''matching program'' means ''any computerized comparison of—(i) two or more automated systems of records or a system of records with non-Federal records'' for certain enumerated purposes. 5 U.S.C. 552a(a)(8). There is a separate statutory definition for ''Federal benefit program.'' See OMB Memorandum M–25–32 at Appendix II, page 2, sec. a.3.iii.1 (recognizing that a single agency matching program may consist of multiple systems of records). Thus, this notice applies to the DNP matching program for multiple Federal benefits programs and associated systems of records within DOI.

Working System for prepayment or pre-award eligibility verification.

## VI. Categories of Records

The categories of records involved in the matching program include identifying, contact, award, payment, and financial information maintained by DOI, and identifying, eligibility, payment, financial, and other payment-verification information maintained in the U.S. Department of the Treasury's Do Not Pay Working System. DOI data elements disclosed for the computerized comparison include Taxpayer Identification Number (TIN), which may include Social Security number (SSN), Employer Identification Number (EIN), or Individual Taxpayer Identification Number (ITIN); awardee/payee name; awardee/payee physical address, including city, state, and ZIP Code; and awardee/payee bank account information, including account number and financial institution routing and transit number. Records returned by the Do Not Pay Working System may include information identifying a potential match and the database or data source in which the potential match was identified.

Records involved in the matching program may also include information returned by the Do Not Pay Working System concerning a potential match and records used or generated by DOI to independently verify the match and conduct any necessary follow-up before taking an action affecting an individual, applicant, awardee, recipient, vendor, or payee. DOI will independently verify information resulting from a potential match before taking such action.

## VII. System(s) of Records

DOI records used in the matching program are maintained, as applicable to each participating program identified in the appendix, in the following systems of records:

- INTERIOR/DOI–85, Payroll, Attendance, Retirement, and Leave Records, 83 FR 34156 (July 19, 2018), modified at 91 FR 10622 (March 4, 2026);
- INTERIOR/DOI–86, Accounts Receivable: FBMS, 73 FR 43772 (July 28, 2008), modified at 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026);
- INTERIOR/DOI–87, Acquisition of Goods and Services: FBMS, 73 FR 43766 (July 28, 2008), modified at 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026); and
- INTERIOR/DOI–89, Grants and Cooperative Agreements: FBMS, 73 FR 43755 (July 28, 2008), modified at 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).

Records in the Do Not Pay Working System are maintained in Department of the Treasury, Bureau of the Fiscal Service .017—Do Not Pay Payment Verification Records, 85 FR 11776 (February 27, 2020), including databases designated for inclusion under applicable law and OMB designation authority.

## Appendix

Below is the list of DOI programs that will match records with the Do Not Pay Working System. For purposes of this notice, matching activities between the programs listed below and the Do Not Pay Working System constitute one agency-wide matching program implementing Do Not Pay for DOI. The applicable DOI systems of records for each program are identified below.

| Bureau/office | Department program name | System of records notice(s) |
|---|---|---|
| Bureau of Indian Affairs (BIA). | Operation and Maintenance, Indian Irrigation Systems, Bureau of Indian Affairs. | INTERIOR/DOI–85, 83 FR 34156 (July 19, 2018); modification published 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–86, 73 FR 43772 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–87, 73 FR 43766 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–89, 73 FR 43755 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026). |
| BIA | Child Care Entitlement to States, Administration for Children and Families, Health and Human Services. | INTERIOR/DOI–86, 73 FR 43772 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–87, 73 FR 43766 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–89, 73 FR 43755 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026). |
| BIA | Low Income Home Energy Assistance, Administration for Children and Families, Health and Human Services. | INTERIOR/DOI–86, 73 FR 43772 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–87, 73 FR 43766 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–89, 73 FR 43755 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026). |
| BIA | Payment to States for the Child Care and Development Block Grant, Administration for Children and Families, Health and Human Services. | INTERIOR/DOI–86, 73 FR 43772 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–87, 73 FR 43766 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–89, 73 FR 43755 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026). |
| BIA | Temporary Assistance for Needy Families, Administration for Children and Families, Health and Human Services. | INTERIOR/DOI–86, 73 FR 43772 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–87, 73 FR 43766 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–89, 73 FR 43755 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026). |
| BIA | Indian Employment Assistance | INTERIOR/DOI–86, 73 FR 43772 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–87, 73 FR 43766 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–89, 73 FR 43755 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026). |
| BIA | Training and Employment Services, Employment and Training Administration, Labor. | INTERIOR/DOI–86, 73 FR 43772 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–87, 73 FR 43766 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–89, 73 FR 43755 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026). |

| Bureau/office | Department program name | System of records notice(s) |
|---|---|---|
| BIA | Minority Business Development, Minority Business Development Agency, Commerce. | INTERIOR/DOI–86, 73 FR 43772 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–87, 73 FR 43766 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–89, 73 FR 43755 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026). |
| BIA | Rehabilitation Services, Education | INTERIOR/DOI–86, 73 FR 43772 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–87, 73 FR 43766 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–89, 73 FR 43755 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026). |
| BIA | Career, Technical, and Adult Education, Education. | INTERIOR/DOI–86, 73 FR 43772 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–87, 73 FR 43766 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–89, 73 FR 43755 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026). |
| BIA | State and Local Law Enforcement Assistance, Office of Justice Programs, Justice. | INTERIOR/DOI–86, 73 FR 43772 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–87, 73 FR 43766 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–89, 73 FR 43755 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026). |
| BIA | Violence Against Women Prevention and Prosecution Programs, Office of Justice Programs, Justice. | INTERIOR/DOI–86, 73 FR 43772 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–87, 73 FR 43766 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–89, 73 FR 43755 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026). |
| BIA | Promoting Safe and Stable Families, Administration for Children and Families, Health and Human Services. | INTERIOR/DOI–86, 73 FR 43772 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–87, 73 FR 43766 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–89, 73 FR 43755 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026). |
| BIA | Children and Families Services Programs, Administration for Children and Families, Health and Human Services. | INTERIOR/DOI–86, 73 FR 43772 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–87, 73 FR 43766 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–89, 73 FR 43755 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026). |
| BIA | Indian Guaranteed Loan Program Account, Bureau of Indian Affairs and Bureau of Indian Education, Interior. | INTERIOR/DOI–85, 83 FR 34156 (July 19, 2018); modification published 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–86, 73 FR 43772 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–87, 73 FR 43766 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026). |
| U.S. Fish and Wildlife Service (FWS). | Partners for Fish and Wildlife | INTERIOR/DOI–86, 73 FR 43772 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–87, 73 FR 43766 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–89, 73 FR 43755 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026). |
| FWS | North American Wetlands Conservation Fund | INTERIOR/DOI–86, 73 FR 43772 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–87, 73 FR 43766 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–89, 73 FR 43755 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026). |
| FWS | Coastal | INTERIOR/DOI–86, 73 FR 43772 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–87, 73 FR 43766 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–89, 73 FR 43755 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026). |
| FWS | Collaborative Landscape Conservation | INTERIOR/DOI–86, 73 FR 43772 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–87, 73 FR 43766 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–89, 73 FR 43755 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026). |
| FWS | North American Wetlands Conservation Fund, United States Fish and Wildlife Service. | INTERIOR/DOI–85, 83 FR 34156 (July 19, 2018); modification published 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–86, 73 FR 43772 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–87, 73 FR 43766 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026).<br>INTERIOR/DOI–89, 73 FR 43755 (July 28, 2008); modifications published 86 FR 50156 (September 7, 2021) and 91 FR 10622 (March 4, 2026). |

**Walter Clay,**

*Departmental Privacy Officer (Acting), U.S. Department of the Interior.*

[FR Doc. 2026–20204 Filed 10–1–26; 8:45 am]

**BILLING CODE 4334–63–P**

## INTERNATIONAL TRADE COMMISSION

**[Investigation Nos. 701–TA–657 and 731–TA–1537 (Review)]**

### Chassis and Subassemblies From China; Scheduling of Expedited Five-Year Reviews

**AGENCY:** United States International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission hereby gives notice of the scheduling of expedited reviews pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping duty and countervailing duty orders on chassis and subassemblies from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

**DATES:** July 6, 2026.

**FOR FURTHER INFORMATION CONTACT:** Peter Stebbins (202) 205–2039), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter 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 (*https://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

**SUPPLEMENTARY INFORMATION:**

*Background.*—On July 6, 2026, the Commission determined that the domestic interested party group response to its notice of institution (91 FR 16223, April 1, 2026) of the subject five-year reviews was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting full reviews.[1] Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Act (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

*Staff report.*—A staff report containing information concerning the subject matter of the reviews has been placed in the nonpublic record, and will be made available to persons on the Administrative Protective Order service list for these reviews on October 5, 2026. A public version will be issued thereafter, pursuant to § 207.62(d)(4) of the Commission's rules.

*Written submissions.*—As provided in § 207.62(d) of the Commission's rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution,[2] and any party other than an interested party to the reviews may file written comments with the Secretary on what determination the Commission should reach in the reviews. Comments are due on or before October 13, 2026, and may not contain new factual information. Any person that is neither a party to the five-year reviews nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the reviews by October 13, 2026. However, should the Department of Commerce (''Commerce'') extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

*Determination.*—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

*Authority:* These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.62 of the Commission's rules.

By order of the Commission.

Issued: September 29, 2026.

**Lisa Barton,**

*Secretary to the Commission.*

[FR Doc. 2026–20201 Filed 10–1–26; 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 Extrusion-Coated Magnet Wire, *DN 3940;* 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

[1] A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's website.

[2] The Commission has found the response submitted on behalf of the Coalition of American Chassis Manufacturers to be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

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 Essex Solutions Inc. and Essex Solutions USA LLC on September 29, 2026. 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 extrusion-coated magnet wire. The complaint names as respondents: Wellascent Electronic (Ganzhou) Co., Ltd. of China; and Wellascent Technologies USA LLC. of Grand Prairie, TX. 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 (5:15 p.m.),[1] eight calendar days after publication of this notice in the **Federal Register**. Complainant(s) may file replies to any written submissions no later than three calendar days after the date on which the written submissions were due. Notwithstanding § 201.14(a) of the Commission's Rules of Practice and Procedure, the deadlines for written submissions and replies shall be counted by calendar days starting with the first calendar day following the **Federal Register** publication date or the due date for written submissions, respectively. The provisions of § 201.14(a) regarding the last day of the period still apply concerning the due date of any filings. 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. 3940'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures.[2] Please note the Secretary's Office will accept only electronic filings unless an exemption is granted. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) 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,[3] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[4]

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: September 29, 2026.

**Lisa Barton,**

*Secretary to the Commission.*

[FR Doc. 2026–20188 Filed 10–1–26; 8:45 am]

**BILLING CODE 7020–02–P**

[1] *See* 19 CFR 201.3(c).

[2] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/secretary/documents/handbook_on_filing_procedures.pdf.*

[3] All contract personnel will sign appropriate nondisclosure agreements.

[4] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

## INTERNATIONAL TRADE COMMISSION

**[Investigation No. 337–TA–1409]**

### Certain Storage Containers and Toolboxes, Organizers, Component Boxes, and Coolers; Notice of a Commission Determination To Find a Violation of Section 337; Issuance of Remedial Orders; Continued Proceedings as to One Patent; Extension of Target Date

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined to find a violation of section 337 of the Tariff Act of 1930, as amended, with respect to U.S. Patent Nos. 11,365,026 (''the '026 patent'') and 11,794,952 (''the '952 patent''). The Commission has determined that the appropriate remedy is the issuance of a limited exclusion

order (''LEO'') and a cease and desist order (''CDO'') with respect to those patents.

The Commission has further determined to set a bond in the amount of eighteen percent (18%) of entered value for covered articles imported or sold during the period of Presidential review. The Commission has not reached a final determination with respect to U.S. Patent No. 11,952,167 (''the '167 patent''). The target date for completion of the above-captioned investigation is extended to November 2, 2026.

**FOR FURTHER INFORMATION CONTACT:** Panyin A. Hughes, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3042. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

**SUPPLEMENTARY INFORMATION:** The Commission instituted this investigation on July 19, 2024, based upon a complaint filed on behalf of Milwaukee Electric Tool Corporation of Brookfield, Wisconsin and Keter Home and Garden Products Ltd. of Israel (collectively, ''Complainants''). 89 FR 58764–65 (July 19, 2024). The complaint, as supplemented, alleges violations 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 storage containers and toolboxes, organizers, component boxes, and coolers by reason of infringement of certain claims of the '026 patent, the '952 patent, and the '167 patent. The Commission's notice of investigation named as the respondent Klein Tools, Inc. of Lincolnshire, Illinois (''Klein''). The Office of Unfair Import Investigations is not a party to this investigation.

Over the course of the investigation, Complainants withdrew their allegations as to certain asserted claims. *See* Order No. 15 (Jan. 24, 2025), *unreviewed by* Comm'n Notice (Feb. 18, 2025); Order No. 19 (Feb. 11, 2025), *unreviewed by* Comm'n Notice (Feb. 24, 2025); Order No. 20 (Feb. 27, 2025), *unreviewed by* Comm'n Notice (Mar. 13, 2025). The asserted claims that remain are claims 4 and 8 of the '026 patent; claims 3, 4, 8, and 16 of the '952 patent; and claims 2, 5, 8, 14, and 15 of the '167 patent. *See* Order No. 20 at 2 n.1.

On August 1, 2025, the Chief Administrative Law Judge (''CALJ'') issued a final initial determination (''FID''), which finds a violation of section 337. Specifically, the FID finds that claims 4 and 8 of the '026 patent; claims 3, 4, 8, and 16 of the '952 patent; and claims 2, 5, 8, 14, and 15 of the '167 patent are infringed and not invalid. The FID also finds that the domestic industry requirement has been satisfied for each of the Asserted Patents pursuant to section 337(a)(3)(A) and (B). The FID declines to make findings as to whether Complainants have satisfied the domestic industry requirement under section 337(a)(3)(C). The FID also includes the CALJ's Recommended Determination, which recommends that, if the Commission finds a violation of section 337, then the Commission should issue a limited exclusion order, a cease and desist order against Klein, and impose a bond of 63 percent of the entered value of infringing articles imported during the period of Presidential review.

On August 15, 2025, Klein filed a petition for Commission review of the FID as to the economic and technical prongs of the domestic industry requirement, and invalidity based on certain prior art. On August 28, 2025, Complainants filed a response to the petition.

On September 2, 2025, Complainants filed a public interest submission pursuant to Commission Rule 210.50(a)(4)(i), 19 CFR 210.50(a)(4)(i). The Commission did not receive any submissions pursuant to the **Federal Register** notice published after issuance of the RD. *See* 90 FR 38175–76 (Aug. 7, 2025).

On January 21, 2026, the Commission determined to review ''the FID's findings concerning the economic prong of the domestic industry requirement, patent invalidity, and the technical prong of the domestic industry requirement, as well as any underlying claim construction findings.'' 91 FR 3220 (Jan. 26, 2026). The Commission determined not to review the remainder of the FID's findings.

The Commission also sought briefing from the parties on certain issues under review and from the parties, interested government agencies, and other interested parties on the issues of remedy, the public interest, and bonding. *Id.*

On February 4, 2026, the Commission received initial submissions from the parties. On February 11, 2026, the Commission received reply submissions from the parties. The Commission received no other submissions.

Having examined the record of this investigation, including the FID, petition, response, and other submissions from the parties, the Commission has determined to find a violation of section 337 with respect to the '952 and '026 patents. Specifically, the Commission has determined to: (1) set aside the FID's finding as to date of the Auer Catalog, but otherwise affirm the FID's finding that Klein failed to show by clear and convincing evidence that any asserted claim was invalid; (2) vacate the FID's alternative reasoning that the technical prong would be satisfied even under Klein's claim construction proposal for ''rib extending [away] from the back wall,'' but otherwise affirm the FID's finding that the technical prong of the domestic industry requirement is satisfied for each asserted claim; and (3) affirm under modified reasoning the FID's finding that the economic prong requirement is satisfied under subsection 337(a)(3)(B) with respect to the '026 and '952 patents. The Commission has not reached a final determination with respect to the '167 patent.

For remedy, the Commission has determined to issue an LEO and a CDO against Klein prohibiting further importation and sale of covered products. The Commission has determined that the public interest factors do not counsel against issuing remedial orders. The Commission has determined that a bond in the amount of eighteen percent (18%) of entered value for covered articles is required for covered products imported or sold during the period of Presidential review.

The investigation is hereby terminated with respect to the '952 and '026 patents. The '167 patent remains pending at the Commission. A Commission opinion issued concurrently with this notice.

The target date for completion of the investigation is extended to November 2, 2026.

The Commission vote for this determination took place on September 29, 2026.

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: September 29, 2026.

**Lisa Barton,**

*Secretary to the Commission.*

[FR Doc. 2026–20208 Filed 10–1–26; 8:45 am]

**BILLING CODE 7020–02–P**

## DEPARTMENT OF JUSTICE

## Drug Enforcement Administration

## By Grace Inc. Counseling Services; Decision and Order

### I. Introduction

On October 29, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to By Grace Inc. Counseling Services of Baltimore, Maryland (Respondent). OSC, at 1. The OSC proposed the revocation of Respondent's DEA registration, No. RB0369733, alleging that Respondent, a narcotic treatment program (NTP), ''demonstrated a lack of effective controls and procedures to guard against the diversion of controlled substances'' and committed numerous recordkeeping violations that rendered DEA unable to determine an accurate and complete inventory of the controlled substances on hand. *Id.* at 2–4 (citing 21 U.S.C. 823(g); 21 U.S.C. 824(a);[1] 21 CFR 1304.11(a)–(c), 1304.11(c), 1304.21(a), (d), 1304.04(a), (f)(2), 1304.24(a), 1305.05). The Government additionally alleged in its Prehearing Statement that Respondent materially falsified its application for a DEA registration by falsely responding ''no'' to Liability Question 4—which asks whether any officer of the corporation has ever been convicted of a crime in connection with controlled substances—and by failing to disclose that its owner was convicted of unlawful possession of controlled substances in Maryland. Administrative Law Judge Exhibit (ALJX) 6, at 2–3.[2]

After conducting a hearing, Administrative Law Judge Paul E. Soeffing (ALJ) issued his Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (Recommended Decision or RD) on May 14, 2025. The RD recommended that the Agency revoke Respondent's registration. RD, at 28. On June 3, 2025, the Government timely filed exceptions. The Agency adopts and hereby incorporates by reference the ALJ's credibility findings,[3] findings of fact, conclusions of law related to the Government's recordkeeping allegations, sanctions analysis, and recommended sanction, and summarizes and clarifies portions thereof herein. The Agency does not adopt the ALJ's conclusions of law related to the Government's material falsification allegation. Specifically, the Agency disagrees with the ALJ's conclusion that the Agency does not have authority to revoke an NTP's registration based on the material falsification of a DEA application and the Agency finds that the Government's material falsification allegation is supported by substantial evidence.

### II. Respondent's Recordkeeping Violations

#### *A. Applicable Law*

Congress enacted the Controlled Substances Act (CSA) ''to conquer drug abuse and control the legitimate and illegitimate traffic in controlled substances.'' *Gonzales* v. *Raich,* 545 U.S. 1, 12 (2005). A particular concern of Congress was ''the need to prevent the diversion of drugs from legitimate to illicit channels,'' and it ''devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.'' *Id.* at 12–13.

The CSA's requirements under this closed regulatory system include that ''every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the [DEA] a registration.'' 21 U.S.C. 822(a)(2); *see also Gonzales* v. *Raich,* 545 U.S. at 27–28. To protect the American people and ensure compliance with the CSA, Congress empowered the Agency to deny, suspend, or revoke a DEA registration if the registrant failed to comply with the CSA's recordkeeping requirements. 21 U.S.C. 824(a); 21 U.S.C. 823(h); *Gonzales* v. *Oregon,* 546 U.S. 243, 251 (2006).

The Respondent in this case is registered as an NTP under 21 U.S.C. 823(h). Under Section 304 of the CSA, ''a registration pursuant to section 823(h)[ ] of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 823(h)[ ][4] of this title.'' 21 U.S.C. 824(a). Section 823(h) outlines three prerequisites for a practitioner applying for a registration to dispense narcotic drugs for maintenance treatment or detoxification treatment:

(1) ''the applicant . . . is determined by the Secretary to be qualified . . . to engage in the treatment with respect to which registration is sought;''

[1] In addition to alleging that Respondent violated 21 U.S.C. 823(h) by failing to maintain adequate records of its dispensing of controlled substances, the OSC alleged that Respondent's recordkeeping violations rendered its registration inconsistent with the public interest under 21 U.S.C. 824(a). OSC, at 2. Because the Government's Post-Hearing Brief discussed Respondent's recordkeeping violations in the context of 21 U.S.C. 823(h) rather than analyzing the public interest factors, the Agency treats the public interest allegation as abandoned and does not consider it.

[2] The Government also alleged that Respondent ordered controlled substances when it lacked state authority. The Agency agrees with the ALJ that the Government did not provide notice in the OSC of the laws violated by this conduct, nor did the Government demonstrate through substantial evidence that Respondent lacked state authority when it ordered the controlled substances. RD, at 18–19.

[3] The Agency adopts the ALJ's summary of each witness's testimony, as well as the ALJ's assessment of each witness's credibility. *See* RD, at 2–13.

[4] The subsection of 21 U.S.C. 823 applicable to narcotic treatment programs was modified on December 2, 2022, and again on December 28, 2022. Prior to the modifications, the relevant subsection applicable to narcotic treatment programs was designated as 21 U.S.C. 823(g)(1), and it had three subparts, A–B, which outlined the prerequisites for registration as a narcotic treatment program. On December 2, 2022, the subsection was redesignated as 21 U.S.C. 823(h)(1), and it retained the same three subparts as the previous version, A–B. On December 28, 2022, the subsection was again redesignated as 21 U.S.C. 823(h), and the three subparts outlining the registration prerequisites were redesignated as 1–3. The December 28, 2022, citation is used throughout this decision.

21 U.S.C. 824(a), which authorizes the Attorney General to suspend or revoke the registration of a narcotic treatment if the registration prerequisites are not met, references back to the relevant subsections of 21 U.S.C. 823. Prior to December 2, 2022, the revocation provisions of § 824(a) referred to the registration prerequisites in § 823(g)(1)(A–B). On December 2, 2022, 21 U.S.C. 824(a) was modified to reference the registration prerequisites in § 823(h)(1)(A–B). However, 21 U.S.C. 824(a) was not modified again to reflect the December 28, 2022 redesignation from 823(h)(1) to 823(h). As explained below, this was clearly an unintentional technical error.

As currently written, 21 U.S.C. 824(a) would only authorize the Attorney General to revoke a registration if the applicant is not ''qualified . . . to engage in the treatment with respect to which registration is sought,'' because it only references 823(h)(1), and not (h)(2) or (h)(3). However, there have not been any substantive changes to § 823 or § 824 that reflect an intent to limit the Attorney General's authority to revoke or suspend. Section 823(h) continues to clearly state that a registrant is not qualified to possess a registration unless all three subparts are met. Therefore, the Agency concludes that the failure to modify § 824(a) on December 22, 2022, was an oversight, and that Congress intended for the Attorney General to retain authority to suspend or revoke a registration if a registrant fails to adhere to any of the three registration prerequisites or standards referred to in section 823(h). *See Dept. of Def., Army Air Force Exchange Serv.* v. *Fed. Labor Relations Auth.,* 659 F.2d 1140, 1160 (D.C. Cir. 1981), cert. denied, 455 U.S. 945 (1982) (A statute should be read in a ''manner which effectuates rather than frustrates the major purpose of the legislative draftsmen.'').

(2) ''the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (A) security of stocks of narcotic drugs for such treatment, and (B) the maintenance of records (in accordance with section 827 of this title) on such drugs''; and

(3) ''the Secretary determines that the applicant will comply with standards established by the Secretary . . . respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.''

21 U.S.C. 823(h).

As the Agency has previously observed, ''in contrast to every other category of registration set forth in section 823, Congress did not characterize these three provisions as 'factors' to be considered and given discretionary weight '[i]n determining the public interest.' . . . Rather, the three subparagraphs of section 823[h] are conditions for registration.'' *Turning Tide, Inc.,* 81 FR 47411, 47413 (2016).

In this matter, the Government's evidence in support of its *prima facie* case relates to Respondent's failure to comply with the requirements of 21 U.S.C. 823(h)(2) regarding ''maintenance of records'' for narcotic drugs. RFAAX 3, at 1–4.

i. Continuing Records

According to the CSA and its implementing regulations, every registrant dispensing controlled substances, including NTPs, ''shall maintain, on a current basis, a complete and accurate record of each controlled substance . . . received, sold, delivered, or otherwise disposed of . . . .'' 21 U.S.C. 827(a)(3); 21 CFR 1304.21(a).[5] These records must include ''the date on which the controlled substances are actually received, distributed, otherwise transferred, or destroyed.'' 21 CFR 1304.21(d). NTPs also must maintain a dispensing log with the following details about each narcotic controlled substance dispensed: ''(1) Name of substance; (2) Strength of substance; (3) Dosage form; (4) Date dispensed; (5) Adequate identification of patient (consumer); (6) Amount consumed; (7) Amount and dosage form taken home by patient; and (8) Dispenser's initials.'' *Id.* § 1304.24(a). The Agency has repeatedly emphasized the importance of maintaining an accurate count of controlled substances on hand, observing that ''the inability to account for a significant number of dosage units creates a grave risk of diversion.'' *Houston Maintenance Clinic,* 83 FR 42144, 42157 (2018) (citing *Med. Shoppe-Jonesborough,* 73 FR 364, 367 (2008); *Paul H. Volkman, M.D.,* 73 FR 30630, 30644 (2008)).

ii. Inventories

NTPs also must maintain an ''initial inventory . . . of all stocks of controlled substances on hand on the date [the pharmacy] first engages in the . . . dispensing of controlled substances,'' as well as a ''biennial inventory . . . of all stocks of controlled substances on hand.'' 21 CFR 1304.11(a)–(c); *see also* 21 U.S.C. 827 (''every registrant . . . shall . . . as soon [] as such registrant first engages in the . . . dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand''). A biennial inventory ''may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.'' 21 CFR 1304.11(a). A biennial inventory shall include, for each controlled substance in finished form: (1) the name of the substance; (2) the finished form of the substance (*e.g.,* 10 mg tablet); (3) the number of units or volume of each finished form in each commercial container (*e.g.,* 100-tablet bottle); and (4) the number of commercial containers of each such finished form (*e.g.,* four 100-tablet bottles). 21 CFR 1304.11(e)(1)(iii); *see* 21 CFR 1304.11(e)(6) (''Each person registered or authorized to dispense or conduct research with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.''). The registrant must make an exact count or measure of controlled substances listed in Schedule I or II. 21 CFR 1304.11(e)(6)(i). For substances in Schedules III, IV, or V, the registrant must ''make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.'' 21 CFR 1304.11(e)(6)(ii). Inventories and other records must be retained in a readily retrievable manner ''for at least 2 years from the date of such inventory or records, for inspection and copying.'' 21 CFR 1304.04(a).

iii. DEA Form 222

The CSA's implementing regulations specify the manner in which a DEA registrant authorized to order Schedule I and II controlled substances must fill out and execute a DEA Form 222. When a purchaser initiates an order of controlled substances, the purchaser fills out the form according to 21 CFR 1305.12. Then, the purchaser makes a copy of the original Form 222 and submits the original to the supplier from which it is ordering. 21 CFR 1305.13(a). Once the order is filled, the purchaser must record on its copy of the Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser. 21 CFR 1305.13(e). If a DEA Form 222 cannot be filled for any reason, ''the supplier must return the original DEA Form 222 to the purchaser with a statement as to the reason,'' and the purchaser must maintain these records. 21 CFR 1305.15(b), (d). ''The purchaser must retain a copy of each executed DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.'' 21 CFR 1305.17(a). ''DEA Forms 222 must be maintained separately from all other records of the registrant . . . [and] are required to be kept available for inspection for a period of two years.'' 21 CFR 1305.17(c).

iv. Powers of Attorney

Generally, only persons who are registered to handle Schedule I or II controlled substances may obtain and use a DEA Form 222 or issue electronic orders for Schedule I or II controlled substances. 21 CFR 1305.04(a). However, a registrant may execute a power of attorney to authorize one or more individuals to issue orders for Schedule I and II controlled substances on the registrant's behalf. 21 CFR 1505.05. If the registrant is not an individual, the power of attorney must be executed by an officer of the registrant in addition to the person to whom the power of attorney is being granted and two witnesses. 21 CFR 1305.05(d). A power of attorney may be revoked at any time by the person who signed the most recent application for DEA registration or reregistration, and the revocation form must be signed by two witnesses. 21 CFR 1305.05(e), (f). Powers of attorney must be ''retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney,'' and they ''must be available for inspection together with other records.'' 21 CFR 1305.05(a).

[5] Pursuant to 21 CFR 1304.03, 1304.21, every registrant, unless exempted, must comply with the recordkeeping and inventory requirements outlined in DEA's implementing regulations. NTPs are explicitly named in 21 CFR 1304.04(f) as a registrant that must maintain records.

*B. Findings of Fact*

Respondent has a history of recordkeeping violations that have resulted in the issuance of Letters of Admission (LOA) by DEA. Tr. 23; RD, at 3–4. The first LOA in 2015 cited several recordkeeping violations, including failing to maintain a biennial inventory, failing to properly fill out DEA Forms 222, and storing 70 bottles of methadone (a Schedule II controlled substance) on the floor of the nurses' station. Tr. 27; GX 2, at 1; RD, at 3. Respondent entered a Memorandum of Agreement (''MOA'') with DEA in 2018 in which Respondent agreed that it had committed numerous recordkeeping violations, including failing to maintain a biennial inventory, failing to accurately record the number of packages received on DEA Forms 222, and failing to maintain a functioning alarm system. Tr. 27–29; GX 3, at 1; RD, at 3, 16. The MOA referenced recordkeeping violations that DEA investigators had discovered during audits in 2009, 2014, and 2017. GX 3, at 1; RD, at 17.

DEA issued another LOA in 2022 outlining further recordkeeping violations found during a September 7, 2022 inspection, including failing to indicate on the biennial inventory whether it was taken at the beginning of business or the close of business, failing to have two witnesses execute a power of attorney, and failing to maintain a written record of individuals authorized to receive controlled substances. Tr. 30–32; GX 4, at 1; RD, at 3. Respondent denied these violations in its Answer to the OSC, ALJX 3, at 1, but the Government submitted a letter written by Respondent on January 23, 2023, indicating that Respondent was taking corrective action to remedy the violations outlined in the 2022 LOA. GX 4, at 3; RD, at 17. This letter indicates that Respondent was aware of the recordkeeping violations in 2022 and did not contest them.

DEA received a complaint from the Maryland Behavioral Health Administration about Respondent in February of 2024 and DEA conducted an onsite inspection of Respondent on March 28, 2024. Tr. 20–21, 158; RD, at 4. DEA investigators [6] were unable to complete the inspection on that date because Respondent's owner, Pamela Dukes (Ms. Dukes), was unable to provide access to the dispensing room or to retrieve requested records, including dispensing records and DEA Forms 222. Tr. 37–38, 160; RD, at 4.

DEA investigators returned to Respondent on April 17, 2024, to complete the audit. Tr. 39–40, 160. Ms. Dukes, S.R. (a nurse), and Respondent's attorney were present. Tr. 40, 45; RD, at 4. DEA investigators retrieved some DEA Forms 222 and dispensing records and conducted a closing count and an alarm test. Tr. 40–41, 43–44, 46; GX 8, 10, 13. At the conclusion of the April 17, 2024 onsite visit, DEA investigators requested, but did not receive, powers of attorney, an alarm testing report, medical licenses, and additional DEA Forms 222. Tr. 47–48. Subsequently, Respondent provided investigators with the powers of attorney via email on April 19 and April 20, 2024. Tr. 48–49, 161; GX 9. Respondent also provided two additional dispensing reports via email. Tr. 51–53; GX 18.

DEA uncovered numerous recordkeeping violations during the 2024 audit.

Continuing Records

DEA's audit of Respondent's controlled substances revealed overages and shortages. Tr. 94–134; GX 12; RD, at 5, 23–24. These included an overage of 102,043 milligrams of methadone liquid,[7] an overage of four 5-mg tablets of methadone,[8] a shortage of eleven 10-mg tablets of methadone, and a shortage of 378 40-mg tablets of methadone. Tr. 106–07, 112–23, 135, 143; GX 12; RD, at 24. The audit also showed that Respondent had commingled 40-mg methadone tablets from various manufacturers into one column of dispensing thereby failing to keep a complete and accurate count of the controlled substances. Tr. 74, 120–21, 174; RD, at 24.

Respondent did not provide any reconciliation for the overages and had no comment on the overages during the closing discussion on July 22, 2024. Tr. 108, 175; RD, at 6. The closing discussion was conducted with S.R. and Ms. Dukes' child because Ms. Dukes excused herself before the closing discussion began. Tr. 124; RD, at 6. DEA investigators were therefore unable to do a reconciliation that reduced the shortage. Tr. 166. At the hearing, Ms. Dukes disputed the Government's calculations of the overages and shortages, but even under Ms. Dukes' calculations, there were still minor overages and shortages.[9] ALJX 18, at 7–8.

Accordingly, the Agency finds substantial evidence that Respondent's controlled substances inventory contained unexplained overages and shortages, which demonstrates that Respondent failed to maintain a complete and accurate record of controlled substances.

Further, DEA investigators reviewed the dispensing records supplied by Respondent on July 22, 2024, and they did not include all the information required by 21 CFR 1304.24(a). Tr. 127, 131–34; GX 11; RD, at 24. The records were missing the patient's full name, the name of the controlled substance and/or the dosage form, the amount administered on site, and/or the take-home dosage. Tr. 132–34; GX 11, at 1–17; RD, at 7, 24. Accordingly, the Agency finds substantial record evidence that Respondent's dispensing records did not contain the information required by 21 CFR 1304.24(a)(3).

Inventories

DEA investigators received five biennial inventories, dated April 4, 2022, October 24, 2022, April 4, 2023, October 1, 2023, and April 4, 2024. Tr. 55; GX 8; RD, at 4, 20. The testimony and evidence demonstrated and the Agency finds substantial evidence that all five inventories failed to include the number of units in each commercial container, Tr. 57–62; GX 8; that the inventories on April 4, 2022, October 24, 2022, and April 4, 2023, failed to indicate whether the inventory was taken at the beginning or the close of business, Tr. 57–59; GX at 3–5; and that the inventory on April 4, 2024, failed to properly name the substance. Tr. 61–62; GX 8, at 1; RD, at 20.

[6] Two Diversion Investigators, DI1 and DI2, testified at the hearing about the investigation. They are referred to collectively throughout this Decision as ''DEA investigators,'' or individually as DI1 and DI2.

[7] The overage indicates that Respondent dispensed more methadone than Respondent had on hand. Tr. 106–07, 143; RD, at 6.

[8] A shortage indicates that tablets that should be on site are missing. Tr. 112–14; RD, at 6. Respondent's only explanation for the shortage was that the methadone had been used. Tr. 114–15; RD, at 6.

[9] Ms. Dukes testified that there were ''glitches'' in the software Respondent used to conduct inventories and testified that the electronic reports would never be accurate. Tr. 241, 244, 249; RD, at 10. Ms. Dukes testified that Respondent maintained hand count inventories that reconciled the shortages. Tr. 244; RD, at 10. For example, Ms. Dukes testified that Respondent's hand count inventories for the 12-month period from April 2023 to April 2024 showed that only 1.25 tablets of Methadone and 0.08 milligrams of liquid Methadone were missing. Tr. 244–45.

DI1 testified that she did not accept Ms. Dukes' reconciliation because the hand records did not contain adequate information. Tr. 129, 135; GX 11. For example, they did not contain the name of the controlled substance, they did not adequately identify the patients, they did not indicate how much of a particular controlled substance was consumed at the window during the dispensing or how much was taken home by the patient, and, other than the first page, they did not include the dosage form. Tr. 132–134; GX 11, at 1–17.

Powers of Attorney

The Government introduced four powers of attorney into evidence. Tr. 65–71; GX 9. The testimony and evidence demonstrated and the Agency finds substantial evidence that all four powers of attorney lacked the requisite witness signatures and therefore were improperly executed and/or improperly revoked. Tr. 65–71; GX 9; RD, at. Specifically, the powers of attorney for J.M. and Y.B. and two powers of attorney for S.R. were missing the second witness signature needed for proper execution, and the revocation of the power of attorney for Y.B. was missing the witness signatures needed for proper revocation. Tr. 66–71; GX 9; RD, at 21.

DEA Forms 222

The testimony and evidence demonstrated and the Agency finds substantial evidence that fifteen DEA Forms 222 were not properly executed because they did not include the proper name or strength of the controlled substance, they did not include the date the controlled substances were received or included incorrect dates, and/or they indicated the wrong number of packages or package size. Tr. 74–85, 88–91; GX 13, RD, at 5, 22. The testimony and evidence also demonstrated, and the Agency finds substantial evidence that, S.R. executed fourteen DEA Forms 222 without a properly executed power of attorney authorizing her to order controlled substances on Respondent's behalf. Tr. 92–93; GX 13, 15; RD, at 22. Finally, the testimony and evidence demonstrated and the Agency finds substantial evidence that Respondent failed to attach a cancellation form to a DEA Form 222 for an order that was cancelled by the distributor. Tr. 89–90; GX 13; RD, at 23.

*C. Conclusions of Law*

Evidence is considered under section 823(h)(2) when it reflects a failure to comply with ''standards established by the Attorney General respecting . . . the maintenance of records (in accordance with [21 U.S.C.] 827 . . .) on such drugs.'' 21 U.S.C. 823(h)(2). Here, based on Respondent's admissions and the findings above, the Agency finds substantial evidence that Respondent: failed to maintain a complete and accurate record of each controlled substance received and disposed of, in violation of 21 U.S.C. 827(a)(3) and 21 CFR 1304.21(a); failed to maintain a dispensing log containing the details required by 21 CFR 1304.24(a); failed to conduct and maintain a biennial inventory with the details required by 1304.11(e)(1)(iii); failed to properly execute fifteen DEA Forms 222, in violation of 21 CFR 1305.13, 1305.15, 1307.74; failed to properly execute and/or revoke four powers of attorney, in violation of 21 CFR 1305.05(d), (e); allowed an individual without a properly executed power of attorney to order controlled substances, in violation of 21 CFR 1305.04; and failed to attach a cancellation form to one DEA Form 222, in violation of 21 CFR 1305.17(a) and 1305.15(d).

The Agency finds that the Government's evidence satisfies its *prima facie* burden of demonstrating that Respondent has failed to comply with the requirements of 823(h)(2) regarding ''maintenance of records'' for narcotic drugs.[10] 21 U.S.C. 823(a); 21 CFR 1301.44. The Agency also finds that there is insufficient mitigating evidence to rebut the Government's *prima facie* case.

**III. Allegation That Respondent Materially Falsified DEA Applications**

*A. Applicable Law*

i. Material Falsification of an Application by an NTP

In this case, there is disagreement about whether DEA has authority under 21 U.S.C. 824(a)(1) to deny, suspend, or revoke an NTP's registration if the NTP has materially falsified an application for a DEA registration. The ALJ concluded that DEA does not have such authority and declined to consider the Government's material falsification allegation. The Government filed Exceptions disagreeing with the ALJ. The Agency agrees with the Government and finds that the CSA authorizes DEA to suspend or revoke an NTP's registration if DEA makes a finding under any of the subsections of 21 U.S.C. 824(a), including that the registrant has materially falsified an application ((a)(1)), has been convicted of a felony related to controlled substances ((a)(2)), has lost state authority to handle controlled substances ((a)(3)), or has been excluded from participation in a federal healthcare program ((a)(5)).[11] This interpretation is supported by a plain language reading of Section 824(a) and is the most logical implementation of Congress' intent.

Background

The CSA's provisions governing registration requirements to manufacture, distribute, or dispense controlled substances are outlined in 21 U.S.C. 823. Section 823 contains separate subsections identifying the registration requirements for different categories of registrants, including manufacturers (section 823(a), (c), (e)), distributors (sections 823(b), (f)), practitioners (section 823(g)), and NTPs (section 823(h)).

The CSA's provisions governing DEA's authority to revoke or suspend DEA registrations are outlined in 21 U.S.C. 824(a). Section 824(a) has two unlettered paragraphs that outline the circumstances under which DEA is authorized to suspend or revoke a registration. The first unlettered paragraph outlines DEA's authority to suspend or revoke any registration granted under 21 U.S.C. 823 if DEA makes a finding related to any of 824(a)'s five subsections (material falsification, felony conviction, loss of state authority, public interest, or federal healthcare exclusion). The second paragraph of Section 823(a) outlines an additional ground for DEA to revoke an NTP's registration if the NTP ''has failed to comply with any standard referred to in section 823(h),'' which outlines the registration requirements for NTPs.

DEA's Authority To Revoke an NTP's Registration

The ALJ, referencing prior Agency decisions, concluded that the second paragraph of section 824(a)—which was added in 1974 with the passage of the Narcotic Addict Treatment Act of 1974 (NATA)—identifies the *only* grounds available for DEA to revoke the registration of an NTP, and that DEA is not authorized to revoke an NTP's registration based on the grounds in section 824(a)(1)–(5). RD, at 14–16

[10] Respondent's recordkeeping violations provide an independent and sufficient basis to revoke Respondent's registration. As discussed below, Respondent repeatedly committed recordkeeping violations over the course of nearly a decade despite DEA's multiple attempts to bring Respondent into compliance. Respondent's failure to unequivocally accept responsibility for these violations demonstrates that DEA cannot trust Respondent with a registration and that revocation is necessary to achieve goals of specific and general deterrence.

[11] The Agency believes that the most logical, plain language interpretation of 21 U.S.C. 824(a) authorizes DEA to revoke an NTP's registration if DEA determines that the NTP's registration is inconsistent with the public interest under 21 U.S.C. 824(a)(4). However, 21 U.S.C. 824(a)(4) instructs the Agency to consider the public interest factors applicable to the registrant under 21 U.S.C. 823, and 21 U.S.C. 823(h) does not identify public interest factors applicable to NTPs. The registration provisions for other registrants—such as practitioners and manufacturers—do identify applicable public interest factors. If the Agency were confronted with a public interest case involving an NTP, the Agency would apply the set of public interest factors under section 823 that are most relevant to the entity's operation considering the facts of the case.

(citing *Turning Tide, Inc.,* 81 FR 47411, 47413 (2016) [12]; *Houston Maintenance Clinic,* 83 FR 42144, 42156 (2018)). The Agency does not find support for this interpretation in 21 U.S.C. 823 or 824(a). A plain language reading of the first paragraph of section 824(a)—which gives DEA authority to revoke ''[a] registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or list I chemical'' for five enumerated reasons—supports the Agency's interpretation that it may revoke the registration of an NTP (which is ''a registration pursuant to section 823'') for any of the five enumerated reasons. There is no language in section 824(a) or 823 that contradicts the straightforward language in the first paragraph or implies that DEA may not revoke the registration of an NTP based on the grounds enumerated in the first paragraph.

The ALJ did not identify any authority suggesting that Congress intended for NTPs—which dispense the most addictive and dangerous of the controlled substances—to have fewer guardrails than other registrants. Of course, an NTP who materially falsifies an application or whose owner has commited a felony related to controlled substances is just as likely to pose a threat to the public as any other registrant who does the same. Thus, the Agency believes that its plain language interpretation implements Congress' intent.

In its Exceptions, the Government identifies a portion of NATA's legislative history that supports the Agency's conclusion that Congress did not intend to limit the Agency's authority to revoke registrations of NTPs. NATA was passed on May 14, 1974, and amended the CSA to require, among other things, that ''[p]ractitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment'' must ''obtain annually a separate registration for that purpose.'' 88 Stat. 124, sec. 3, codified at 21 U.S.C. 823(g) (1974). NATA also added the subparagraph referenced above to section 21 U.S.C. 824(a) adding additional grounds for revocation of NTPs' registrations.

The Senate Bill that introduced these amendments (S. 1115, Mar. 6, 1973) proposed to add ''or'' between the already-included revocation grounds (which, at the time, were limited to material falsification, felony conviction, and loss of state authority) and the new paragraph containing the additional revocation ground for NTPs. S. 1115, 93rd Cong., 1st Sess., at 3 (Mar. 6, 1973). The inclusion of ''or'' would have removed any ambiguity as to whether an NTP's registration could be revoked on the original revocation grounds. The bill that was ultimately passed included alternate language from the text of the House Bill, introduced as H.R. 12503 by Representative Hastings on February 4, 1974, which laid out the new revocation grounds for NTPs as a separate sentence and did not include the word ''or.'' H.R. 12503, 93rd Cong., 2d Sess., at *3 (Feb. 4, 1974). However, as the Government observes in its Exceptions, ''nothing in the legislative history suggests that there is any meaningful difference between the bills' differing approaches to amending 21 U.S.C. 824(a), or that Congress intended the House bill's approach to limit the Attorney General's authority for revoking/suspending NTP registrations.'' Government's Exceptions, at 5.

Accordingly, the Agency concludes that it has authority to revoke an NTP's registration based on the material falsification of an application.

ii. Material Falsification of an Application

A DEA registration may be denied, suspended, or revoked upon a finding that the applicant or registrant materially falsified any application filed pursuant to or required by the CSA. 21 U.S.C. 824(a)(1).[13] To present a *prima facie* case for material falsification, the Government's record evidence must show (1) the submission of an application, (2) containing a false statement and/or omitting information that the application requires, (3) when the submitter knew or should have known that the statement is false and/or that the omitted information existed and the application required its disclosure, and (4) the false statement and/or required but omitted information is material, that is, it ''connect[s] to at least one of [the section 823] factors that, according to the CSA, [the Administrator] 'shall' consider'' when analyzing ''whether issuing a registration 'would be inconsistent with the public interest.' '' *Frank Joseph Stirlacci, M.D.,* 85 FR 45229, 45238 (2020) (citing 21 U.S.C. 823 and *Kungys,* 485 U.S. at 771); *see also Sasha Melissa Ikramelahai,* 90 FR 32017, 32019 (2025); *Michael Bouknight,* 90 FR 31247, 31249 (2025).

Regarding materiality, *Kungys* holds that a statement is material if it is ''predictably capable of affecting, *i.e.,* had a natural tendency to affect, the [Agency's] official decision,'' or stated differently, ''had a natural tendency to influence the decision.'' *Kungys,* 485 U.S. at 771–72. As already discussed, materiality, for the purposes of the CSA, is tied to the factors that the Administrator ''shall'' consider when determining whether issuance of a registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823; *Kungys,* 485 U.S. at 771–72; *Stirlacci,* 85 FR at 45234, 45238. The Government must establish material falsification with record evidence that is clear, unequivocal, and convincing. *Kungys,* 485 U.S. at 772; *Stirlacci,* 85 FR at 45230–39.

*B. Findings of Fact*

Respondent submitted its initial application for a DEA registration in 2008 and has submitted at least 16 renewal applications since then. Tr. 193:24–194:7, GX 14a, 14b. On each application, Respondent answered ''no'' to Liability Question 4, which states, ''If the applicant is a corporation, association, partnership, or pharmacy, has any officer, partner, stockholder or proprietor been convicted of a crime in connection with controlled substances under state or federal law[ . . . ]?'' GX 14b. The testimony and evidence demonstrated, and the Agency finds clear and convincing record evidence, that these responses were false. Ms. Dukes, the owner of Respondent and signatory on Respondent's DEA registration applications, was convicted of Controlled Dangerous Substance unlawful possession—a crime related to controlled substances—on June 5, 1991, in Anne Arundel District Court. GX 15.

[12] In *Turning Tide,* a prior administration determined that DEA did not have authority to revoke an NTP's registration on public interest grounds in part because the NTP registration provision, 21 U.S.C. 823(h), does not seem to authorize DEA to deny an NTP's application on public interest grounds, in contrast to the registration provisions for manufacturers, distributors, and practitioners. 21 U.S.C. 823. The prior administration also inferred that because the revocation provision in 21 U.S.C. 824(a) contains a second paragraph that states that it specifically applies to NTPs, Congress did not intend for the first paragraph to apply to NTPs. As discussed herein, the Agency interprets these provisions differently. Nevertheless, in this case, the Agency is tasked with determining whether it has authority to revoke an NTP's registration based on a material falsification allegation, not a public interest allegation, as in *Turning Tide.* The potential complexities associated with applying the public interest factors to an NTP are not present in a material falsification case.

[13] A statutory basis to deny an application pursuant to section 823 is also a basis to revoke or suspend a registration pursuant to section 824, and vice versa, because doing ''otherwise would mean that all applications would have to be granted only to be revoked the next day . . . .'' *Robert Wayne Locklear, M.D.,* 86 FR 33738, 33744–45 (2021) (collecting cases).

The Supreme Court's decision in *Kungys* v. *United States,* 485 U.S. 759 (1988), and its progeny, guide the Agency's implementation of these CSA provisions.

*C. Conclusions of Law*

As the Agency found above, Respondent submitted at least 17 applications for a DEA registration that contained false statements.[14] These false statements were material because they ''deprived [DEA] of information potentially relevant to'' the Agency's analysis. *Stirlacci,* 85 FR at 45234–35; 21 U.S.C. 823(h). Respondent's falsities are connected to two of the determinations that must be made before registering an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment. 21 U.S.C. 823(h). First, the falsity is potentially relevant to DEA's determination of whether the applicant will ''comply with standards established by the Attorney General respecting (A) security of stocks of narcotic drugs for such treatment, and (B) the maintenance of records . . . on such drugs.'' 21 U.S.C. 823(h)(2). Second, the falsity is potentially relevant to the Health and Human Services analysis regarding whether the applicant will ''respect[] the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.'' 21 U.S.C. 823(h)(3). Because Respondent's false statements deprived the Agency of information potentially relevant to its analysis, they were ''predictably capable of affecting . . . [DEA's] official decision'' regarding whether Applicant met ''the requirements for'' registration. *Kungys,* 485 U.S. at 771. DI2 testified that if Respondent had disclosed Ms. Dukes' conviction, DEA would have conducted ''further research into the charges and how it could potentially affect [Respondent's] handling controlled substances in their proposed business activity.'' Tr. 195.

In sum, the Agency finds clear, unequivocal, and convincing record evidence that Respondent submitted materially false applications for registration.[15] 21 U.S.C. 824(a)(1).[16]

As a result of this established violation, the Agency finds that the Government has established a *prima facie* case for sanction, that Registrant did not rebut that *prima facie* case, and that there is clear, unequivocal, and convincing record evidence supporting the revocation of Registrant's registration. 21 U.S.C. 824(a)(1).

## IV. Sanction

Where, as here, the Government has met its prima facie burden of showing that Respondent's continued registration is inconsistent with the public interest due to its numerous violations pertaining to controlled substances, the burden shifts to Respondent to show why it can be entrusted with a registration. *Morall,* 412 F.3d. at 174; *Jones Total Health Care Pharmacy,* 881 F.3d 823, 830 (11th Cir. 2018); *Garrett Howard Smith, M.D.,* 83 FR 18882 (2018). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent. *Jeffrey Stein, M.D.,* 84 FR 46968, 46972 (2019); see also *Jones Total Health Care Pharmacy,* 881 F.3d at 833. Moreover, as past performance is the best predictor of future performance, DEA Administrators have required that a registrant who has committed acts inconsistent with the public interest must accept responsibility for those acts and demonstrate that it will not engage in future misconduct. *Jones Total Health Care Pharmacy,* 881 F.3d at 833. A registrant's acceptance of responsibility must be unequivocal. *Id.* at 830–31. In addition, a registrant's candor during the investigation and hearing has been an important factor in determining acceptance of responsibility and the appropriate sanction. *Id.* Further, DEA Administrators have found that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Id.* at 834 and n.4. DEA Administrators have also considered the need to deter similar acts by the respondent and by the community of registrants. *Jeffrey Stein, M.D.,* 84 FR at 46972–73.

*A. Acceptance of Responsibility*

Here, the ALJ found, and the Agency agrees, that Respondent did not unequivocally accept responsibility for its misconduct. RD, at 27. Although Respondent stated multiple times in its post-hearing brief that it accepts responsibility for the recordkeeping violations, *e.g.,* ALJX 18, at 7, 14, Respondent repeatedly minimized these violations. For example, Respondent referred to them as ''technical missteps'' and argued that it was ''grossly misguided'' for the Government to assert that these errors warranted revocation. *Id.* Respondent's attempts to minimize this egregious misconduct undermine any purported acceptance of responsibility. *Michael A. White* v. *Drug Enf't Admin.,* 626 F. App'x 493, 496–97 (5th Cir. 2015); *see also Phong H. Tran, M.D.,* 90 FR at 14385.

Respondent also attempted to shift blame for the overages and shortages to ''glitches'' in the Methasoft software it used and suggested that it was ''not fair'' that DEA investigators conducted a physical hand count of controlled

[14] Ms. Dukes testified at the hearing that she did not know that she had been convicted of a crime because ''it [ ] showed up as nolle processed.'' Tr. 215–16. Respondent seems to concede in its Post-Hearing Brief that Ms. Dukes knew about the conviction, but that her ''failure to disclose was the result of a good-faith belief that the aged conviction, having long since been resolved, was not material to the registration process.'' ALJX 18, at 13. Accordingly, the Agency finds that Ms. Dukes knew about the conviction that she failed to disclose.

[15] Respondent argues in its Post-Hearing Brief that Ms. Dukes' failure to disclose her criminal conviction was not a material misrepresentation because the conviction occurred in 1991, nearly three decades ago and approximately seventeen years before Respondent's first DEA application. ALJX 18, at 13. According to Respondent, the conviction occurred during ''a period of Ms. Duke[s'] life that has no bearing on her current professional conduct or eligibility,'' and ''[s]ince that time, Ms. Dukes has fully been rehabilitated, maintained an unblemished professional record, and had no further interactions with law enforcement or disciplinary authorities.'' *Id.* In support of Respondent's argument regarding materiality, Respondent asserts that ''[c]ourts have repeatedly rejected attempts to use 'distant, isolated convictions as dispositive grounds for denial without evidence of current risk or misconduct''' and provides a citation to a case that the Agency was unable to locate. Respondent's Post-Hearing Brief, at 14 (citing *Garcia* v. *Drug Enforcement Admin.,* 2013 U.S. App. LEXIS 24307 (D.C. Cir. 2013)). Because it was unable to locate this case, the Agency cannot verify Respondent's assertion.

Respondent further argues that the Government has not met its burden of proof regarding materiality because it ''has not shown that this seventeen-year-old conviction—if it had been disclosed—would have led to a denial of the application.'' ALJX 18, at 13. However, the Government need not prove that the application would have been denied, but rather that the information that was omitted was ''predictably capable of affecting . . . [DEA's] official decision'' regarding whether Applicant met ''the requirements for'' registration. *Kungys,* 485 U.S. at 771. DEA has held that information is material if it ''connect[s] to at least one of [the section 823] factors that, according to the CSA, [the Administrator] 'shall' consider'' when analyzing whether or not to register an applicant. *Frank Joseph Stirlacci, M.D.,* 85 FR 45229, 45238 (2020) (citing 21 U.S.C. 823 and *Kungys,* 485 U.S. at 771); *see also Sasha Melissa Ikramelahai,* 90 FR 32017, 32019 (2025); *Michael Bouknight,* 90 FR 31247, 31249 (2025). As discussed above, Respondent's conviction relates to two such factors and DI2 testified that DEA would have conducted further research if Respondent had disclosed this conviction. Therefore, the Agency concludes that Respondent's failure to disclose Ms. Dukes' conviction was material.

[16] Although Respondent's material falsification of its DEA applications provides an additional ground to revoke Respondent's registration, the Agency would have revoked Respondent's registration solely based on the substantial evidence that Respondent has repeatedly violated recordkeeping regulations over the course of nearly a decade. Based on Respondent's recidivism, revocation is necessary to achieve goals of specific and general deterrence.

substances at the nurse's station and did not provide her with documentation. RD, at 26 (citing tr. 241, 249). Ms. Dukes opted out of the closing discussion on July 22, 2024, which would have been her opportunity to reconcile any overages or shortages. Tr. 108, 175; RD, at 6. Respondent's implication that DEA's investigation was unfair is not supported by the record and undermines any acceptance of responsibility. *Cf. Ester Mark, M.D.,* 86 FR 16760, 16762 (2021) (finding that the respondent did not accept responsibility because she ''pass[ed] blame on DEA for not telling her how to comply with recordkeeping requirements'').

Respondent also provided incredulous testimony about the material falsification charge that amounted to a denial of responsibility and raised significant concerns about the Agency's ability to trust Respondent moving forward. Ms. Dukes initially testified that she did not disclose her criminal conviction in response to Liability Question #4 because she did not know that she was convicted of any crime until she was served with the OSC. Tr. 215. She further testified that she answered ''no'' because:

> I didn't understand it. I don't know. It was . . . so long ago, and it looked like—it was [sic] showed up as nolle processed. [ ] I don't know what I thought. I don't know. I was told that. I don't know. I just—I'm not going to sit here. I don't know. I just don't know. I was confused. I don't know.

Tr. 215–16. She continued to explain that she did not know about the conviction until she received the OSC and discussed it with her lawyer. Tr. 216. It is not credible for Ms. Dukes to testify that she did not know that she was convicted of a crime when court records show that she pled guilty and served one year of probation. GX 15, at 1. Moreover, if Ms. Dukes was uncertain how to truthfully respond to Liability Question #4, she should have investigated and inquired rather than submitting a falsified form to a federal Agency.

*B. Remedial Measures*

When a registrant fails to make the threshold showing of acceptance of responsibility, the Agency need not address the registrant's remedial measures. *Ajay S. Ahuja, M.D.,* 84 FR 5479, 5498 n.33 (2019) (citing *Jones Total Health Care Pharmacy,* 81 FR at 79202–03); *Daniel A. Glick, D.D.S.,* 80 FR 74800, 74801, 74810 (2015). Even so, the Agency finds that Respondent's evidence of remedial measures would not change the result of this case even if Respondent had unequivocally accepted responsibility. Respondent's limited remedial evidence consisted of Ms. Dukes' testimony that she has employed engineers to rectify issues with Respondent's electronic inventory system and that Respondent now utilizes two large, graduated cylinders to accurately measure its Methadone. ALJX 18, at 8. The Agency finds that these remedial efforts are trivial considering Respondent's decade of recordkeeping errors, and they are not sufficient to restore the Agency's trust.

*C. Deterrence and Egregiousness*

In addition to unequivocally accepting responsibility, the Agency considers both specific and general deterrence when determining an appropriate sanction. *Daniel A. Glick,* 80 FR at 74810. In this case, the Agency agrees with the ALJ that the interests of specific deterrence militate in favor of revocation given Respondent's repeated recordkeeping violations over nearly a decade and Respondent's failure to remediate despite ''repeated actions by DEA to educate the Respondent and bring it into compliance with DEA requirements.'' RD, at 28. The interests of general deterrence also support revocation, as a lack of sanction in the current matter would send a message to the registrant community that the failure to maintain accurate records can be excused. *Id.* As the ALJ stated, where Respondent has ''failed to comply with the requirements concerning controlled substances, despite numerous attempts by the agency to bring the respondent into long-term compliance, the unmistakable message to the regulated community of imposing no sanction or a limited sanction that permits the continued handling of controlled substances by the respondent would be that such conduct can be overlooked.'' *Id.*

Moreover, the Agency agrees with the ALJ that Respondent's actions were egregious. As the ALJ stated, ''Respondent's violations were not limited to a single instance or a single type of violation, but consisted of widespread violations involving numerous biennial inventories over several years, overages and shortage of controlled substances, improper combination of controlled substances in its records, incorrectly filling out DEA 222 forms, and incorrectly executing powers of attorney.'' [17] RD, at 27.

Accordingly, the Agency will order the revocation of Respondent's registration.

**Order**

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby revoke DEA Certificate of Registration No. RB0369733 issued to By Grace Inc. Counseling Services. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby deny any pending applications of By Grace Inc. Counseling Services to renew or modify the named registrations, as well as any other pending application of By Grace Inc. Counseling Services for additional registration in Maryland. This Order is effective November 2, 2026.

**Signing Authority**

This document of the Drug Enforcement Administration was signed on September 25, 2026, by DEA Administrator Terrance C. 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**.

**Heather Achbach,**

*Federal Register Liaison Officer, Drug Enforcement Administration.*

[FR Doc. 2026–20226 Filed 10–1–26; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### St. Michael's Pharmacy; Decision and Order

On September 10, 2025, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to St. Michael's Pharmacy of Rosenberg, Texas (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1. The OSC/ISO informed Registrant of the

[17] Respondent's Post-Hearing Brief cites to a 2010 DEA decision and asserts that, in that case, ''DEA declined to revoke a pharmacy's registration despite 'significant' recordkeeping issues, noting the absence of diversion and the registrant's good-faith corrective measures.'' *East Main Street Pharmacy,* 75 FR 66149 (2010). Respondent misrepresents the case's holding—the Agency determined that the case was moot. Moreover, the Agency affirmed the issuance of an Immediate Suspension Order and noted that, ''[w]hile there is only the suspension order to review . . . , had Respondent filed a renewal application, I would have denied it.'' *Id.* at 66165.

immediate suspension of its DEA Certificate of Registration, No. FS0483951, pursuant to 21 U.S.C. 824(d), alleging that Registrant's continued registration constitutes '' 'an imminent danger to the public health or safety.' '' *Id.* (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposed the revocation of Registrant's DEA Certificate of Registration, alleging that Registrant's continued registration is inconsistent with the public interest. *Id.* (citing 21 U.S.C. 823(g)(1); 824(a)(4)).[1]

The OSC/ISO alleged that from at least March 2023 through February 2025, Registrant violated federal and Texas state law by continuously filling Schedule II controlled substance prescriptions despite obvious red flags of abuse and/or diversion and without addressing or resolving those red flags. RFAAX 1, at 1, 4–5. The OSC/ISO alleged that these unresolved red flags of abuse and/or diversion included pattern prescribing; prescriptions for controlled substances commonly known to be abused, prescriptions for controlled substances at their highest strength and/or in large quantities, the same patient obtaining similar drugs from multiple practitioners, and shared addresses of patients. *Id.* at 1–2, 5–7.

Further, the OSC/ISO alleged that as recently as March 2025, Registrant failed to maintain effective controls against diversion or otherwise comply with the obligations of a registrant. *Id.* at 2, 7–8. Specifically, the OSC/ISO alleged that large quantities of controlled substances were unaccounted for and that records for those controlled substances were not kept in compliance with law. *Id.* at 2, 7–8.

The OSC/ISO alleged that Registrant violated the following federal regulations: 21 CFR 1304.04(a); 21 CFR 1304.11(a)–(c); 21 CFR 1304.21(a); 21 CFR 1306.04(a).[2] RFAAX 1, at 2. The OSC/ISO also alleged that Registrant violated the following Texas state regulations: Tex. Health & Safety Code Ann. § 481.074(a)(1); Tex. Health & Safety Code Ann. § 481.128(a)(1); 22 Tex. Admin. Code Ann. § 291.29(a)–(b), (f); 22 Tex. Admin. Code § 291.33(c)(2)(A)(i)–(ii), (iv); 22 Tex. Admin. Code § 291.33(c)(2)(C); 22 Tex. Admin. Code Ann. § 291.34(a), (b)(1). *Id.* at 3–4.

On October 20, 2025, the Government submitted an RFAA requesting that the Agency issue a default final order revoking Registrant's registration. RFAA, at 6. Further, on June 8, 2026, the Government submitted a Notice of Change of [Registrant]'s State Authority (State Authority Notice). In its State Authority Notice, the Government indicated that on March 11, 2026, the Texas State Board of Pharmacy revoked Registrant's state pharmacy license, thus rendering Registrant without authority to handle controlled substances in Texas, the state in which Registrant is registered with DEA. State Authority Notice, at 1.[3]

On July 28, 2026, the Agency served Registrant via email with a Notice of Allegation and Briefing Order (Allegation Notice). In its Allegation Notice, the Agency notified Registrant of the Government's allegation that Registrant's lack of state authority to handle controlled substances in Texas was an additional basis for revocation of its DEA registration. Allegation Notice, at 2. Additionally in its Allegation Notion, the Agency notified Registrant that Registrant could contest the Government's allegation by submitting a written response and supporting documentary evidence within fifteen days of service of the Allegation Notice. *Id.* To date, the Agency has not received any correspondence from Registrant regarding the Allegation Notice.

After carefully reviewing the entire record and conducting the analysis as set forth in more detail below, the Agency grants the Government's RFAA and revokes Registrant's registration.

## I. Default Determination

Under 21 CFR 1301.43, a registrant entitled to a hearing who fails to file a timely hearing request ''within 30 days after the date of receipt of the [OSC/ISO] . . . shall be deemed to have waived their right to a hearing and to be in default'' unless ''good cause'' is established for the failure. 21 CFR 1301.43(a) & (c)(1). In the absence of a demonstration of good cause, a registrant who fails to timely file an answer also is ''deemed to have waived their right to a hearing and to be in default.'' 21 CFR 1301.43(c)(2). Unless excused, a default is deemed to constitute ''an admission of the factual allegations of the [OSC/ISO].'' 21 CFR 1301.43(e).

Here, the OSC/ISO notified Registrant of its right to file a written request for hearing, and that if it failed to file such a request, it would be deemed to have waived its right to a hearing and be in default. RFAAX 1, at 9–10 (citing 21 CFR 1301.43). According to the Government's RFAA, Registrant failed to request a hearing. RFAA, at 2. Thus, the Agency finds that Registrant is in default and therefore has admitted to the factual allegations in the OSC/ISO.

21 CFR 1301.43(e).

## II. Loss OF State Authority

In addition to the above failures resulting in default, Registrant failed to exercise his opportunity to be heard on his loss of state authority by not responding to the Allegation Notice.

### *A. Findings of Fact*

According to Texas online records, of which the Agency takes official notice,[4] Registrant's Texas pharmacy license 33705 is revoked. Texas State Board of Pharmacy, Texas Pharmacy Search, *https://www.pharmacy.texas.gov/dbsearch/phy_search.asp* (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed to operate as a pharmacy in Texas, the state in which it is registered with DEA.[5]

[1] Based on the Government's submissions in its RFAA dated October 20, 2025, the Agency finds that service of the OSC/ISO on Registrant was adequate. Specifically, the Declaration from a DEA Diversion Investigator (DI) indicates that on September 12, 2025, the OSC/ISO was personally served on Registrant at its registered address. RFAAX 2, at 1; *see also id.,* Attachment A (Form DEA–12 signed by a representative of Registrant acknowledging receipt of the OSC/ISO).

[2] The Agency need not adjudicate the criminal violations alleged in the OSC/ISO. *Ruan* v. *United States,* 597 U.S. 450 (2022) (decided in the context of criminal proceedings).

[3] Although the lack of state authority allegation was not noticed in the OSC, previous Agency decisions have stated that the Government is not required to issue an amended OSC to notice an allegation of lack of state authority that arises during the pendency of a proceeding regarding a DEA registration. *Hatem M. Ataya, M.D.,* 81 FR 8221, 8244–46 (2016). Additionally, previous Agency decisions have stated that because the possession of state authority is a prerequisite for obtaining and maintaining a registration, the issue of state authority can be raised at any stage of a proceeding, even *sua sponte* by the Administrator. *Id.* at 8,244; 21 U.S.C. 824(a)(3); *see also Joe W. Morgan, D.O.,* 78 FR 61961, 61973–74 (2013). However, ''the Agency must give some sort of notice and an opportunity to contest the new allegations.'' *Cypress Creek Pharmacy, LLC,* 86 FR 71927, 71927 (2021); *see also Shelton W. Barnes. M.D.,* 85 FR 5983, 5983 n.3 (2020); *Maura Tuso, D.M.D.,* 86 FR 59196, 59197 n.2 (2021); *Lawrence E. Stewart,* 86 FR 15257, 15257 (2021).

[4] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979).

[5] Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' The material fact here is that Registrant, as of the date of this Order, is not licensed to operate as a pharmacy in Texas. Accordingly, Registrant may dispute the Agency's finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to the Office of the Administrator, Drug Enforcement Administration, at *dea.addo.attorneys@dea.gov.*

*B. Discussion*

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under 21 U.S.C. 823 ''upon a finding that the registrant . . . has had [its] State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *Gonzales* v. *Oregon,* 546 U.S. at 270 (''The Attorney General can register a physician to dispense controlled substances 'if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.' . . . The very definition of a 'practitioner' eligible to prescribe includes pharmacies and physicians 'licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices' to dispense controlled substances. 802(21).''). The Agency has applied these principles consistently. *See, e.g., Irina Gross, D.P.M.,* 91 FR 38016 (2026); *Phong H. Tran, M.D.,* 90 FR 14383 (2025); *Palafox Pharmacy,* 84 FR 18320 (2019).[6]

According to Texas statute, ''dispense'' means ''the delivery of a controlled substance in the course of professional practice or research, by a practitioner or person acting under the lawful order of a practitioner, to an ultimate user or research subject. The term includes the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.'' Tex. Health & Safety Code Ann. § 481.002(12) (West 2026). Further, a ''practitioner'' includes ''a pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in this state.'' *Id.* § 481.002(39)(B).

Here, the undisputed evidence in the record is that Registrant lacks authority to operate as a pharmacy in Texas because its Texas pharmacy license was revoked. As discussed above, a pharmacy must be licensed as a practitioner to dispense or prescribe a controlled substance in Texas. Thus, because Registrant currently lacks authority to operate as a pharmacy in Texas and, therefore, is not currently authorized to handle controlled substances in Texas, Registrant is not eligible to maintain a DEA registration. Accordingly, the Agency finds that Registrant's lack of state authority to handle controlled substances provides an independent basis for revocation of Registrant's DEA registration. 21 U.S.C. 824(a)(3).

## III. Public Interest

*A. Applicable Law*

As the Supreme Court stated in *Gonzales* v. *Raich,* 545 U.S. 1 (2005), ''the main objectives of the [Controlled Substances Act (CSA)] were to conquer drug abuse and control the legitimate and illegitimate traffic in controlled substances.'' 545 U.S. at 12. *Gonzales* explained that:

> Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA . . . . The CSA and its implementing regulations set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping.

*Id.* at 12–14.

The OSC/ISO's allegations concern the CSA's ''statutory and regulatory provisions . . . mandating . . . compliance with . . . security controls to guard against diversion, recordkeeping and reporting obligations, and prescription requirements'' and, therefore, go to the heart of the CSA's ''closed regulatory system'' specifically designed ''to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances,'' and ''to prevent the diversion of drugs from legitimate to illicit channels.'' *Id.* at 12–14, 27.

*Allegation That Registrant Filled Prescriptions Without Addressing or Resolving Red Flags of Abuse and/or Diversion*

According to the CSA's implementing regulations, a lawful prescription for a controlled substance is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). Although ''[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . a corresponding responsibility rests with the pharmacist who fills the prescription.'' *Id.* Pursuant to the CSA's implementing regulations, only a pharmacist ''acting in the usual course of his [or her] professional practice'' may fill a prescription for a controlled substance. 21 CFR 1306.06.

As for state law, Texas regulations state that a Texas pharmacist ''shall exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order'' they dispense and ''shall make every reasonable effort to ensure that any prescription drug order . . . has been issued for a legitimate medical purpose by a practitioner in the course of medical practice.'' 22 Tex. Admin. Code Ann. § 291.29(a)–(b); *see also* 22 Tex. Admin. Code Ann. § 291.34(b)(1); RFAAX 1, at 3.

Texas Administrative Code § 291.29(f) states that ''[a] pharmacist shall make every reasonable effort to prevent inappropriate dispensing due to fraudulent, forged, invalid, or medically inappropriate prescriptions in violation of a pharmacist's corresponding responsibility,'' and provides a list of nineteen ''patterns (*i.e.,* red flag factors) [that] are relevant to preventing the non-therapeutic dispensing of controlled substances.'' 22 Tex. Admin. Code § 291.29(f). The statute further states that these red flags ''shall be considered by evaluating the totality of the circumstances rather than any single factor.'' *Id.* These ''red flag factors'' include:

> (1) the pharmacy dispenses a reasonably discernible pattern of substantially identical prescriptions for the same controlled substances, potentially paired with other drugs, for numerous persons, indicating a lack of individual drug therapy in prescriptions issued by the practitioner; . . .
>
> (3) prescriptions by a prescriber presented to the pharmacy are routinely for controlled substances commonly known to be abused drugs, including opioids, benzodiazepines, muscle relaxants, psychostimulants, and/or cough syrups containing codeine, or any combination of these drugs; . . .
>
> (5) prescriptions for controlled substances are commonly for the highest strength of the

[6] This rule derives from the text of two provisions of the Controlled Substances Act (CSA). First, Congress defined the term ''practitioner'' to mean ''a physician . . . pharmacy . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(g)(1). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., Irina Gross, D.P.M.,* 91 FR 38016; *Phong H. Tran, M.D.,* 90 FR 14383; *Palafox Pharmacy,* 84 FR 18320.

drug and/or for large quantities (*e.g.,* monthly supply), indicating a lack of individual drug therapy in prescriptions issued by the practitioner; . . .

(10) the Texas Prescription Monitoring Program indicates the person presenting the prescriptions is obtaining similar drugs from multiple practitioners, and/or that the person is being dispensed similar drugs at multiple pharmacies; [and]

(11) multiple persons with the same address present substantially similar controlled substance prescriptions from the same practitioner.

22 Tex. Admin. Code Ann. § 291.29(f); RFAAX 1, at 4.

Regarding the operational standards for a pharmacist filling a new prescription, the Texas Board of Pharmacy requires a pharmacist to: (i) review the patient's medication record and, at a minimum, identify clinically significant information such as ''reasonable dose and route of administration; . . . drug-drug interactions; . . . and [ ] proper utilization, including overutilization or underutilization,'' (ii) ''take appropriate steps to avoid or resolve [any] problem'' identified, ''including consultation with the prescribing practitioner''; and (iv) resolve any questions with the prescriber and document the resolution. 22 Tex. Admin. Code Ann. § 291.33(c)(2)(A)(i)–(ii), (iv); RFAAX 1, at 3.[7]

Texas regulations further state that ''[a] pharmacist may not: (1) dispense . . . a controlled substance . . . except under a valid prescription and in the course of professional practice.'' Tex. Health & Safety Code Ann. § 481.074(a)(1); RFAAX 1, at 3.[8]

Allegation That Registrant Failed to Adequately Maintain Complete and Accurate Records

Federal law requires that pharmacies maintain current, complete, and accurate records of all controlled substances. 21 CFR 1304.11(a)–(c); 21 CFR 1304.21(a) (as referenced in 21 CFR 1304.21(c)); RFAAX 1, at 2. This includes a requirement that pharmacies take a complete and accurate inventory of all stock of controlled substances on hand from the date the pharmacy first engages in the dispensing of controlled substances. 21 CFR 1304.11(a)–(c); RFAAX 1, at 2. Such inventories must be kept for at least two years from the date of their creation. 21 CFR 1304.04(a); RFAAX 1, at 2. Federal law also requires that original signed electronic 222 order forms be retained, linked, and maintained on a central server. 21 CFR 1305.27(a), (c).

*B. Findings of Fact*

Allegation That Registrant Filled Prescriptions Without Addressing or Resolving Red Flags of Abuse and/or Diversion

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC/ISO are deemed admitted. 21 CFR 1301.43(e). Accordingly, Registrant is deemed to have admitted and the Agency finds that from at least January 2023 through at least February 2025, Registrant repeatedly filled controlled substance prescriptions that contained multiple red flags of abuse and/or diversion without addressing or resolving those red flags. RFAAX 1, at 5–7.

Pattern Prescribing, Controlled Substances Known To Be Abused, and Highest Strength/Large Quantities

Registrant admits that ''pattern prescribing'' occurs when practitioners prescribe the same controlled substances in identical or substantially similar quantities, thus indicating a lack of individualized care. RFAAX 1, at 5. Registrant admits that DEA has recognized pattern prescribing to be a red flag consistent with abuse and/or diversion that needs to be addressed prior to dispensing. *Id.* (citing *The Med. Shoppe,* 79 FR 59504, 59512 (2014)).

Further, as discussed above, *see* Section III.A., Texas regulations have recognized pattern prescribing as a red flag consistent with abuse and/or diversion that needs to be addressed prior to dispensing. 22 Tex. Admin. Code Ann. § 291.29(f)(1); RFAAX 1, at 5. Texas regulations have also recognized that prescriptions for controlled substances commonly known to be abused (such as opioids and narcotics) and prescriptions for controlled substances prescribed at the highest strength and/or in large quantities (*e.g.,* a monthly supply) are red flags consistent with abuse and/or diversion that need to be addressed prior to dispensing. 22 Tex. Admin. Code Ann. § 291.29(f)(3), (5); RFAAX 1, at 5.

Registrant admits that from at least January 2023 through at least February 2025, Registrant repeatedly failed to appropriately identify and resolve red flags associated with pattern prescribing. RFAAX 1, at 5–6. Moreover, the controlled substance prescriptions filled by Registrant that were indicative of pattern prescribing posed additional red flags because they were for controlled substances commonly known to be abused and were prescribed at the highest strength and/or in large quantities. *Id.*

Registrant admits that between January 2023 and February 2025, Registrant routinely filled prescriptions for oxycodone 30 mg (a Schedule II opioid), hydrocodone (a Schedule II opioid), and oxycodone/acetaminophen while repeatedly failing to identify and resolve the red flag of pattern prescribing from the same practitioners. *Id.* at 5. Specifically, Drs. C.I., D.C., A.P., C.H., L.B., and M.Q. prescribed 65% of all prescriptions that Registrant dispensed for oxycodone 30 mg (786 prescriptions out of 1,213 total); Drs. M.Q., C.I., L.N., J.R., E.N., A.J., D.C., and C.H. prescribed 53% of all prescriptions that Registrant dispensed for hydrocodone 10/325 mg (442 prescriptions out of 830 total); and Drs. S.N., J.R., T.D., Z.M., E.N., M.C., L.N., and A.J. prescribed 62% of all prescriptions that Registrant dispensed for oxycodone/acetaminophen 10/325 mg (105 prescriptions out of 170 total). *Id.*

Registrant also admits that it repeatedly failed to identify and resolve red flags of pattern prescribing controlled substances known to be abused and at the highest strength and/or large quantities, including the following:

*Dr. C.H.:* Between June 16, 2023, and January 3, 2024, Registrant filled five prescriptions for oxycodone 30 mg (100–105 tablets) issued by Dr. C.H. for D.S. RFAAX 1, at 6. Between June 9, 2023, and November 17, 2023, Registrant filled five prescriptions for oxycodone 30 mg (100–110 tablets) issued by Dr. C.H. for Q.R. *Id.* On November 4, 2023, Registrant filled a prescription for oxycodone 30 mg (100 tablets) issued by Dr. C.H. for J.J. *Id.*

*Dr. C.I.:* On September 29, 2023, Registrant filled a prescription for oxycodone 30 mg (103 tablets) issued by Dr. C.I. for O.J. *Id.* On June 14, 2023, and September 19, 2023, Registrant filled a prescription for oxycodone 30 mg (100 tablets) issued by Dr. C.I. for A.B. *Id.*

*Dr. A.P.:* On March 8, 2024, and June 15, 2024, Registrant filled a prescription for oxycodone 30 mg (100 tablets) issued by Dr. A.P. for J.J. *Id.* On January

[7] Such documentation must be ''on the prescription or in the pharmacy's data processing system associated with the prescription . . . and shall include . . . (i) [the] date the prescriber was consulted; (ii) [the] name of the person communicating the prescriber's instructions; (iii) any applicable information pertaining to the consultation; and (iv) [the] initials or identification code of the pharmacist performing the consultation clearly recorded for the purpose of identifying the pharmacist who performed the consultation.'' 22 Tex. Admin. Code Ann. § 291.33(c)(2)(C); RFAAX 1, at 3.

[8] Texas regulations state that it is unlawful for a ''registrant or dispenser'' to dispense a controlled substance in violation of Sections 481.061–481.080 of the Texas Health and Safety Code. Tex. Health & Safety Code Ann. § 481.128(a)(1); RFAAX 1, at 3.

13, 2024, and April 12, 2024, Registrant filled a prescription for oxycodone 30 mg (100 tablets) issued by Dr. A.P. for T.N. *Id.*

Accordingly, the Agency finds substantial record evidence that Registrant dispensed over 1,000 tablets of oxycodone 30 mg over a two-year period without first resolving the red flags arising from pattern prescribing controlled substances known to be abused, and at their highest strength and/or in large quantities.

Same Patient Obtaining Similar Drugs From Multiple Practitioners

As discussed above, *see* Section III.A., Texas regulations have recognized that it is a red flag consistent with abuse and/or diversion that needs to be addressed prior to dispensing when ''the Texas Prescription Monitoring Program indicates the person presenting the prescriptions is obtaining similar drugs from multiple practitioners, and/or that the person is being dispensed similar drugs at multiple pharmacies.'' 22 Tex. Admin. Code Ann. § 291.29(f)(10); RFAAX 1, at 6.

Registrant admits that from at least September 2023 through at least February 2025, Registrant repeatedly filled prescriptions for individuals who presented prescriptions for the same or similar drugs from a combination of doctors, without resolving the red flag prior to dispensing. RFAAX 1, at 6–7. For example, Registrant filled a prescription for M.V., who received hydrocodone-acetaminophen 10/325 mg prescriptions from three doctors and filled them at five different pharmacies. *Id.* at 7. Registrant also filled a prescription for M.W., who received oxycodone 30 mg and hydrocodone-acetaminophen 10/325 mg prescriptions from five doctors and filled them at seven different pharmacies. *Id.* Registrant filled a prescription for C.G., who received oxycodone 30 mg and hydrocodone-acetaminophen 10/325 mg prescriptions from six doctors and filled them at five different pharmacies. *Id.* Finally, Registrant filled a prescription for J.J., who received oxycodone 30 mg prescriptions from five doctors and filled them at three different pharmacies. *Id.* at 7.

Accordingly, the Agency finds substantial record evidence that Registrant filled four controlled substances prescriptions for individuals who presented prescriptions for the same or similar drugs from a combination of doctors, without resolving the red flag prior to dispensing.[9]

Expert Review

DEA retained an independent pharmacy expert to review, among other materials, Registrant's Prescription Monitoring Program data, prescriptions, prescription profiles, and patient notes. RFAAX 1, at 8. The pharmacy expert concluded, and Registrant admits, that Registrant repeatedly filled prescriptions without properly resolving red flags of drug abuse or diversion. *Id.* The pharmacy expert also concluded, and Registrant admits, that from March 2023 through at least February 2025, Registrant repeatedly filled prescriptions for controlled substances in violation of federal law and binding minimal standards that govern the practice of pharmacy in Texas. *Id.*

In consideration of all of the above, the Agency finds substantial record evidence that Registrant repeatedly dispensed the above-referenced prescriptions without first resolving the above-referenced red flags, in violation of the standard of care in Texas.

Allegation That Registrant Failed to Adequately Maintain Complete and Accurate Records

On March 25, 2025, DEA investigators conducted an on-site administrative inspection at Registrant's registered address. RFAAX 1, at 7. Registrant admits that during this inspection, DEA investigators observed that Registrant did not possess the expected physical stock of controlled substances relative to its ordering practices. *Id.* Registrant admits and the Agency finds that between May 1, 2023, and March 5, 2025, a comparison of Registrant's dispensing data to Registrant's distributor ordering data demonstrated that Registrant could not account for at least the following controlled substances: 43,003.5 dosage units of hydrocodone 10/325 mg tablets, which amounts to a 123.63% variance of calculated inventory; 25,960 dosage units of oxycodone 30 mg tablets, which amounts to a 39.91% variance of calculated inventory; 2,975 dosage units of oxycodone 10/325 mg tablets, which amounts to a 39.67% variance of calculated inventory; 187 dosage units of methadone 10 mg tablets (a Schedule II opioid), which amounts to a 6.93% variance of calculated inventory; 100 dosage units of dextroamphetamine 20 mg tablets (a Schedule II stimulant), which amounts to a 25% variance of calculated inventory; 1,005 dosage units of acetaminophen/codeine 300/30 mg tablets (a Schedule III narcotic analgesic combination), which amounts to a 191.43% variance of calculated inventory; and 116 dosage units of tramadol 50 mg (a Schedule IV opioid), which amounts to a 13.83% variance of calculated inventory. RFAAX 1, at 7–8.

Accordingly, the Agency finds substantial record evidence that Registrant failed to account for large quantities of controlled substances.

Further, regarding recordkeeping of controlled substances, Registrant is deemed to have admitted and the Agency finds that Registrant failed to provide complete and accurate records, failed to meet general inventory requirements, and failed to retain, link, and maintain on a central server original signed electronic 222 Order Forms. *Id.* at 8.

Accordingly, the Agency finds substantial record evidence that Registrant failed to keep and maintain complete and accurate controlled substance records as required by law.

*C. Legal Background on Public Interest Determinations*

The Attorney General ''may deny, suspend, or revoke [a] registration if . . . the [registrant's] registration would be 'inconsistent with the public interest.' '' *Gonzales* v. *Oregon,* 546 U.S. 243, 251 (2006) (quoting 21 U.S.C. 824(a)(4)). The Attorney General's ''discretion in exercising [the authority to register and deregister practitioners] is spelled out in very broad terms.'' *Id.* at 292 (Scalia, J., dissenting); *see also Neumann's Pharmacy, L.L.C.* v. *Drug Enf't Admin.,* No. 25–60068, 2026 WL 411942 (5th Cir. Feb. 13, 2026) (''DEA unquestionably has broad authority to deregister pharmacies and substantial discretion to shape policy within statutory bounds.''). In executing this broad mandate, DEA must continuously balance the CSA's public interest goals of curbing the ''illegal . . . distribution[ ] and possession[,] and improper use of controlled substances[, which has] a substantial and detrimental effect on the health and general welfare of the American people,'' while ensuring that the public has access to medications that ''have a useful and legitimate medical purpose and are necessary to maintain the health

[9] The OSC also alleges, and it is deemed admitted, that from at least March 2023 through at least January 2024, Registrant filled at least 13 prescriptions for oxycodone 30 mg written by Drs. A.M.P. and C.H., for Patients Q.R. and D.S., two individuals living at the same address. RFAAX 1, at 7. This admission is not sufficient to establish that Registrant ignored the red flag of a shared address. This red flag is implicated when ''multiple persons with the same address present substantially similar controlled substance prescriptions from the *same* practitioner.'' 22 Tex. Admin. Code Ann. § 291.29(f)(11) (emphasis added).

and general welfare of the American people.'' 21 U.S.C. 801(1), (2); *see* Joanna R. Lampe, Cong. Rsch. Serv., R45948, The Controlled Substances Act (CSA): A Legal Overview for the 119th Congress (2025), *https://www.congress.gov/crs-product/R45948.*

In the case of a ''practitioner,'' which is defined in 21 U.S.C. 802(21) to include a ''pharmacy,'' Congress directed the Attorney General to consider five factors in making the public interest determination. 21 U.S.C. 823(g)(1)(A–E).[10] Just as the phrase ''inconsistent with the public interest'' is broad, the five factors that Congress directed DEA to consider in determining the public interest are similarly broad, suggesting that Congress intended for DEA to have discretion and flexibility to interpret this language as necessary to implement its critical mission to protect the public from drug abuse and diversion. *See Loper Bright Enters.* v. *Raimondo,* 603 U.S 369, 394–95 (2024) (noting that ''[i]n a case involving an agency . . . the statute's meaning may well be that the agency is authorized to exercise a degree of discretion,'' such as where the statute uses terms or phrases like 'appropriate or reasonable' '' (internal citations omitted)). Indeed, courts have recognized the Agency's broad discretion to deny applications and deregister practitioners for a wide variety of conduct that the Agency has determined is inconsistent with the public interest. *See, e.g., Orusa* v. *Drug Enf't Admin.,* No. 22–3132, 2023 WL 3886403 (6th Cir. June 8, 2023) (physician issuing prescriptions outside the usual course of professional practice and beneath the standard of care); *St. Croix* v. *Drug Enf't Admin.,* No. 21–1116, 2022 WL 2092177 (D.C. Cir. June 10, 2022) (physician failing to maintain adequate records, prescribing controlled substances without a legitimate medical purposes, storing controlled substances at an unregistered location, failing to provide effective controls to guard against theft or diversion of these substances); *Suntree Pharmacy* v. *Drug Enf't Admin.,* No. 20–14626, 2022 WL 444357 (11th Cir. Feb. 14, 2022), cert. denied, 143 S. Ct. 305 (2022) (pharmacy filling prescriptions outside the usual course of practice).

The CSA's five public interest factors are considered in the disjunctive. *Gonzales* v. *Oregon,* 546 U.S. at 292–93 (Scalia, J., dissenting) (''It is well established that these factors are to be considered in the disjunctive,'' quoting *In re Arora,* 60 FR 4447, 4448 (1995)); *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993); *see Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 181 (D.C. Cir. 2005) (describing the Agency's adjudicative process as ''applying a multi-factor test through case-by-case adjudication,'' quoting *LeMoyne-Owen Coll.* v. *N.L.R.B.,* 357 F.3d 55, 61 (D.C. Cir. 2004)). Any one factor, or combination of factors, may be decisive, *David H. Gillis, M.D.,* 58 FR at 37508, and the Agency ''may give each factor the weight . . . deem[ed] appropriate in determining whether a registration should be revoked or an application for registration denied.'' *Morall,* 412 F.3d. at 185 n.2 (Henderson, J., concurring) (quoting *Robert A. Smith, M.D.,* 70 FR 33207, 33208 (2007)); *see also Penick Corp.* v. *Drug Enf't Admin.,* 491 F.3d 483, 490 (D.C. Cir. 2007).

Moreover, while the Agency is required to consider each of the factors, it ''need not make explicit findings as to each one.'' *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman* v. *U.S. Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009)); *Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018); *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). ''In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, Agency decisions have explained that findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

The Government has the burden of proof in this proceeding, 21 CFR 1301.44(e), and the Agency must make its findings based on ''substantial [record] evidence.'' 5 U.S.C. 556(d); *see* 5 U.S.C. 706(2); 21 U.S.C. 877. If the Government meets its burden of establishing a *prima facie* case that Registrant's registration is not in the public interest, then the burden shifts to Registrant to rebut the Government's case. *Pharmacy Doctor Enters., Inc.* v. *Drug Enf't Admin.,* 789 Fed. Appx. 724, 729 (11th Cir. 2019) (citing *Jones Total Health Care Pharmacy,* 881 F.3d at 830).

Registrant is registered in Texas, and the OSC/ISO has alleged violations of state laws in Texas. RFAAX 1, at 3–4. Accordingly, the Agency must evaluate the Government's evidence under Texas law. *See Henry Emery, M.D.,* 90 FR 46927, 46929 (2025) (explaining the Agency analyzes public interest allegations according to the laws in the state where registrant is registered with DEA); *see also* 21 U.S.C. 903 (''No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.'').

*D. Discussion*

While the Agency has considered all the public interest factors of 21 U.S.C. 823(g)(1), the Government's evidence in support of its *prima facie* case primarily implicates Factors B and D. RFAA, at 5–6; RFAAX 1, at 5. Evidence is considered under Factor B when it reflects experience dispensing controlled substances and under Factor D when it reflects compliance or non-compliance with laws related to controlled substances. *Kareem Hubbard, M.D.,* 87 FR 21156, 21162 (2022). Although Factors B and D have some overlap such that the Agency has frequently analyzed them together, Congress must have intended Factor B to encompass conduct that is not captured under Factor D. *See Kungys* v. *United States,* 485 U.S. 759, 778 (1988) (referencing the ''cardinal rule of statutory interpretation that no provision should be construed to be entirely redundant'').

i. Factor B

As already discussed, the CSA gives the Attorney General authority to revoke a registration if he determines that the registrant ''has committed such acts as would render his registration . . . inconsistent with the public interest as determined under [section 823].'' 21 U.S.C. 824(a). One of the five factors that the Attorney General must consider in making this determination is the registrant's ''experience in dispensing

[10] The five factors are:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(B) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

(C) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(E) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(g)(1)(A–E).

. . . controlled substances.'' 21 U.S.C. 823(g)(1)(B) (Factor B). Neither the statute nor the implementing regulations defines the term ''experience'' or places any limitations on the type of conduct that may be considered as ''experience'' under Factor B.[11]

Historically, the Agency's Factor B [12] analysis considered ''both the qualitative manner and quantitative volume of the [practitioner's] experience . . . as expressed through his patients and employees,'' and concluded that the record must contain quantitative evidence regarding the practitioner's experience for the Agency to find that Factor B weighs against a practitioner. *E.g., Clair L. Pettinger,* 78 FR 61592, 61619 (2013). In 2015, the Agency abandoned this language, observing that the text of Factor B did not require DEA to consider the practitioner's ''quantity'' of prescribing. *See JM Pharmacy Group, Inc.,* 80 FR 28667, 28667–68 (2015); *see also Wesley Pope, M.D.,* 82 FR 14944, 14982 (2017). The Agency reviewed dictionary definitions of ''experience,'' including:

(1) The ''direct observation of or participation in events as a basis for knowledge,'' (2) ''the fact or state of having been affected by or gained knowledge through direct observation or participation,'' (3) ''practical knowledge, skill, or practice derived from direct observation of or participation in events or in a particular activity,'' and (4) ''the length of such participation.''

80 FR at 28667 n.2 (citing *Webster's Collegiate Dictionary* 409 (10th ed. 1998);

*The Random House Dictionary of the English Language* 681 (2d ed. 1987)).

The word ''dispense'' means ''to deliver a controlled substance[ ] to an ultimate user or research subject by, or pursuant to the lawful order of a practitioner, including the prescribing or administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery.'' 21 U.S.C. 802(10). This definition encompasses, among other things, practitioners who prescribe controlled substances and pharmacies who fill controlled substance prescriptions. *Id.* The term ''controlled substance'' simply means ''a drug or other substance . . . included in schedule I, II, III, IV, or V . . . .'' 21 U.S.C. 802(6). Thus, the phrase ''experience in dispensing'' means the direct participation in the act of delivering, prescribing, dispensing, or administrating a controlled substance to an ultimate user.

The phrase ''experience in dispensing'' must be considered within the context of DEA's broad mandate under 21 U.S.C. 824(a) to deregister practitioners who ''ha[ve] committed such acts as would render [their] registration . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). In other words, in determining what type of conduct is relevant under Factor B, DEA's primary focus is to determine whether a registrant's ''experience in dispensing'' is ''inconsistent with the public interest'' or whether a registrant's dispensing constitutes ''acts'' that are inconsistent with the public interest. 21 U.S.C. 823(g)(1), 824(a)(4).

The word ''inconsistent'' is not defined in the CSA, but it is commonly defined as ''lacking consistency: such as (a) not compatible with another fact or claim, [and] (b) containing incompatible elements.'' *Inconsistent,* Merriam-Webster, *https://www.merriam-webster.com/dictionary/inconsistent* (last visited on the date of signature). ''Public interest'' is a broad, discretionary term not explicitly defined in the CSA, but Congress identifies the primary goals in the CSA's introductory section as ensuring access to controlled substances used for a ''legitimate medical purpose'' while protecting the public from the ''illegal . . . distribution . . . and improper use of controlled substances[, which] have a substantial and detrimental effect on the health and general welfare of the American people.'' 21 U.S.C. 801(1) & (2).

Considering these goals, DEA's Factor B analysis primarily concerns whether a registrant's ''experience in dispensing'' reflects illegal distribution or improper use of controlled substances that is inconsistent with the public interest. *Id.* In the context of a pharmacy, this would require the Agency to evaluate whether a pharmacy has dispensed controlled substances in a manner that is improper, illegal, or inconsistent with the public interest; for example, by ignoring indicators that a prescription lacked a legitimate medical purpose or would be improperly used, by filling a prescription in a manner that is inconsistent with state law or the state's standards of practice, or by distributing controlled substances in a way that creates a risk of diversion.[13]

Of course, the Agency is not only concerned with acts of intentional diversion,[14] as DEA has explained that ''[c]areless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify the revocation of an existing registration . . .'' *Samson K. Orusa, M.D.,* 87 FR 2986, 3018 (2022) (quoting *Paul J. Caragine, Jr.,* 63 FR 51592, 51602 (1998)); *see also Dewey C. MacKay, M.D.,* 75 FR 49956, 49974 n.35 (2010) (''Accordingly, under the public interest standard, DEA has authority to consider those prescribing practices of a physician, which, while not rising to the level of intentional or knowing misconduct, nonetheless create a substantial risk of diversion.''). Indeed, neither 21 U.S.C. 824(a) nor 21 U.S.C. 823(g) requires DEA to find that a registrant has intentionally diverted controlled substances. Ultimately, a registrant whose dispensing practices create an environment that encourages or is indifferent to the abuse or diversion of controlled substances is acting outside the public's interest. As the opioid epidemic surges and other controlled substances, such as amphetamines, ketamine, and benzodiazepines, are increasingly abused, DEA must remain vigilant to protect the public against registrants who fail to employ the CSA's safeguards to ensure the health and general wellness of the American public.

Registrants ''may continue to introduce evidence as to . . . lawful . . . dispensing activities.'' [15] However,

[11] The only limitation discussed in the legislative history on DEA's authority under Factor B is that DEA should not ''construe[ this factor] in any way to hinder registration of recent graduates of professional schools who may have no professional experience dispensing or conducting research with controlled substances.'' H.R. REP. NO. 98–835, pt. 1, at 14 (1984).

[12] Historically, the Agency referred to ''Factor B'' as ''Factor Two.'' Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Public Law 117–215, 136 Stat. 2257 (2022) (Marijuana Research Amendments or MRA), amended the CSA and other statutes. Relevant to this matter, the MRA redesignated the public interest factors outlined at 21 U.S.C. 823(f)(1–5), which the Agency referred to as Factors One through Five, as 21 U.S.C. 823(g)(1)(A–E), which the Agency now refers to as Factors A through E. Accordingly, this Decision cites to the current designation, 21 U.S.C. 823(g)(1)(B), ''Factor B.''

[13] Analysis of whether a prescription is illegally filled, distributed, or possessed also fits within Factor D, ''Compliance with applicable State, Federal, or local laws relating to controlled substances.'' 21 U.S.C. 823(g)(1)(D).

[14] Only criminally unlawful conduct requires an act of intentional diversion such as proof that a physician ''used 'his authority to prescribe controlled substances . . . not for treatment of a patient, but for the purpose of assisting another in the maintenance of a drug habit' or some other illegitimate purposes, such as his own 'personal profit.' '' *United States* v. *McIver,* 470 F.3d 550, 559 (4th Cir. 2006) (quoted in *Laurence T. McKinney,* 73 FR 43260, 43266 (2008). *Compare* 21 U.S.C. 823 and 824 *with* 21 U.S.C. 841, 842, 843.

[15] *Randall L. Wolff, M.D.,* 77 FR 5106, 5153 (2012) (finding that evidence of lawful prescribing is ''entitled to some evidentiary weight only in cases where a practitioner credibly demonstrates an acceptance of responsibility and reform of past practices''); *see also Roberto Zayas, M.D.,* 82 FR 21410, 21422 n.27 (2017) (''[T]he Agency properly considers a [registrant's] evidence of a lengthy history of compliance after the Government makes

the Agency has found that ''evidence that a practitioner has treated thousands of patients does not negate a *prima facie* showing that the practitioner has committed acts inconsistent with the public interest.'' [16] *Krishna-Iyer,* 74 FR at 463. Accordingly, the Agency has consistently rejected registrants' arguments that acts of unlawful prescribing were mitigated by years of lawful prescribing. *See, e.g., Syed-Jawed Akhtar-Zaidi,* 80 FR 42961, 42967 (2015), pet. for rev. denied, 841 F.3d 707, 713 (6th Cir. 2016) (rejecting respondent's argument that he was denied a ''fair adjudication'' because the Government seized 400 patient files but only proved the illegality of a handful of prescriptions issued during undercover visits, and finding that ''the physician's prescribings to thousands of other patients do not . . . render her prescribings to the undercover officers any less unlawful, or any less acts which are inconsistent with the public interest'') (internal quotations and citations omitted).[17]

Here, as found above, Registrant is deemed to have admitted and the Agency finds that Registrant repeatedly filled controlled substance prescriptions that contained multiple red flags of abuse and/or diversion without addressing or resolving those red flags. Registrant has further admitted that ''it repeatedly filled prescriptions for controlled substances in violation of federal law and binding minimal standards that govern the practice of pharmacy in the State of Texas.'' RFAAX 1, at 8–9. The Agency finds that Registrant's failure to adhere to the minimum standards governing Texas pharmacy practice and its repeated issuance of prescriptions without addressing or resolving red flags reflects ''experience in dispensing . . . controlled substances'' that created an opportunity for the abuse or diversion of controlled substances and was outside the public interest. Registrant also failed to maintain accurate records of controlled substances which created further opportunities for abuse and diversion—indeed Registrant could not account for over 73,000 dosage units of controlled substances. Registrant did not request a hearing and thus did not provide the Agency with any evidence related to its ''experience in dispensing'' that served the public's interest. Accordingly, the Agency finds that Factor B weighs strongly against Registrant's continued registration.[18]

ii. Factor D

Under Factor D, the Agency considers a registrant's ''[c]ompliance with applicable State, Federal, or local laws relating to controlled substances.'' 21 U.S.C. 823(g)(1)(D). Here, as found above, Registrant is deemed to have admitted and the Agency finds that Registrant failed to account for large quantities of controlled substances—over 73,000 dosage units—and failed to keep and maintain complete and accurate controlled substance records.[19] As such, the Agency finds substantial record evidence that Registrant violated the maintenance of records and inventories requirements of 21 CFR 1304.04(a); the inventory requirements of 21 CFR 1304.11(a)–(c); and the recordkeeping requirements of 21 CFR 1304.21(a).[20]

The Agency finds that after considering the public interest factors of 21 U.S.C. 823(g)(1), Factors B and D weigh in favor of revocation of Registrant's registration. Accordingly, the Government has satisfied its *prima facie* burden of showing that Registrant's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). The Agency also finds that there is insufficient mitigating evidence to rebut the Government's *prima facie* case. Thus, the only remaining issue is whether, in spite of the public interest determination, Registrant can be trusted with a registration.

## IV. Sanction

Where, as here, the Government has met the burden of showing that Registrant's registration is inconsistent with the public interest, the burden shifts to Registrant to show why it can be entrusted with a registration. *Morall,* 412 F.3d. at 174; *Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018); *Garrett Howard Smith, M.D.,* 83 FR 18882, 18904 (2018). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual registrant. *Jeffrey Stein, M.D.,* 84 FR 46968, 46972 (2019); *see also Jones Total Health Care Pharmacy,* 881 F.3d at 833. Moreover, as past performance is the best predictor of future performance, the Agency requires that a registrant that has committed acts inconsistent with the public interest accept responsibility for those acts and demonstrate that it will not engage in future misconduct. *See Jones Total Health Care Pharmacy,* 881 F.3d at 833; *ALRA Labs, Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995). The Agency requires a registrant's unequivocal acceptance of responsibility. *Janet S. Pettyjohn, D.O.,* 89 FR 82639, 82641 (2024); *Mohammed Asgar, M.D.,* 83 FR 29,569, 29,573 (2018); *see also Jones Total Health Care Pharmacy,* 881 F.3d at 830–31. In addition, a registrant's candor during the investigation and hearing is an important factor in determining acceptance of responsibility and the appropriate sanction. *See Jones Total Health Care Pharmacy,* 881 F.3d at 830–31; *Hoxie,* 419 F.3d at 483–84. Further, the Agency considers the egregiousness and extent of the misconduct as significant factors in determining the appropriate sanction. *See Jones Total Health Care Pharmacy,* 881 F.3d at 834 & n.4. The Agency also considers the need to deter similar acts by a registrant and by the community of registrants. *Jeffrey Stein, M.D.,* 84 FR at 46972–73.

Here, Registrant did not request a hearing and was deemed to be in default. *See supra* I. To date, Registrant has not filed a motion with the Office of the Administrator to excuse the default. 21 CFR 1301.43(c)(1). Registrant has thus failed to answer the allegations contained in the OSC/ISO and has not

out its *prima facie* case, as determining what sanction is necessary to protect the public interest is the ultimate purpose of these provisions.''). In other words, this evidence may be relevant to the Agency's sanctions analysis.

[16] ''[E]very registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of [their] professional career.'' *Krishna-Iyer,* 74 FR at 463. Accordingly, except where the Agency has found in its decision that a prescription was issued outside the public interest or in violation of law, the Agency assumes that all controlled substance prescriptions dispensed by a pharmacy are dispensed for a legitimate medical purpose and in accordance with relevant laws. *See Dewey C. Mackay, M.D.,* 75 FR at 49977.

[17] In an unreported opinion, the Sixth Circuit affirmed DEA's conclusion that the respondent's acts of unlawful prescribing outweighed his years of work experience. *Orusa* v. *Drug Enf't Admin.,* 2023 WL 3886403 at *5 (''Orusa's credentials and years of work experience, which the agency acknowledged, do nothing to disturb the agency's detailed review of his prescribing history—the relevant ''experience in dispensing . . . controlled substances.'').

[18] While the Agency has determined that Respondent's dispensing conduct is relevant to Factors B and D, to the extent that the found conduct does not fall within these factors, it would nevertheless constitute ''other conduct which may threaten the public health and safety.'' 21 U.S.C. 823(g)(1)(E). Respondent's repeated dispensing of controlled substances without addressing or resolving red flags, and its failure to account for large quantities of controlled substances, may threaten the public health and safety by creating the risk that controlled substances may leave the CSA's closed distribution system and be abused or diverted.

[19] The inability to account for a significant number of dosage units creates a grave risk of diversion. *The Medicine Shoppe,* 79 FR 59504, 59516 (2014); *see also Paul H. Volkman,* 73 FR 30630, 30644 (2008), *pet. for rev. denied* 567 F.3d 215, 224 (6th Cir. 2009) (finding that ''a registrant's accurate and diligent adherence to [recordkeeping regulations] is absolutely essential to protect against the diversion of controlled substances'').

[20] *See also* 21 CFR 1304.21(c).

otherwise availed itself of the opportunity to refute the Government's case. As such, Registrant has made no representations regarding its future compliance with the CSA nor made any demonstration that it can be trusted with registration. Moreover, the evidence presented by the Government shows that Registrant filled well over a thousand controlled substance prescriptions outside the usual course of professional practice in Texas and in violation of the CSA, as well as failed to maintain effective controls against diversion and failed to comply with its recordkeeping obligations, further indicating that Registrant cannot be entrusted.

Accordingly, the Agency will order the revocation of Registrant's registration.

**Order**

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby revoke DEA Certificate of Registration No. FS0483951 issued to St. Michael's Pharmacy. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by

21 U.S.C. 823(g)(1), I hereby deny any pending application of St. Michael's Pharmacy to renew or modify this registration as well as any other pending application of St. Michael's Pharmacy for additional registration in Texas. This Order is effective November 2, 2026.

**Signing Authority**

This document of the Drug Enforcement Administration was signed on September 25, 2026, by DEA Administrator Terrance C. 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**.

**Heather Achbach,**

*Federal Register Liaison Officer, Drug Enforcement Administration.*

[FR Doc. 2026–20227 Filed 10–1–26; 8:45 am]

**BILLING CODE 4410–09–P**

## NATIONAL LABOR RELATIONS BOARD

### Sunshine Act Meetings Notice

**DATES AND TIME:** Every second Wednesday of every month through Fiscal Year 2027 at 2:00 p.m. Eastern Time beginning on October 21, 2027. Changes in date and time will be posted at *www.nlrb.gov.*

**PLACE:** Meetings will be held in person in the Board Agenda Room, Room 5065A, 1015 Half St. SE, Washington DC, with an option for participation via videoconference as needed. Any meetings held entirely via videoconference will be noted at *www.nlrb.gov.*

**STATUS:** Closed.

**MATTERS TO BE CONSIDERED:** Pursuant to § 102.139(a) of the Board's Rules and Regulations, the Board or a panel thereof will consider ''the issuance of a subpoena, the Board's participation in a civil action or proceeding or an arbitration, or the initiation, conduct, or disposition . . . of particular representation or unfair labor practice proceedings under section 8, 9, or 10 of the [National Labor Relations] Act, or any court proceedings collateral or ancillary thereto.'' See also 5 U.S.C. 552b(c)(10).

**FOR FURTHER INFORMATION CONTACT:** Roxanne L. Rothschild, Executive Secretary, 1015 Half Street SE, Washington, DC 20570. Telephone: (202) 273–1940.

Submitted by

Dated: September 30, 2026.

**Roxanne L. Rothschild,**

*Executive Secretary, National Labor Relations Board.*

[FR Doc. 2026–20250 Filed 9–30–26; 4:15 pm]

**BILLING CODE 7545–01–P**

## NATIONAL SCIENCE FOUNDATION

### Agency Information Collection Activities: Comment Request

**AGENCY:** National Science Foundation.

**ACTION:** Notice and request for comments.

**SUMMARY:** The National Science Foundation (NSF) is announcing plans to reinstate this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing opportunity for public comments on this action. After obtaining and considering public comment, NSF will prepare the submission requesting Office of Management and Budget (OMB) clearance of this collection for no longer than 3 years.

**DATES:** Written comments on this notice must be received by December 1, 2026 to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to the address below.

**FOR FURTHER INFORMATION CONTACT:** Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, Randolph Building, 401 Dulany Street, Alexandria, VA 22314, or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays). Copies of the submission may be obtained by calling 703–292–7556.

*Comments:* Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**SUPPLEMENTARY INFORMATION:**

*Title of Collection:* Notification Requirements Regarding Sexual Harassment, Other Forms of Harassment, or Sexual Assault.

*OMB Number:* 3145–0249.

*Type of Request:* Reinstatement with change of an information collection.

*Proposed Project:* The primary purpose of this data collection is for institutional authorized organizational representatives to inform NSF of any finding/determination regarding the Principal Investigator (PI) or any co-PI that demonstrates a violation of awardee policies or codes of conduct, statutes, regulations, or executive orders relating to sexual harassment, other forms of harassment, or sexual assault; and/or if the PI or any co-PI is placed on administrative leave or if any administrative action has been imposed on the PI or any co-PI by the awardee relating to any finding/determination or an investigation of an alleged violation

of awardee policies or codes of conduct, statutes, regulations, or executive orders relating to sexual harassment, other forms of harassment, or sexual assault.

The awardee is required to notify NSF of: (1) Any finding/determination regarding the PI or any co-PI that demonstrates a violation of awardee policies or codes of conduct, statutes, regulations, or executive orders relating to sexual harassment, other forms of harassment, or sexual assault; and/or (2) if the PI or any co-PI is placed on administrative leave or if any administrative action has been imposed on the PI or any co-PI by the awardee relating to any finding/determination or an investigation of an alleged violation of awardee policies or codes of conduct, statutes, regulations, or executive orders relating to sexual harassment, other forms of harassment, or sexual assault. Such notification must be submitted by the Authorized Organizational Representative (AOR) or designee to NSF's Office of Civil Rights at: *https://www.nsf.gov/od/ocr/awardee-civil-rights/notification* within ten business days from the date of the finding/determination, or the date of the placement of a PI or co-PI by the awardee on administrative leave or the imposition of an administrative action, whichever is sooner. Each notification must include the following information:

- NSF Award Number;
- Name of PI or co-PI being reported;
- Awardee Information (including awardee name and address, Authorized Organizational Representative name, title, phone number and email address);

*Type of Notification:* Select all that apply to the notification:

—Finding/Determination that the reported individual has been found to have violated awardee policies or codes of conduct, statutes, regulations, or executive orders relating to sexual harassment, other forms of harassment, or sexual assault; and/or

—Placement by the awardee of the reported individual on administrative leave or the imposition of any administrative action on the PI or any co-PI by the awardee relating to any finding/determination or an investigation of an alleged violation of awardee policies or codes of conduct, statutes, regulations, or executive orders relating to sexual harassment, other forms of harassment, or sexual assault.

- Description of the finding/determination and action(s) taken, if any; and
- Reason(s) for, and conditions of, placement of the PI or any co-PI on administrative leave or imposition of administrative action.

*Use of the Information:* NSF will use the information in consultation with the awardee to determine whether the NSF awardee's actions adequately address the safety and security of personnel supported by the NSF award, the overall impact to the NSF-funded activity, the continued advancement of taxpayer-funded investments in science and scientists, and whether the awardee has taken appropriate action(s) to ensure the continuity of science and that continued progress under the funded project can be made.

*Burden on the Public:* It has been estimated that respondents will expend an average of one hour to complete the form.

Dated: September 30, 2026.

**Suzanne H. Plimpton,**

*Reports Clearance Officer, National Science Foundation.*

[FR Doc. 2026–20236 Filed 10–1–26; 8:45 am]

**BILLING CODE 7555–01–P**

## NUCLEAR REGULATORY COMMISSION

**[NRC–2026–0001]**

### Sunshine Act Meetings

**TIME AND DATE:** Week of September 28, 2026.

**PLACE:** Via Teleconference.

**STATUS:** Open.

**MATTERS TO BE CONSIDERED:**

**Week of September 28, 2026**

*Thursday, October 1, 2026*

10:00 a.m. Affirmation Session (Public Meeting) (Tentative)

(a) Direct Final Rule: Exemptions from Material Licensing (Tentative)

(b) Constellation Energy Generation, LLC (Christopher M. Crane Clean Energy Center); Appeal of LBP–26–6 (Ruling on Intervention Petition) (Tentative)

(Contact: Wesley Held: 301–287–3591)

**ADDITIONAL INFORMATION:** By a vote of 5–0 on September 29 and September 30, 2026, the Commission determined pursuant to 5 U.S.C. 552b(e)(1) and 10 CFR 9.107 these items be affirmed with less than one week notice to the public. These items will be affirmed in the meeting being held on October 1, 2026. The public is invited to attend the Commission's meeting live; via teleconference. Details for joining the teleconference in listen only mode can be found at *https://www.nrc.gov/pmns/mtg.*

**CONTACT PERSON FOR MORE INFORMATION:** For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.* The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please contact the Reasonable Accommodations Resource by email at *Reasonable_Accommodations.Resource@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Betty.Thweatt@nrc.gov* or *Samantha.Miklaszewski@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: September 30, 2026.

For the Nuclear Regulatory Commission.

**Wesley W. Held,**

*Policy Coordinator Office of the Secretary.*

[FR Doc. 2026–20274 Filed 9–30–26; 4:15 pm]

**BILLING CODE 7590–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–106524; File No. SR–DTC–2026–011]**

### Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Clearing Agency Risk Management Framework

September 29, 2026.

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 September 18, 2026, The Depository Trust Company (''DTC'') filed with the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. DTC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act [3] and Rule 19b–4(f)(4) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

## I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of amendments to the Clearing Agency Risk Management Framework (''Risk Management Framework'' or ''Framework'') of DTC and its affiliates, Fixed Income Clearing Corporation (''FICC'') and National Securities Clearing Corporation (''NSCC,'' and together with FICC and DTC, the ''Clearing Agencies'').[5] Specifically, the proposed rule change would amend the Risk Management Framework to clarify and update the Framework. The proposed changes would update and clarify the Framework by (1) revising the format and structure of various sections to reflect internal policy and procedure governance requirements, (2) updating the descriptions to reflect that the Risk Management Framework supports the Clearing Agencies' compliance with Rules 17ad–25(j) [6] and 17ad–26 [7] under the Act; (3) adding a description of the Clearing Agency Framework for Certain Requirements on Governance and Conflicts of Interests, which was adopted by the Clearing Agencies in 2024 [8] and (4) adding clarifying, conforming, and administrative updates that do not alter how the Clearing Agencies comply with the applicable requirements of Rule 17ad–22(e) under the Act.[9]

## II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

### *(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

DTC proposes to amend the Risk Management Framework of the Clearing Agencies. Specifically, the proposed rule change would amend the Risk Management Framework to clarify and update the Framework. The proposed changes would update and clarify the Framework by (1) revising the format and structure of various sections to reflect internal policy and procedure governance requirements, (2) updating the descriptions to reflect that the Risk Management Framework supports the Clearing Agencies' compliance with Rule 17ad–25(j) and Rule 17ad–26; (3) adding a description of the Clearing Agency Framework for Certain Requirements on Governance and Conflicts of Interests, which was adopted by the Clearing Agencies in 2024 and (4) adding clarifying, conforming, and administrative updates that do not alter how the Clearing Agencies comply with the applicable requirements of Rule 17ad–22(e).

Risk Management Framework

The Clearing Agencies adopted the Risk Management Framework [10] to provide an outline for how each of the Clearing Agencies (i) comprehensively manages legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by it; (ii) maintains a well-founded, clear, transparent and enforceable legal basis for each aspect of its activities; (iii) identifies, monitors, and manages risks related to links it establishes with one or more clearing agencies, financial market utilities, or trading markets; (iv) publicly discloses certain information, including market data; (v) meets the requirements of its participants and the markets it serves efficiently and effectively; (vi) uses, or at a minimum accommodates, relevant internationally accepted communication procedures and standards in order to facilitate efficient payment, clearing and settlement; and (vii) conducts an annual review of the Government Securities Division of FICC's access models. In this way, the Risk Management Framework currently supports the Clearing Agencies' compliance with Rules 17ad–22(e)(1), (3), (18), (20), (21), (22), (23), 17ad–25(j) and 17ad–26 under the Act,[11] as described in the Framework Filings.

In addition to setting forth the manner in which each of the Clearing Agencies addresses these requirements, the Risk Management Framework also describes the Framework ownership and the required governance process for review and approval of changes to the Framework. In connection with the annual review and approval of the Framework by the Board of Directors of each of DTC, FICC and NSCC (each a ''Board'' and collectively, the ''Boards''), the Clearing Agencies are proposing to make certain revisions to the Framework.

Proposed Changes

1. Revising Format and Structure

The proposed changes would reformat and reorganize the Framework to align with the Clearing Agencies' internal governance guidelines for policies, procedures and frameworks. Each Clearing Agency maintains guidelines regarding the required structure, organization, and content of such documents which are intended to ensure that the Clearing Agencies' policies, procedures and frameworks are well-written, well-structured, accurate and easy to understand.

The proposed revisions are intended to conform the Framework to those guidelines and include the following changes:[12]

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[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(4).

[5] *See* Securities Exchange Act Release Nos. 81635 (Sept. 15, 2017), 82 FR 44224 (Sept. 21, 2017) (SR–DTC–2017–013, SR–FICC–2017–016, SR–NSCC–2017–012) (''Initial Filing''); 89271 (July 9, 2020), 85 FR 42933 (July 15, 2020) (SR–NSCC–2020–012); 89269 (July 9, 2020), 85 FR 42954 (July 15, 2020) (SR–DTC–2020–009); 89270 (July 9, 2020), 85 FR 42927 (July 15, 2020) (SR–FICC–2020–007); 96799 (Feb. 03, 2023), 88 FR 8506 (Feb. 9, 2023) (SR–DTC–2023–001); 96800 (Feb. 3, 2023), 88 FR 8491 (Feb. 9, 2023) (SR–FICC–2023–001); 96801 (Feb. 3, 2023), 88 FR 8502 (Feb. 9, 2023) (SR–NSCC–2023–001); 99097 (Dec. 6, 2023), 88 FR 86186 (Dec. 12, 2023) (SR–FICC–2023–016); 99098 (Dec. 6, 2023), 88 FR 86183 (Dec. 12, 2023) (SR–NSCC–2023–012); 99108 (Dec. 07, 2023), 88 FR 86430 (Dec. 13, 2023) (SR–DTC–2023–012); 101685 (Nov. 21, 2024), 89 FR 93689 (Nov. 27, 2024) (SR–DTC–2024–003, SR–FICC–2024–006, SR–NSCC–2024–003); 102652 (Mar. 13, 2025), 90 FR 12858 (Mar. 19, 2025) (SR–DTC–2025–002); 102653 (Mar. 13, 2025), 90 FR 12870 (Mar. 19, 2025) (SR–FICC–2025–004); and 102654 (Mar. 13, 2025), 90 FR 12844 (Mar. 19, 2025) (SR–NSCC–2025–002) (together with the Initial Filing, the ''Framework Filings'').

[6] 17 CFR 240.17ad–25(j) (''Rule 17ad–25(j)'').

[7] 17 CFR 240.17ad–26 (''Rule 17ad–26'').

[8] *See* Securities Exchange Act Release No. 101764 (Nov. 26, 2024), 82 FR 44224 (Dec. 3, 2024) (SR–DTC–2024–009, SR–FICC–2024–010, SR–NSCC–2024–006).

[9] 17 CFR 240.17ad–22(e) (''Rule 17ad–22(e)'').

[10] *Supra* note 5.

[11] 17 CFR 240.17ad–22(e)(1), (3), (18), (20), (21), (22), (23), 17ad–25(j), and 17ad–26.

[12] References to Section numbers herein are referring to Section numbers following the proposed changes.

| Section | Proposed changes |
| --- | --- |
| Section 1 | Rename the section ''Executive Summary'' to ''Purpose'' and revise the accompanying description to articulate the purpose of the Framework.<br>Delete the sentence defining DTCC and identifying it as the parent of the Clearing Agencies, and relocate that definition to the first reference to DTCC in Section 2.<br>Delete the four paragraphs describing the Framework, the treatment of risks not addressed by the Framework, supporting documentation, and the meaning of references, and relocate that content to Section 2. |
| Section 2 | Rename the section ''Framework Ownership and Change'' to ''Roles and Responsibilities'' and move language from Section 1 to this Section as described above.<br>Delete the sentence addressing ownership of the Framework and move it to Section 3.<br>Delete the paragraph describing ownership of the processes addressed by the Framework and move it to Section 3.<br>Delete the paragraph describing the approval process for changes to the Framework and move it to Section 8.<br>Delete the sentence regarding review of the Framework by the General Counsel's Office and move it to Section 3.<br>Delete the sentence addressing annual Board approval of the Framework and move it to Section 8.<br>Delete the sentence regarding the legend associated with the Framework and move it to Section 8. |
| Sections 3–6 | Create new Section 3, titled ''Audience'' and move language from Section 2 to this Section as described above.<br>Renumber the headings and subheadings in current Sections 3 through 5 to reflect the addition of the new Section 3. |
| Section 7 | Create a new Section 7, titled ''Exceptions,'' describing the process for escalating, approving, and documenting exceptions to the Framework in accordance with applicable internal compliance guidelines governing policies, procedures, and frameworks. |
| Section 8 | Create a new Section 8, titled ''Framework Governance'' and relocate the governance-related provisions currently contained in Section 2 to this Section as described above. |

2. Updating Descriptions To Reflect Support of Compliance With Rule 17ad–25(j) and Rule 17ad–26

The proposed changes include additional disclosures intended to address the Clearing Agencies' compliance with the requirements of Rule 17ad–25(j), related to the management of risks presented by core service providers and the solicitation of stakeholder views, and the requirements set forth in Rule 17ad–26, relating to the maintenance of the Clearing Agencies' recovery and wind-down plans.[13]

Specifically, Section 1 would be revised to include references to Rule 17ad–25(j) and Rule 17ad–26, clarifying that the Framework supports compliance with those requirements. Section 5.2.1 would be updated to state that, consistent with Rule 17ad–25(j), the Clearing Agencies have established policies and procedures to manage risks arising from relationships with providers of core services. Section 5.3 would be enhanced to include a description of the Clearing Agencies' advisory councils as part of their compliance with Rule 17ad–25(j). In addition, Section 6 would be revised to reference Rule 17ad–26 and to state that it requires the recovery and wind-down plans to identify the core staffing and providers of core services necessary to support the continued provision of core services.

3. Add Reference to Clearing Agency Framework for Certain Requirements on Governance and Conflicts of Interests

Section 4.3.3 currently lists additional frameworks adopted by the Clearing Agencies that support the Framework. The proposed revision would add the Clearing Agency Framework for Certain Requirements on Governance and Conflicts of Interest, adopted by the Clearing Agencies in 2024,[14] and include a brief description of its purpose and scope.

4. Immaterial Changes for Clarification Purposes

The proposed changes include a number of clarifying, conforming, and administrative updates to improve the accuracy, consistency, and readability of the Framework.

The following changes would be made throughout the Framework: (i) replace references to 17 CFR 240.17Ad–22(e) with 17 CFR 240.17ad–22(e), (ii) replace references to the Risk Department with the Group Chief Risk Office to reflect the department's current name; and (iii) update section references to align with the organizational and formatting revisions described above.

Additional revisions would be made to specific sections of the Framework. In Section 4.1.1, a semicolon would be added in two places. In Section 4.1.2, a period would replace a comma in the first bullet point of the renamed Group Chief Risk Office subsection. In Section 4.1.3, the phrase ''independent validation'' would be replaced with ''independent and objective assurance'' to more accurately describe the role of the Internal Audit department. In Section 4.2, the description of the policy governing the establishment and oversight of internal committees and councils would be enhanced to clarify that each committee is periodically reviewed to confirm that it continues to fulfill its intended purpose effectively. In Section 4.3.1, the apostrophe after ''Agencies''' would be removed and ''business person'' would be replaced with ''businessperson'' for grammatical consistency. In Section 4.3.3, definitions that are not used in the Framework would be removed, and the Clearing Agency Securities Valuation Framework would be renamed the Clearing Agency Price and Margin Input Data Framework to reflect its current title.

Further clarifications would be made in Section 5.1, including the removal of the phrase ''among other things'' as unnecessary, clarification that each of FICC and NSCC publishes public guides describing the methodologies used to calculate their respective Clearing Fund components and provides calculators that estimate certain margin requirements as examples of information available to participants, the addition of the word ''with'' for clarity, and the insertion of a comma after ''time'' to improve readability. In Section 5.2.1, a comma would be added after ''time,'' a sentence that was inadvertently presented as a separate bullet would be incorporated into the preceding bullet, and ''third party'' would be revised to ''third-party.'' In

[13] *See* 17 CFR 240.17ad–25(j) and 17ad–26.

[14] *See supra* note 8.

Section 5.2.2, the word ''relevant'' would be capitalized because it is the first word of the sentence. Section 5.3 would be updated to more accurately describe the processes and year-end reporting used by the Clearing Agencies to measure and monitor performance against their goals and targets. In Section 5.4, ''its'' would be replaced with ''their'' for grammatical correctness. Finally, Section 6 would be revised to reflect that Board approval of the Recovery and Wind-down Plans is now required annually, rather than biennially.

2. Statutory Basis

The Clearing Agencies believe that the proposed changes are consistent with Section 17A(b)(3)(F) of the Act [15] for the reasons described below. Section 17A(b)(3)(F) of the Act requires, in part, that the rules of a registered clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions, and to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible.[16]

The proposed changes would clarify and enhance the descriptions in the Risk Management Framework and correct errors in those descriptions by, for example, (1) revising the format and structure of various sections to reflect internal policy and procedure governance requirements, (2) updating the descriptions to reflect that the Risk Management Framework supports the Clearing Agencies' compliance with Rule 17ad–25(j) and Rule 17ad–26; (3) adding a description of Clearing Agency Framework for Certain Requirements on Governance and Conflicts of Interests, and (4) adding clarifying, conforming, and administrative updates that do not alter how the Clearing Agencies comply with the applicable requirements of Rule 17ad–22(e) under the Act.[17] By creating clearer, updated descriptions and correcting errors, the Clearing Agencies believe that the proposed changes would make the Risk Management Framework more effective in providing an overview of the important risk management activities of the Clearing Agencies, as described therein.

As described in the Framework Filings, the risk management functions described in the Risk Management Framework allow the Clearing Agencies to continue to promote the prompt and accurate clearance and settlement of securities transactions and continue to assure the safeguarding of securities and funds which are in their custody or control or for which they are responsible. The proposed changes to improve the clarity and accuracy of the descriptions of risk management functions within the Framework would assist the Clearing Agencies in carrying out these risk management functions. Therefore, the Clearing Agencies believe these proposed changes are consistent with the requirements of Section 17A(b)(3)(F) of the Act.[18]

*(B) Clearing Agency's Statement on Burden on Competition*

The Clearing Agencies do not believe that the proposed changes to the Framework described above would have any impact, or impose any burden, on competition. As described above, the proposed rule changes would improve the comprehensiveness of the Framework by creating clearer, updated descriptions and correcting errors, thereby making the Risk Management Framework more effective in providing an overview of the important risk management activities of the Clearing Agencies. As such, the Clearing Agencies do not believe the proposed rule changes would have any impact on competition.

*(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

The Clearing Agencies have not received or solicited any written comments relating to this proposal. If any written comments are received, they will be publicly filed as an Exhibit 2 to this filing, as required by Form 19b–4 and the General Instructions thereto.

Persons submitting comments are cautioned that, according to Section IV (Solicitation of Comments) of the Exhibit 1A in the General Instructions to Form 19b–4, the Commission does not edit personal identifying information from comment submissions. Commenters should submit only information that they wish to make available publicly, including their name, email address, and any other identifying information.

All prospective commenters should follow the Commission's instructions on how to submit comments, *available at www.sec.gov/rules-regulations/how-submit-comment.* General questions regarding the rule filing process or logistical questions regarding this filing should be directed to the Main Office of the Commission's Division of Trading and Markets at *tradingandmarkets@sec.gov* or 202–551–5777.

The Clearing Agencies reserve the right not to respond to any comments 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) of the Act [19] and paragraph (f) of Rule 19b–4 thereunder.[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.

## 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 (*www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–DTC–2026–011 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to file number SR–DTC–2026–011. 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 DTC and on DTCC's website (*www.dtcc.com/legal/sec-rule-filings*). 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

[15] 15 U.S.C. 78q–1(b)(3)(F).

[16] *Id.*

[17] 17 CFR 240.17ad–22(e).

[18] 15 U.S.C. 78q–1(b)(3)(F).

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f).

to File Number SR–DTC–2026–011 and should be submitted on or before October 23, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

**Sherry R. Haywood,**

*Assistant Secretary.*

[FR Doc. 2026–20230 Filed 10–1–26; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–106529; File No. SR–LTSE–2026–21]**

## Self-Regulatory Organizations; Long-Term Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Update the LTSE Market Maker Rules To Provide Mechanisms That Would Allow the Exchange To Initiate and Operate a Market Maker Program

September 29, 2026.

Pursuant to the provisions of Section 19(b)(1) under the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 21, 2026, Long-Term Stock Exchange, Inc. (''LTSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule 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 proposed rule change to: (1) add definitions for ''Market Maker'' and ''Market Maker Authorized Trader'' or ''MMAT'' to Rule 1.160; (2) restate Rule 11.150 (Registration as a Market Maker) to create a comprehensive, practical registration framework; (3) amend Rule 11.151 (Market Maker Obligations) to establish new obligations not related to performance of Market Makers and provide exceptions to the existing Two-Sided Quote Obligation; (4) adopt a new Rule 11.152 (Obligations of Market Maker Authorized Traders), which governs the obligations of Market Maker Authorized Traders (''MMATs''); (5) adopt new Rule 11.153 (Registration of Market Makers in Securities); and (6) delete current Rule 11.153 (Voluntary Termination of Registration), which would be replaced by proposed Rule 11.153(b).

The text of the proposed rule change is available at the Exchange's website at *https://longtermstockexchange.com/,* and at the principal office of the Exchange.

### II. Self-Regulatory Organization's Statement on 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 self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

Background and Overview of the Proposal

LTSE has never registered a Market Maker. To improve market quality in Dually-Listed Securities [3] and securities traded on the Exchange pursuant to unlisted trading privileges, the Exchange seeks to encourage market making activity. The proposed rule modifications establish practical mechanisms designed to allow LTSE to initiate, operate, and monitor market making in Non-LTSE-Primary-Listed Securities traded on the Exchange.[4] For example, the proposed rule change would fortify the Exchange's market maker registration framework, establish a means for Exchange oversight over authorized traders who perform market making activities on behalf of registered Market Makers, and institute processes for registering in a security and, if necessary, suspending or terminating registrations in a security or securities.[5] As discussed in greater detail below, these updates to LTSE's Market Maker rules are substantially similar to rules of another national securities exchange.

Proposed Changes

In summary, the Exchange proposes to: (1) add definitions for ''Market Maker'' and ''Market Maker Authorized Trader'' or ''MMAT'' to Rule 1.160; (2) restate Rule 11.150 (Registration as a Market Maker) to create a comprehensive, practical registration framework; (3) amend Rule 11.151 (Market Maker Obligations) to establish new obligations not related to performance of Market Makers and provide exceptions to the existing Two-Sided Quote Obligation; (4) adopt a new Rule 11.152 (Obligations of Market Maker Authorized Traders), which governs the obligations of Market Maker Authorized Traders (''MMATs''); (5) adopt new Rule 11.153 (Registration of Market Makers in Securities); and (6) delete current Rule 11.153 (Voluntary Termination of Registration), which would be replaced by proposed Rule 11.153(b).

Proposed Amendments to Rule 1.160 (Definitions)

The Exchange is proposing to add two new definitions to Rule 1.160, the Exchange's central definitions rule. These new definitions anchor the proposed market maker framework in the Exchange's definitions rule and are consistent with the approach taken by other national securities exchanges.

First, the Exchange proposes to add the definition of ''Market Maker'' in new Rule 1.160(ww). The proposed definition provides that ''Market Maker'' means a Member that acts as a Market Maker pursuant to Chapter 11 of the LTSE Rules. The term currently appears throughout Chapter 11 without a formal definitional anchor in Rule 1.160. The proposed addition clarifies that Market Maker status is a distinct role conferred through Chapter 11 registration, separate from general Exchange membership.[6]

Second, the Exchange proposes to add the definition of ''Market Maker Authorized Trader'' or ''MMAT'' in new Rule 1.160xx). The proposed definition provides that ''MMAT'' means an

[21] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Rule 14.210(a) (defining ''Dually-Listed Securities'').

[4] *See* Rule 1.160z) (defining ''Non-LTSE-Primary-Listed Securities''). Currently, only Non-LTSE-Primary -Listed Securities are traded on the Exchange. Before allowing for market making in LTSE-Primary-Listed Securities (as defined in Rule 1.160s), LTSE will file another proposed rule change to adopt a second class for Market Makers in those securities.

[5] In a separate proposed rule change, LTSE intends to introduce incentives for Market Makers that satisfy certain quoting thresholds, but those incentives would not constitute performance obligations. In the event a Market Maker fails to meet any of those heightened thresholds in a security it simply would not receive an incentive payment for that security; failure would not trigger suspension or termination of the Market Maker's registration in the security or subject the Market Maker to disciplinary action.

[6] The proposed definition is substantially similar to the definition of ''Market Maker'' in Cboe BZX Exchange, Inc. (''Cboe BZX'') Rule 1.5(l).

authorized trader who performs market making activities pursuant to Chapter 11 on behalf of a Market Maker. This definition is new to the LTSE rulebook. It is consistent with the definition of ''Market Maker Authorized Trader'' in Cboe BZX Rule 1.5(m), which similarly defines the term as ''an authorized trader who performs market making activities pursuant to Chapter XI on behalf of a Market Maker.'' [7] Both definitions anchor individual market making authorization to the firm-level market maker registration framework. The MMAT concept in the LTSE Rules is also an extension of the Exchange's existing Authorized Trader framework under Rule 11.140 and Rule 1.160(d), applied specifically to the market making context. The MMAT definition in proposed Rule 1.160(xx) anchors the comprehensive individual-level registration and oversight framework set forth in proposed Rule 11.152, discussed below.

Proposed Amendment to Rule 9.218 (Violations Appropriate for Disposition Under Plan Pursuant to Exchange Act Rule 19d–1(c)(2))

The Exchange is proposing to update a cross-reference in paragraph (f) to reflect the renumbering of the paragraphs of Rule 11.151.

Proposed Amendments to Rule 11.150 (Registration as a Market Maker)

The Exchange proposes to delete the existing text of Rule 11.150 in its entirety and replace it with a comprehensive Market Maker registration framework consisting of six new provisions, as described below.[8]

Proposed Rule 11.150(a) requires any applicant for registration as a Market Maker to file a written application on a form prescribed by the Exchange. Applications are to be reviewed by the Exchange based on factors including, but not limited to, capital, operations, personnel, technical resources, and disciplinary history. The rule also codifies a minimum net capital requirement: each Market Maker must have and maintain minimum net capital of at least the amount required under Rule 15c3–1 under the Act.

Proposed Rule 11.150(b) provides that an applicant's registration as a Market Maker becomes effective upon receipt by the Member of notice of the Exchange's approval of registration. This provision would replace the existing Rule 11.150(b)'s same-day, submission-based effectiveness with an approval-based model, which provides the Exchange with the ability to evaluate applicant qualifications before granting Market Maker status.[9]

Proposed Rule 11.150(c) codifies the grounds on which the Exchange may suspend or terminate a Market Maker's registration. The Exchange may take such action if it determines that: (1) the Market Maker has substantially or continually failed to engage in dealings in accordance with Rule 11.151 or elsewhere in the LTSE Rules; (2) the Market Maker has failed to meet the minimum net capital conditions in paragraph (a); (3) the Market Maker has failed to maintain fair and orderly markets; or (4) the Market Maker does not have at least one registered MMAT qualified to perform market making activities as set forth in Rule 11.152(b)(5), with the clarification that a MMAT whose registration is itself suspended under this paragraph shall not be deemed qualified.

Proposed Rule 11.150(d) provides that any registered Market Maker may withdraw its registration by giving written notice to the Exchange. The Exchange may require a minimum prior notice period and may impose conditions on withdrawal and re-registration as it deems appropriate in the interest of maintaining fair and orderly markets.[10]

Proposed Rule 11.150(e) provides that any person aggrieved by any determination under Rules 11.150, 11.152, or 11.153 may seek review under Chapter 9 of the Exchange Rules governing adverse action. The provision consolidates the appeal right for determinations across the three rules governing Market Maker and MMAT registration as well as suspensions and terminations of registrations in a security in a single location.

Proposed Rule 11.150(f) provides that registered Market Makers are designated as dealers on the Exchange for all purposes under the Act and the rules and regulations thereunder.

Proposed Amendments to Rule 11.151 (Market Maker Obligations)

The Exchange would retain the existing provisions of the rule governing the Two-Sided Obligation, pricing obligations, bid and offer quotation requirements, the Designated Percentage and Defined Limit framework, MPID provisions, firm quotations, impaired quotation ability, and locked and crossed markets and renumber those paragraphs to accommodate several new provisions. The proposed new provisions are: (a) a general obligations preamble enumerating specific Market Maker duties; (b) a provision establishing Market Maker responsibility for its MMAT's acts and omissions; and (c) a provision addressing disciplinary consequences for failure to engage in a course of dealings. Each new provision is discussed below.

Proposed Rule 11.151(a) provides that a member registered as a Market Maker in one or more Non-LTSE-Primary-Listed Securities traded on the Exchange shall engage in a course of dealings for its own account to assist in the maintenance, insofar as reasonably practicable, of fair and orderly markets. The proposed rule enumerates five specific responsibilities that flow from this obligation: (1) maintaining continuous two-sided quotations consistent with the requirements of Rule 11.151(d); (2) remaining in good standing with the Exchange and in compliance with all applicable Exchange Rules; (3) informing the Exchange of any material change in financial or operational condition or personnel; (4) maintaining a current list of MMATs who are permitted to enter orders on behalf of the Market Maker and providing updated versions to the Exchange upon any change; and (5) clearing and settling transactions through the facilities of a registered clearing agency, whether by direct participation, direct clearing services, or correspondent clearing arrangement.[11]

Proposed Rule 11.151(b) provides that a Market Maker shall be responsible for the acts and omissions of its MMATs.[12] The proposed provision makes that accountability explicit in the LTSE Rules: because individual MMATs are authorized to enter orders on behalf of a Market Maker, the Market Maker firm retains supervisory responsibility and legal accountability for those individuals' conduct. This accountability is consistent with general supervisory responsibility principles

[7] The proposed definition is substantially similar to the definition of ''Market Maker Authorized Trader'' in Cboe BZX Rule 1.5(m).

[8] This proposed rule is substantially similar to the ''Registration of Market Makers'' rule in Cboe BZX Rule 11.5.

[9] This approval-based effectiveness model is identical to Cboe BZX Rule 11.5(b) and MEMX Rule 11.17(b), and differs from existing LTSE Rule 11.150(b), under which registration becomes effective on the day the request was entered.

[10] The Exchange will notify Market Makers of the minimum prior notice period required for withdrawal as well as any conditions on withdrawal and re-registration via Information Circular.

[11] Cboe BZX Rule 11.8(a) (Obligations of Market Makers) is substantially similar to this rule, except that LTSE's proposed rule is limited to the Member being registered as a Market Maker in one or more Non-LTSE-Primary-Listed Securities traded on the Exchange and Cboe BZX's rule applies to all securities traded on the exchange.

[12] This is identical to Cboe BZX 11.8(b). *See also* MEMX Rule 11.20(b).

applicable to broker-dealers under the Act and reflects the Exchange's codification of that responsibility rather than relying solely on general supervisory rules.[13]

Proposed Rule 11.151(c) provides that if the Exchange finds any substantial or continued failure by a Market Maker to engage in a course of dealings as specified in Rule 11.151(a), such Market Maker will be subject to disciplinary action, including, without limitation, suspension or revocation of registration in one or more securities. The provision also preserves all Exchange powers under the By-Laws, Rules, and procedures of the Exchange and provides that any Member aggrieved by a determination under Rule 11.151 may seek review under Chapter 9 of the Exchange Rules.[14]

Proposed Rules 11.151(d) through 11.151(h) carry forward the substantive content of existing Rules 11.151(a) through 11.151(e), respectively, renumbered to accommodate the new provisions described above. No changes are made to the substance of the Two-Sided Obligation, pricing obligations (except as discussed below), bid and offer quotation requirements, the Designated Percentage and Defined Limit framework, MPID provisions, firm quotation requirements (except as discussed in the footnote),[15] impaired quotation provisions, or locked and crossed market provisions. The renumbering updates all internal cross-references within Rule 11.151 to conform to the new paragraph structure and updates to outdated terms and cross-references to other rules in the rulebook. Three new sub-provisions are added to the Two-Sided Obligation section in proposed Rule 11.151(d)(1): subparagraph (A) provides that the duration of an Exchange system failure shall not be counted against the Market Maker's compliance with the quoting standard; subparagraph (B) provides that the continuous quoting obligation is suspended during trading halts, suspensions, or pauses (and shall not recommence until after the first regular-way transaction on the primary listing market), and is also suspended for the duration of any Limit State[16] or Straddle State;[17] and subparagraph (C) provides that the Exchange may consider other exceptions to the Two-Sided Obligation based on demonstrated legal or regulatory requirements or other mitigating circumstances. Sub-provisions (A), (B), and (C) are consistent with corresponding provisions in Cboe BZX Rules 11.8(d)(1)(A)–(C).[18] The Designated Percentage and Defined Limit thresholds carried forward in proposed Rule 11.151(d)(6) and (7) are unchanged from the thresholds in current LTSE Rule 11.151.[19]

Proposed New Rule 11.152 (Obligations of Market Maker Authorized Traders)

To operationalize LTSE's Market Maker rules, the Exchange proposes to add new Rule 11.152, which governs the registration and obligations of MMATs.[20] This rule is substantially similar to Cboe BZX Rule 11.6 (Obligations of Market Maker Authorized Traders), differing only with respect to cross-references to other LTSE Rules, including the reference in proposed Rule 11.152(b)(2) to the proficiency and continuing education requirements applicable to Authorized Traders under LTSE Rule 2.160. The Exchange's current rules do not expressly provide for MMATs.[21] In contrast, proposed Rule 11.152 expressly permits Market Makers to trade via MMATs and establishes registration procedures, eligibility requirements, and delineates suspension and withdrawal criteria and procedures.

Proposed Rule 11.152(a) provides that MMATs are permitted to enter orders only for the account of the Market Maker for which they are registered, establishing that the MMAT role is a principal account trading function. Rule 11.152(b) provides that the Exchange may, upon receiving a written application from a Market Maker on a prescribed form, register a person as a MMAT. MMATs may be officers, partners, employees, or other associated persons of Members registered with the Exchange as Market Makers. To be eligible for registration, a person must successfully complete proficiency examinations and continuing education requirements applicable to Authorized Traders under Rule 2.160 and any additional training and certification programs required by the Exchange. The Exchange may require a Market Maker to provide additional information it deems necessary to evaluate whether registration should be granted and may grant conditional registration subject to conditions it considers appropriate in the interest of maintaining a fair and orderly market. Rule 11.152(b)(5) places an affirmative obligation on the Market Maker firm to ensure that each MMAT is properly qualified to perform market making activities.

Proposed Rule 11.152(c) provides that the Exchange may suspend or withdraw MMAT registration if it determines that: (A) the MMAT has caused the Market Maker to fail to comply with applicable securities laws or Exchange Rules; (B) the MMAT is not properly performing MMAT responsibilities; (C) the MMAT has failed to meet registration conditions; or (D) the MMAT has failed to maintain fair and orderly markets. If the Exchange suspends MMAT registration, the Market Maker must not allow the MMAT to submit orders into the System. MMAT registration is withdrawn upon the written request of the sponsoring Market Maker Member submitted on the Exchange's prescribed form.

Proposed New Rule 11.153 (Registration of Market Makers in a Security)

The Exchange proposes to adopt new Rule 11.153 governing the security-level registration of Market Makers.[22] This rule addresses how a Member, once registered as a Market Maker at the firm level under Rule 11.150, becomes

[13] *See, e.g.,* Sections 15(b)(4)(E) and 15(b)(6) of the Act.

[14] This provision is consistent with Cboe BZX Rule 11.8(c), which similarly provides for Exchange action against market makers that fail to meet their obligations; the LTSE proposed provision differs only with respect to specific cross-references to rules.

[15] In proposed Rule 11.151(e), the Exchange proposes an updating change, replacing the term Anti- Internalization Group Identifier (''AGID'') modifier with Self Trade Protection (''STP'') modifier. This update corresponds to a change in self trade functionality used by the Exchange. *See* Securities Exchange Act Release Nos. 100783 (August 20, 2024), 89 FR 68481 (August 26, 2024) (SR–LTSE–2024–03) (order approving the proposal); and 100205 (May 21, 2024), 89 FR 46225, 46235 (May 28, 2024) (SR–LTSE–2024–03) (notice of, among other changes, the proposal to replace the AGID modifier with the STP modifier).

[16] The term ''Limit State'' is defined in the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS under the Act.

[17] The term ''Straddle State'' is defined in the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS under the Act.

[18] *See also* Cboe EDGA Exchange, Inc. Rules 11.20(d)(1)(A)–(C); Cboe EDGX Exchange, Inc. Rules 11.20(d)(1)(A)–(C); Cboe BYX Exchange, Inc. Rules 11.8(d)(1)(A)–(C).

[19] The thresholds under BZX's rules differ, reflecting BZX's own market structure calibration.

[20] This rule is substantially similar to Cboe BZX Rule 11.6 (Obligations of Market Maker Authorized Traders), differing only with respect to LTSE-specific cross-references. Additionally, the Exchange proposes to renumber current Rules 11.152 and 11.154 as proposed Rules 11.154 and 11.155, respectively, to accommodate the addition of 2 new proposed rules and the proposed deletion of current Rule 11.153.

[21] Arguably, MMATs may be permitted implicitly under LTSE Rule 11.150(a), which allows the entry of quotations and quotation sizes by an ''entity approved by LTSE to function in a market-making capacity.''

[22] This proposed rule is substantially similar to Cboe BZX Rule 11.7 (Registration of Market Makers in a Security), differing only with respect to LTSE-specific cross-references.

authorized to make markets in specific securities.

Proposed Rule 11.153(a) provides that a Market Maker may become registered in a newly authorized security or in a security already admitted to dealings on the Exchange by filing a security registration form with the Exchange. Registration in the security becomes effective on the same day as the Exchange's approval, unless otherwise provided by the Exchange. In considering approval, the Exchange may take into account: (1) the financial resources available to the Market Maker; (2) the Market Maker's experience, expertise, and past performance in making markets, including its performance in other securities; (3) operational capability; (4) the maintenance and enhancement of competition among Market Makers in each security; (5) the existence of satisfactory clearing arrangements; and (6) the character of the market for the security, including price, volatility, and relative liquidity.

Proposed Rule 11.153(b) provides that a Market Maker may voluntarily terminate its registration in a security by providing written notice of termination to the Exchange, subject to any minimum prior notice period or other conditions the Exchange may require in the interest of maintaining fair and orderly markets. A Market Maker that fails to provide advance written notice may be subject to formal disciplinary action under Chapter 9 of the LTSE Rules.

Proposed Rule 11.153(c) provides that the Exchange may suspend or terminate any Market Maker's registration in a security whenever it determines that: (1) the Market Maker has not met any of its obligations as set forth in the LTSE Rules; or (2) the Market Maker has failed to maintain fair and orderly markets.[23]

Proposed Rule 11.153(d) preserves all other powers of the Exchange under the By-Laws, Rules, and procedures of the Exchange with respect to the registration of a Market Maker and with respect to any violation by a Market Maker of the provisions of the Rule. These provisions are consistent with the corresponding review and reservation-of-authority provisions in Cboe BZX Rule 11.7(d), and parallel the analogous provisions the Exchange proposed at the firm level in Rules 11.150(e) and 11.151(c).

Amendments to Proposed Rule 11.154 (Withdrawal of Quotations)

The Exchange proposes to update cross-references in paragraphs (d) and (g) to reflect the proposed renumbering discussed above and the proposed deletion of current Rule 11.153 discussed below.

Deletion of Current Rule 11.153 (Voluntary Termination of Registration)

Current Rule 11.153 sets forth the procedures for a Market Maker to voluntarily terminate its registration in a security,[24] provides for the Exchange to reinstate a registration where withdrawal was accidental,[25] and specifies a Market Maker's avenue for review of its reinstatement denial.[26] The Exchange proposes to delete this rule because, as discussed above, proposed Rule 11.153(b) governs the voluntary termination of a Market Maker's registration in a security.[27]

(b) Statutory Basis

The proposed rule change is consistent with the provisions of Sections 6 and 19 of the Act[28] generally, and is consistent with the particular provisions of the Act discussed below. Before analyzing the proposed rules specifically, the Exchange makes four general points about the proposed rule change's consistency with the Act.

First, the proposed rule change creates a workable framework that will allow the Exchange to attract and monitor Market Makers who promote additional displayed liquidity on the Exchange. More specifically, the proposed rule change establishes a comprehensive, transparent framework for registering and overseeing Market Makers and MMATs and allowing Market Makers to register in particular securities. Because Market Makers are—and would be—required to maintain two-sided quotations that facilitate continuous trading and improve execution quality and, as dedicated liquidity providers Market Makers may help absorb market imbalances and reduce extreme price volatility, the proposed rule change advances the objectives of Section 6(b)(5) of the Act[29] to remove impediments to and perfect the mechanism of a free and open market and a national market system and protect investors and the public interest.

Second, the Exchange believes that the proposed rule change removes impediments to and perfects the mechanism of a free and open market and a national market system, and fosters cooperation and coordination with persons engaged in facilitating transactions in securities, by harmonizing the Exchange's market maker framework with the substantially similar, previously approved framework of another national securities exchange. Harmonization reduces regulatory divergence across exchanges and the associated compliance burden for Members that conduct market making activity on multiple venues, and provides Members with a familiar framework based on rules that have already been approved by the Commission and have been operating within the national market system.[30]

Third, the proposed rule change is consistent with Section 6(b)(5) of the Act in that it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed rule change would not change the scope of securities eligible for market making, and therefore does not discriminate among issuers: a Market Maker may register in one or more Non-LTSE- Primary-Listed Securities,[31] and all securities traded on the Exchange are Non-LTSE-Primary-Listed Securities.[32] The proposed rule change does not unfairly discriminate among brokers or dealers.[33] The proposed criteria for registering as a Market Maker apply equally to all Members, and the Exchange would

[23] In addition to suspending a Market Maker's registration in a security, under current Rule 11.154 (proposed Rule 11.155), LTSE may suspend, condition, limit, prohibit, or terminate the authority of a Market Maker (or Member) to enter quotations in one or more authorized securities for violations of applicable requirements or prohibitions. These two available remedies are distinct.

[24] *See* LTSE Rules 11.153(a) and (d).

[25] *See* LTSE Rules 11.153(b) and (c). LTSE Rule 11.153(b) specifies certain reinstatement eligibility requirements. *See* LTSE Rule 11.153(b)(3)–(5). LTSE Rule 11.153(c) enumerates the factors that the Exchange will consider in granting reinstatement.

[26] *See* LTSE Rule 11.153(e).

[27] Unlike current Rules 11.153(b) and (c), proposed Rule 11.153(b) does not contemplate accidental withdrawal. Accidental withdrawal was reasonably foreseeable under the current rule, which provided for withdrawal simply by a Market Maker withdrawing its two-sided quote. *See* Rule 11.153(a). In contrast, the method of voluntary withdrawal under proposed Rule 11.153(b) is mindful: written notice is required. Accordingly, the Exchange believes that a process for reinstatement after accidental withdrawal is unnecessary.

[28] 15 U.S.C. 78f and 15 U.S.C. 78s, respectively.

[29] 15 U.S.C. 78f(b)(5).

[30] In the ways discussed above, the proposed rule change is consistent with the rules of other national securities exchanges, including Cboe BZX and MEMX.

[31] *See* proposed Rule 11.151(a).

[32] *See supra* note 4.

[33] *See* proposed Rule 11.150(f) (designating all registered Market Makers as dealers on the Exchange for all purposes under the Act and the rules and regulations thereunder). This provision is found in the rulebooks of many national securities exchanges. *See, e.g.,* NYSE American Rule 7.20E(a); MIAX Pearl Rule 600(i).

apply the factors in a manner consistent with the Act and the Exchange's rules.

Fourth, aspects of the proposed rule change are consistent with Sections 6(b)(1) and 19(g) of the Act in that they will assist the Exchange in complying with its rules. For example, the proposal includes updating cross-references (proposed Rules 9.218(f)), 11.151(d)(12), 11.151(d)(13), and 11.154(g)). In addition, the proposed new definitions in Rule 1.160 will provide clarity that will facilitate consistent interpretation of the proposed rules in LTSE Rule Series 11.100.

*Proposed Rule 11.150 (Registration as a Market Maker).*[34] The proposed framework for registering Market Makers set forth in proposed Rule 11.150 protects investors and the public interest and promotes just and equitable principles of trade, consistent with Section 6(b)(5) of the Act, by ensuring that only qualified Members are authorized to perform market making activities on the Exchange. In particular, the application and review requirements of proposed Rule 11.150(a), the minimum net capital requirement that conforms to Rule 15c3–1 under the Act, the approval-based effectiveness model of Rule 11.150(b), and the suspension and termination grounds of Rule 11.150(c) are each designed to ensure that a Member granted Market Maker status has the capital, operational capability, personnel, and regulatory history necessary to perform a market making function consistent with the maintenance of fair and orderly markets.

Additionally, the right of review under Chapter 9 of the Exchange Rules provided for in proposed Rule 11.150(e) ensures that Market Makers have a fair process for challenging adverse Exchange determinations. This proposed provision is consistent with Section 6(b)(7) of the Act, which requires (in pertinent part) that the rules of an exchange provide a fair procedure for the disciplining of members and persons associated with members.

*Proposed Rule 11.151 (Market Maker Obligations).*[35] Consistent with Section 6(b)(5) of the Act, the proposed Market Maker obligations framework set forth in proposed Rule 11.151 protects investors and the public interest by codifying the affirmative obligations of Market Makers, including the general course-of-dealings obligation in proposed Rule 11.151(a), the firm-level supervisory responsibility for MMATs in proposed Rule 11.151(b), and the disciplinary consequences for failure to engage in a course of dealings in proposed Rule 11.151(c). Proposed Rule 11.151(b), which provides that a Market Maker shall be responsible for the acts and omissions of its MMATs, is consistent with consistent with general supervisory responsibility principles applicable to broker-dealers under Sections 15(b)(4)(E) and 15(b)(6) of the Act. The three new sub-provisions to the Two-Sided Obligation in proposed Rule 11.151(d)(1)(A), (B), and (C) are substantially similar to rules of other national securities exchanges that have been previously approved by the Commission.[36]

In addition, proposed Rule 11.151(c) ensures that Market Makers have a fair process for challenging adverse Exchange determinations, and therefore is consistent with Section 6(b)(7) of the Act, which requires (in pertinent part) that the rules of an exchange provide a fair procedure for the disciplining of members and persons associated with members.

*Proposed Rule 11.152 (Obligations of MMATs).*[37] The proposed framework for registering MMATs set forth in proposed Rule 11.152 protects investors and the public interest and promotes just and equitable principles of trade consistent with Section 6(b)(5) of the Act by ensuring that only qualified persons may effect market making activity on behalf of Market Makers. Additionally, the proposed individual-level registration framework for MMATs protects investors and the public interest by ensuring that persons authorized to enter orders on behalf of Market Makers meet minimum qualification standards. The proficiency examination and continuing education requirements of proposed Rule 11.152(b)(2), which apply the requirements applicable to Authorized Traders under LTSE Rule 2.160, the conditional registration authority of Rule 11.152(b)(4), and the suspension and withdrawal standards in proposed Rule 11.152(c) are each designed to ensure that individual market making activity on the Exchange is performed by qualified personnel and to provide the Exchange with appropriate authority to address conduct that poses a risk to fair and orderly markets.

*Proposed Rule 11.153 (Registration of Market Makers in a Security).*[38] The Exchange believes that the proposed security-level registration framework set forth in Rule 11.153 protects investors and the public interest and promotes just and equitable principles of trade by establishing a clear process for a Market Maker to become registered in specific securities, by enumerating the factors the Exchange may consider in reviewing such registration, and by establishing express grounds for voluntary termination and Exchange-initiated suspension or termination of security-level registration. The right of review under Chapter 9 of the Exchange Rules provided for in Rule 11.150(e) ensures that Market Makers have a fair process for challenging adverse Exchange determinations, consistent with Section 6(b)(7) of the Act, which requires (in pertinent part) that the rules of an exchange provide a fair procedure for the disciplining of members and persons associated with members.

*Proposed Deletion of Current Rule 11.153 (Voluntary Termination of Registration).* The proposed deletion of current Rule 11.153 is consistent with Sections 6(b)(1) and 19(g) of the Act in that it will assist the Exchange in complying with its rules. As discussed above, proposed Rule 11.153(b), which is substantively identical to the rule of another national securities exchange,[39] governs the voluntary termination of security registration and thus deleting current Rule 11.153 would prevent confusion arising out of contradictory provisions.

For these reasons, the Exchange believes that the proposed rule change is consistent with the Act and does not raise any new or novel material issues that have not already been considered by the Commission.[40]

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The proposed rule change is designed to establish a comprehensive, transparent framework for registering and overseeing Market Makers and MMATs. As described in Items 3(a) and 3(b) above, the proposed rules are in large part similar to previously approved rules of other national securities exchanges.

The Exchange does not believe that the proposed rule change imposes any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed Market Maker registration

[34] Proposed Rule 11.150 is substantially similar to Cboe BZX Rule 11.5.

[35] Proposed Rule 11.151 is substantially similar to Cboe BZX Rule 11.8

[36] *See supra* note 18 and accompanying text.

[37] Proposed Rule 11.152 is substantially similar to Cboe BZX Rule 11.6.

[38] Proposed Rule 11.153 is substantially similar to Cboe BZX Rule 11.7.

[39] *See* Cboe BZX Rule 11.7(b).

[40] The proposed rule change is consistent with Section 6(b)(4) of the Act, which requires that the Exchange's rules provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. No new benefits are being proposed for Market Makers.

requirements of Rule 11.150, the Market Maker obligations of Rule 11.151, the MMAT registration requirements of Rule 11.152, and the security-level registration requirements of Rule 11.153 apply on a uniform, non-discriminatory basis to all Members that seek to become Market Makers, to all individuals that seek to register as MMATs, and to all Members that seek to register in particular securities.

The Exchange operates in a highly competitive environment and competes with other national securities exchanges and other trading venues for order flow in the securities it trades.[41] The Exchange does not believe that the proposed rule change imposes any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, by harmonizing the Exchange's market maker framework with the substantially similar, previously approved framework of another national securities exchange, the proposed rule change reduces regulatory divergence across exchanges and the associated compliance burden for Members that conduct market making activity on multiple venues. Adoption of a framework based on familiar rules that have already been approved by the Commission[42] allows the Exchange to compete more effectively with other trading venues in attracting Members willing to perform market making functions. To the extent the Market Maker program enables the Exchange to enhance the market quality of Non-LTSE-Primary-Listed Securities traded on the Exchange, the proposed rule change is procompetitive: it equips the Exchange to compete more effectively with other trading venues that trade those same securities by improving the quality of executions available to investors on the Exchange.

For the foregoing reasons, the Exchange does not believe that the proposed rule change raises any substantial competitive issues, and the Exchange does not believe the proposed rule change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

The Exchange neither solicited nor received comments on the proposed rule change.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[43] and subparagraph (f)(6) of Rule 19b–4 thereunder.[44]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[45] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[46] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that it plans to launch its Market Maker program on October 1, 2026 and that waiver of the operative delay would permit timely commencement of this initiative, which is designed to improve quoting and displayed liquidity on the Exchange. In addition, the Exchange's proposed rules are substantially similar to the rules of other national securities exchanges.[47] For these reasons, and because the proposed rule change raises no new or novel legal or regulatory issues, the Commission finds that waiver of the operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission waives the 30-day operative delay and designates the proposed rule change to be operative upon filing.[48]

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 would otherwise further 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–LTSE–2026–21 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–LTSE–2026–21. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of LTSE and on its internet website at *https://longtermstockexchange.com/.* 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–LTSE–2026–21 and should be submitted on or before October 23, 2026.

[41] As noted above, *see supra* note 4, only Non-LTSE-Primary-Listed Securities are traded on the Exchange.

[42] *See supra* note 30, and accompanying text.

[43] 15 U.S.C. 78s(b)(3)(A)(iii).

[44] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[45] 17 CFR 240.19b–4(f)(6).

[46] 17 CFR 240.19b–4(f)(6)(iii).

[47] *See e.g., supra* notes 34–38 and accompanying text.

[48] 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).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[49]

**Sherry R. Haywood,**

*Assistant Secretary.*

[FR Doc. 2026–20200 Filed 10–1–26; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–106523; File No. SR–NYSEARCA–2026–99]**

## Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Change To Amend NYSE Arca Rule 5.32–O

September 29, 2026.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on September 16, 2026, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rules 5.32–O (Terms of Flexible Exchange (''FLEX'') Options). 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 Rules 5.32–O (Terms of FLEX Options) FLEX Options as it relates to FLEX Equity Options where the underlying security is an ETF that is eligible for cash settlement. Specifically, the proposed amendments would: (i) permit newly FLEX-eligible ETFs that satisfy heightened eligibility thresholds of $600 million average daily notional value and 5,616,000 shares ADV, based on the previous one-month period of trading statistics to be eligible for cash settlement as a contract term; (ii) establish tiered criteria governing the treatment of cash-settled FLEX ETF Options where the underlying ETF ceases to satisfy the requirements of Rule 5.32–O(f)(3)(ii) at the time of the Exchange's bi-annual review; and (iii) eliminate the existing provision limiting cash settlement as a contract term to no more than 50 underlying ETFs.

This filing is based on substantially identical proposals by Cboe Exchange, Inc. (''Cboe''),[4] Nasdaq ISE, LLC (''ISE'')[5] and Nasdaq PHLX Exchange (''PHLX'').[6]

Background

Generally, FLEX Equity Options are settled by physical delivery of the underlying security,[7] while all FLEX Index Options are settled in cash.[8] In February 2020, however, the Exchange amended Rule 5.32–O to permit cash settlement for up to 50 FLEX Equity Options with an underlying security that is an ETF meeting certain criteria: an average daily notional value of $500 Million or more and a national average daily volume of 4,680,000 shares, measured over the prior six-month period. Where more than 50 ETFs qualify, the Exchange selects the 50 with the highest average daily volume.[9]

The Exchange adopted these specific thresholds to limit cash-settled FLEX ETF Options to the most highly liquid and actively-traded ETFs, thereby mitigating concerns about susceptibility to manipulation at settlement. With respect to the notional value threshold, the Exchange determined that average daily notional value is an appropriate proxy for selecting underlying securities that are not readily susceptible to manipulation for purposes of establishing a settlement price. The Exchange noted that average daily notional value takes into account both the trading activity and the price of an underlying security. As a general matter, the more expensive an underlying security's price, the less cost-effective manipulation could become. Further, manipulation of the price of a security encounters greater difficulty the more volume that is traded.

With respect to the ADV threshold, the Exchange determined that a requirement of 4,680,000 shares per day is appropriate because it represents average trading in the underlying ETF of approximately 200 shares per second, a level of continuous trading activity that the Exchange believes meaningfully limits the ability to influence the ETF's price for purposes of establishing a settlement value. The Exchange acknowledged that no security is immune from all manipulation, but determined that the combination of these two requirements would appropriately limit cash settlement of FLEX ETF Options to underlying securities that are less susceptible to manipulation.

Under this framework, the Exchange conducts a bi-annual review on January 1 and July 1 of each year to identify qualifying ETFs. The rule caps the number of eligible underlying ETFs at 50; if more than 50 ETFs satisfy the criteria, the Exchange selects the top 50 by highest ADV. This cap was designed to prevent the scope of cash-settled FLEX ETF Options from expanding considerably without a corresponding evaluation of whether the level of the requirements remains reasonable, while still providing flexibility to add ETFs given that the initial list of eligible ETFs numbered well below 50 at the time of

[49] 17 CFR 200.30–3(a)(12), (59).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 105929 (July 16, 2026), 91 FR 45856 (July 21, 2026) (SR–Cboe–2026–035) (Notice of Filing of Amendment No. 1 and Order Approving a Proposed Rule Change, as Modified and Superseded by Amendment No. 1, To Amend Rule 4.21 (Series of FLEX Options) (''Cboe Approval'').

[5] *See* Securities Exchange Act Release No. 106015 (July 30, 2026), 91 FR 49470 (August 4, 2026) (SR–ISE–2026–44) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend FLEX Options Listing Rules) (''ISE Notice'').

[6] *See* Securities Exchange Act Release No. 106016 (July 30, 2026), 91 FR 49476 (August 4, 2026) (SR–PHLX–2026–49) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend FLEX Electronic Options Listing Rules) (''PHLX Notice'').

[7] *See* Rule 5.32–O(f)(3)(i).

[8] *See* Rule 5.32–O(e)(2) and (3). Similarly, pursuant to Exchange rules, Binary Return Derivatives (''ByRDs'') are also settled in cash (*See* Rule 5.82–O(b)) and, as discussed below, cash settlement is also permitted in the over-the-counter (''OTC'') market.

[9] *See* Rule 5.32–O(f)(3)(ii)(B). *See also* Securities Exchange Release No. 104692 (January 27, 2026), 91 FR 4145 (January 27, 2026) (SR–NYSEARCA–2026–4) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Amend Rules 5.32–O and 5.35–O Related to Flexible Exchange Options).

adoption. In the event a previously eligible ETF fails to satisfy the criteria at the time of a bi-annual review, any new positions overlying that ETF must be physically settled and any existing open cash-settled positions may be traded only to close. This provision was designed to address how to wind down outstanding cash-settled positions in an ETF that no longer qualifies under the liquidity and volume criteria, thereby addressing manipulation concerns while still permitting market participants to exit existing positions.

In connection with the adoption of this framework, the Exchange committed to conducting a five-year review of cash-settled FLEX ETF Option trading activity and furnishing the Commission with five annual reports. Pursuant to this commitment, the Exchange has submitted two annual monitoring reports to the Commission covering the two years of trading. The report assessed trading volume and open interest in cash-settled FLEX ETF options relative to physically settled options on the same underlying ETFs, market maker participation, the liquidity of the market for such options products and the underlying ETF, and any manipulation concerns arising in connection with the trading of cash-settled FLEX ETF Options under the proposed rule. The reports also discuss any recommendations the Exchange may have for enhancements to the listing standards based on its review. The Exchange had no recommendations for enhancements to the listing standards based on its reviews. The Exchange had no open investigation, inquiry, or enforcement matter relating to the manipulation of cash-settled FLEX ETF options or their underlying ETFs.

As discussed in the Cboe Approval, Cboe noted that it submitted two annual monitoring reports to the Commission covering the periods of August 1, 2023 through July 31, 2024 and August 1, 2024 through July 31, 2025, respectively.[10] The reports assessed trading volume and open interest in cash-settled FLEX ETF options relative to physically settled options on the same underlying ETFs, market maker participation, position limit activity, and manipulation concerns.[11] Cboe had no recommendations for enhancements to the listing standards based on either review.[12] Also, Cboe noted that in both review periods, neither Cboe nor any affiliated Cboe securities exchange had an open investigation, inquiry, or enforcement matter relating to the manipulation of cash-settled FLEX ETF options or their underlying ETFs.[13] Financial Industry Regulatory Authority (''FINRA''), acting as Cboe's regulatory services provider for position limit surveillance, confirmed the same finding for both periods.[14] While both of Cboe's reports note that certain regulatory matters arose during each period involving the applicable ETFs or related physically-settled options, Cboe's surveillance and investigatory staff confirmed in each instance that the activity did not appear to relate to manipulation of an ETF for the purpose of benefiting a cash-settled FLEX ETF option position.[15]

The review period reflects broad and stable market maker participation across the eligible underlying ETFs. Cboe stated that the highest levels of FLEX market maker participation were observed in SPY (9 to 12 per month), QQQ (6 to 10 per month), and IWM (3 to 15 per month).[16] Cboe noted that participation in less actively traded eligible ETFs was more limited but consistent across both periods, reflecting a well-supported and liquid product across the eligible universe.[17]

Proposal

The Exchange proposes to amend Rule 5.32–O(f)(3)(ii) to refine two aspects of the framework governing cash-settled FLEX ETF Options and to eliminate the 50- ETF cap. First, the Exchange proposes to permit newly FLEX-eligible ETFs to qualify for cash settlement as a contract term based on one month of trading statistics outside of the Exchange's regular bi-annual review cycle.[18] Second, the Exchange proposes to replace the existing provision governing ETFs that cease to satisfy the eligibility criteria with a tiered framework that more precisely calibrates treatment to the actual state of open interest in cash-settled FLEX ETF Options overlying the affected ETF.[19] Third, the Exchange proposes to eliminate the existing cap limiting cash settlement as a contract term to no more than 50 underlying ETFs.[20]

One-Month Lookback for Newly Eligible ETFs

Under the current rule, the Exchange determines eligible underlying ETFs bi-annually, on January 1 and July 1 of each year, using six months of prior trading statistics, with newly eligible ETFs permitted to list cash-settled FLEX options beginning on February 1 and August 1, respectively. No mechanism currently exists to add newly FLEX-eligible ETFs to the eligible list between bi-annual reviews. As a result, an ETF that becomes FLEX-eligible after a bi-annual review has been conducted may not be considered for cash-settled FLEX ETF Option eligibility for up to six months, even if it otherwise satisfies the notional value and ADV requirements of Rule(f)(3)(ii).

The Exchange proposes to address this gap by permitting, outside of the regular bi-annual review, the Exchange to determine that a newly FLEX-eligible ETF satisfies heightened notional value and trading volume requirements of $600 million average daily notional value and 5,616,000 shares ADV based on the previous one-month period of trading statistics. Any ETF satisfying such requirements on that basis shall be eligible for cash settlement as a contract term.

The Exchange believes a one-month lookback is appropriate in this context because an ETF that has newly become FLEX-eligible and simultaneously satisfies both the $600 million average daily notional value threshold and the 5,616,000-share ADV requirement over the prior month has already demonstrated the degree of liquidity and trading activity that the eligibility criteria are designed to capture. These thresholds represent a 20% increase over the standard $500 million and 4,680,000-share thresholds that apply to the bi-annual review, reflecting the Exchange's determination that heightened criteria are appropriate for ETFs seeking to qualify based on a shorter lookback period. The Exchange believes Cboe's and its annual monitoring reports demonstrate that the existing criteria are an effective proxy for identifying ETFs that are not readily susceptible to manipulation. Requiring newly eligible ETFs to await the next bi-annual review before becoming eligible for cash settlement would delay investor access to the product.

Cboe's back-testing analysis of newly listed FLEX ETFs supports the appropriateness of the heightened thresholds.[21] Under the standard eligibility criteria ($500 million average daily notional value and 4,680,000 shares ADV), ten ETFs would have qualified based on one month of trading data. Under the 20% increased

[10] *See* Cboe Approval, *supra* note 4.

[11] *See Id.*

[12] *See Id.*

[13] *See Id.*

[14] *See Id.*

[15] *See Id.*

[16] *See Id.*

[17] *See Id.*

[18] *See* proposed Rule 5.32–O(f)(3)(ii)(A).

[19] *See* proposed Rule 5.32–O(f)(3)(ii)(B).

[20] *See* proposed Rule 5.32–O(f)(3)(ii)(A).

[21] For purposes of the back-testing analysis, Cboe reviewed all newly listed FLEX-eligible ETFs from January 1, 2025 through April 6, 2026.

thresholds ($600 million average daily notional value and 5,616,000 shares ADV), only eight ETFs qualified. Cboe noted that the two ETFs excluded by the heightened thresholds did not qualify at their next six-month bi-annual review, demonstrating that the heightened thresholds effectively filter out ETFs whose initial trading activity may not be sustained.

The Exchange believes the heightened thresholds for the one-month lookback appropriately address the concern that a newly listed ETF may experience elevated trading activity in its initial period that is not representative of sustained liquidity. By requiring newly eligible ETFs to satisfy thresholds that are 20% above the standard bi-annual review criteria, the Exchange ensures that only those ETFs demonstrating a meaningfully higher level of liquidity and trading activity—beyond what may reflect initial market interest—are eligible for cash settlement based on the shorter lookback period.

Further, the Exchange represents that it will continue to monitor the one-month lookback criteria on an ongoing basis to assess the appropriateness of the threshold. As part of this ongoing monitoring, the Exchange will evaluate whether the heightened criteria continue to effectively identify ETFs with sustained liquidity and trading activity, and will propose adjustments to the threshold if warranted by the Exchange's review.

Tiered Criteria for ETFs Ceasing To Satisfy Eligibility Requirements

Under the current rule, if the Exchange determines at the time of a bi-annual review that an underlying ETF ceases to satisfy the eligibility criteria, any new position overlying that ETF must be physically settled and any existing open cash-settled positions may be traded only to close. While this provision addresses the wind-down of cash-settled activity in a straightforward manner, it does not distinguish between ETFs with active open interest and those with no meaningful cash-settled activity, nor does it account for the possibility that an ETF may temporarily fall below the eligibility thresholds and subsequently recover.

The Exchange proposes to replace this provision with a tiered framework that more precisely calibrates the treatment of an ineligible ETF to the actual state of the market for cash-settled FLEX ETF Options overlying that ETF. Under the proposed framework, if no open interest in cash-settled FLEX Equity Options overlying the ETF exists during the previous six-month period at the time of the bi-annual review determination, the existing treatment will apply: any new position must be physically settled and any open cash-settled positions may be traded only to close. Where open interest in cash-settled FLEX Equity Options overlying the ETF does exist during the previous six-month period, the Exchange will permit the opening of new cash-settled positions in that ETF for a period of one year from the date of the bi-annual review, after which any new position must be physically settled and any remaining open cash-settled positions may be traded only to close. This one-year continuation period is intended to provide market participants holding or seeking to manage existing cash-settled positions with a reasonable and predictable runway to do so, rather than abruptly restricting new position activity at the time of the bi-annual review determination.

The proposed framework also includes a recovery provision: if the underlying ETF satisfies the eligibility criteria at the time of either bi-annual review conducted during the one-year continuation period, that period will terminate and the ETF will resume full eligibility for cash settlement as a contract term. The Exchange believes this provision appropriately accounts for the possibility that an ETF's trading statistics may fluctuate around the eligibility thresholds and prevents an unnecessarily disruptive wind-down in cases where the ETF promptly returns to eligibility.

Elimination of the 50–ETF Cap

The Exchange also proposes to eliminate the existing provision limiting cash settlement as a contract term to no more than 50 underlying ETFs. The cap was adopted at the outset of the program to prevent the scope of cash-settled FLEX ETF Options from expanding considerably without a corresponding evaluation of whether the level of the eligibility requirements remained reasonable. While the number of ETFs satisfying the eligibility criteria remained well below 50 during the initial period of the program's operation, over the two-year period that Cboe monitored the market, the number of qualifying ETFs has grown to exceed that threshold (as of February 1, 2026, 60 ETFs were eligible), such that the cap now operates as an active constraint on the availability of cash-settled FLEX ETF Options on ETFs that otherwise satisfy the established eligibility criteria. The Exchange does not believe this result is consistent with the purpose of the cap, which was intended as a programmatic guardrail rather than a permanent numerical ceiling. As noted above, neither the Exchange nor Cboe identified manipulation concerns in their reviews. Given the same eligibility criteria and position and exercise limits would apply to any cash-settled FLEX ETF option, as would the Exchange's surveillance program, the Exchange believes the 50–ETF cap is no longer necessary. The Exchange believes these protections and the eligibility criteria themselves sufficiently mitigate any manipulation concerns associated with cash-settled FLEX ETF Options.

The Exchange also notes that, consistent with its commitment in the original proposal, it will continue to furnish the Commission with annual reports for the remainder of the five-year review period. The Exchange believes that the continued reporting commitment, together with the proposed amendments, appropriately positions the cash-settled FLEX ETF Option framework to address the operational gaps identified through the Exchange's review to date while preserving the monitoring mechanisms that allow the Exchange and the Commission to evaluate the ongoing impact of the program.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[22] in general, and furthers the objectives of Section 6(b)(5) of the Act,[23] 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 mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. In addition, the Exchange believes that the proposed rule change is consistent with the Section 6(b)(5)[24] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

One-Month Lookback for Newly Eligible ETFs

The Exchange believes the proposed one-month lookback for newly FLEX-eligible ETFs is consistent with the Act because it removes an impediment to the offering of cash-settled FLEX ETF Options on ETFs that have already demonstrated the liquidity and trading activity that the eligibility criteria are designed to capture, without

[22] 15 U.S.C. 78f(b).

[23] 15 U.S.C. 78f(b)(5).

[24] 15 U.S.C. 78f(b)(5).

compromising the manipulation-resistant features of those criteria. Under the current rule, an ETF that becomes FLEX-eligible after a bi-annual review has been conducted must wait up to six months before it may be considered for cash-settled FLEX ETF Option eligibility, even if it satisfies both the $600 million average daily notional value threshold and the 5,616,000-share ADV requirement at the time it becomes FLEX-eligible. The Exchange believes this gap is not necessary to protect against manipulation.

An ETF that satisfies both heightened thresholds over the prior one-month period has demonstrated a degree of liquidity and breadth of trading activity exceeding that which the six-month bi-annual review is designed to identify as indicative of reduced susceptibility to manipulation. The heightened thresholds, which represent a 20% increase over the standard $500 million and 4,680,000-share thresholds applicable to the bi-annual review, are designed to account for the possibility that a newly listed ETF may experience elevated trading activity in its initial period that is not representative of sustained liquidity. As noted above, Cboe's and the Exchange's annual monitoring reports have demonstrated the existing eligibility criteria are an effective and reliable proxy for identifying ETFs that are not readily susceptible to manipulation, and neither Cboe nor the Exchange has identified any manipulation concerns in connection with cash-settled FLEX ETF Options or their underlying ETFs during that period. The Exchange therefore believes that permitting a one-month lookback for newly FLEX-eligible ETFs between bi-annual reviews, subject to the heightened thresholds, removes an impediment to and perfects the mechanism of a free and open market and protects investors and the public interest by providing timely investor access to a cash-settlement alternative on ETFs that satisfy the established eligibility criteria, while maintaining the protections afforded by those criteria.

Cboe's back-testing analysis further supports the consistency of the heightened thresholds with the Act's anti-manipulation objectives. Under the standard criteria, ten newly listed FLEX ETFs would have qualified based on one month of trading data, but under the 20% increased thresholds only 8 qualified. The two names excluded (AMDL and SIVR) did not qualify at their next six-month bi-annual review, confirming that the heightened thresholds effectively identify and exclude ETFs whose initial trading statistics do not reflect sustained market activity. The Exchange believes this empirical evidence demonstrates that the heightened thresholds are reasonably designed to prevent ETFs with potentially transient liquidity from qualifying for cash settlement based on the shorter lookback period.

Tiered Criteria for ETFs Ceasing To Satisfy Eligibility Requirements

The Exchange believes the proposed tiered framework for ETFs that cease to satisfy the eligibility criteria at the time of a bi-annual review is consistent with the Act because it is reasonably designed to prevent fraudulent and manipulative acts and practices while also promoting just and equitable principles of trade and protecting investors. The current rule applies a single, uniform wind-down treatment to any ETF that falls below the eligibility thresholds at bi-annual review, regardless of whether active open interest in cash-settled FLEX ETF Options overlying that ETF exists. The Exchange believes this one-size-fits-all approach does not adequately account for the legitimate interests of market participants that hold existing cash-settled positions or that need the ability to open new positions to manage existing risk exposure in an ETF that has temporarily fallen below the thresholds.

The proposed tiered framework addresses this concern in a manner consistent with the Act's investor protection and anti-manipulation objectives. Where no open interest in cash-settled FLEX ETF Options overlying the affected ETF has existed during the previous six-month period, the current treatment would continue to apply, because the Exchange believes an immediate restriction on new cash-settled positions would not disrupt market participants' activity. Where open interest does exist at the time of the bi-annual review, the proposed one-year continuation period provides market participants with a reasonable and predictable runway to manage existing positions, which the Exchange believes promotes just and equitable principles of trade. The Exchange further believes that the recovery provision, under which the continuation period terminates and full eligibility is restored if the ETF satisfies the criteria at either bi-annual review during the one-year period, is consistent with the Act because it prevents an unnecessarily disruptive wind-down where an ETF's trading statistics temporarily dip below the eligibility thresholds and then recover, and it reinforces the principle that the eligibility criteria, rather than arbitrary timing, are the appropriate determinant of cash-settlement eligibility. Taken together, the Exchange believes the tiered framework is a reasonable means to address manipulation concerns while not unduly burdening market participants with existing cash-settled positions, as it eliminates the current immediate disruption to their investment strategies.

Elimination of the 50–ETF Cap

The Exchange believes the elimination of the 50–ETF cap is consistent with the Act because the cap is no longer necessary to protect against the concerns it was designed to address and, as currently operative, functions as an impediment to the offering of cash-settled FLEX ETF Options on ETFs that otherwise satisfy the established eligibility criteria. The cap was adopted at the outset of the program to prevent the scope of cash-settled FLEX ETF Options from expanding considerably without a corresponding evaluation of whether the level of the eligibility requirements remained reasonable. While the number of qualifying ETFs remained well below 50 during the initial period of the program's operation, that number has more recently grown to exceed the cap, such that the cap now actively restricts the availability of cash-settled FLEX ETF Options on ETFs that fully satisfy the notional value and ADV requirements of Rule 5.32–O. The Exchange believes that retaining this arbitrary restriction is inconsistent with the Act's objectives because Cboe's two-year monitoring record demonstrates that the eligibility criteria themselves limit the availability of cash settlement to FLEX ETF Options. The liquidity and trading activity requirements mitigate manipulation concerns for any ETF that satisfies those requirements, not just the top 50.

During the first two years that cash-settled FLEX ETF Options were available on Cboe, it identified (and its annual monitoring reports demonstrated) no manipulation concerns in connection with cash-settled FLEX ETF Options or their underlying ETFs. The Exchange did not identify any manipulation in its two years of monitoring. The Exchange believes the eligibility criteria, position and exercise limits, and surveillance program applicable to the 50 ETFs eligible for FLEX options with cash-settlement provide adequate protections against manipulation and market disruption to all ETFs that satisfy the criteria, regardless of the number of qualifying ETFs. The Exchange therefore believes that eliminating the cap

removes an impediment to and perfects the mechanism of a free and open market, protects investors and the public interest, and is otherwise consistent with the Act.

*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 substantially similar in all material respects to proposals submitted by Cboe, ISE and PHLX.[25]

The Exchange does not believe that the proposed rule change will impose any burden on inter-market competition as the proposal is not competitive in nature. The Exchange expects that all option exchanges have or will adopt substantively similar proposals, such that the Exchange's proposal would benefit competition. For these reasons, 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 Exchange's proposal does not burden intra-market competition because all Options Trading Permit (''OTP'') Holders and OTP Firms would be subject to the proposed changes to Rule 5.32–O. The Exchange believes that the proposed rule change will also provide additional opportunities for market participants to continue to efficiently achieve their investment and trading objectives for equity options on the Exchange.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

No written comments were solicited or received with respect to the proposed rule change.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[26] and Rule 19b–4(f)(6) thereunder.[27] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)[28] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[29] 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. Waiver of the 30-day operative delay would allow the Exchange to immediately align its rules with the current rules of Cboe, ISE and PHLX. 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 operative upon filing.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[30] 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–NYSEARCA–2026–99 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSEARCA–2026–99. 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–NYSEARCA–2026–99 and should be submitted on or before October 23, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

**Sherry R. Haywood,**

*Assistant Secretary.*

[FR Doc. 2026–20196 Filed 10–1–26; 8:45 am]

**BILLING CODE 8011–01–P**

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## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–106526; File No. SR–FICC–2026–010]**

## Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Clearing Agency Risk Management Framework

September 29, 2026.

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 September 18, 2026, Fixed Income

[25] Cboe Approval Order, ISE Notice and PHLX Notice, *supra* notes 4–6.

[26] 15 U.S.C. 78s(b)(3)(A)(iii).

[27] 17 CFR 240.19b–4(f)(6).

[28] 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.

[29] 17 CFR 240.19b–4(f)(6)(iii).

[30] 15 U.S.C. 78s(b)(2)(B).

[31] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Clearing Corporation (''FICC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. FICC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act [3] and Rule 19b–4(f)(4) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

## I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of amendments to the Clearing Agency Risk Management Framework (''Risk Management Framework'' or ''Framework'') of FICC and its affiliates, The Depository Trust Company (''DTC'') and National Securities Clearing Corporation (''NSCC,'' and together with DTC and FICC, the ''Clearing Agencies'').[5] Specifically, the proposed rule change would amend the Risk Management Framework to clarify and update the Framework. The proposed changes would update and clarify the Framework by (1) revising the format and structure of various sections to reflect internal policy and procedure governance requirements, (2) updating the descriptions to reflect that the Risk Management Framework supports the Clearing Agencies' compliance with Rules 17ad–25(j) [6] and 17ad–26 [7] under the Act; (3) adding a description of the Clearing Agency Framework for Certain Requirements on Governance and Conflicts of Interests, which was adopted by the Clearing Agencies in 2024 [8] and (4) adding clarifying, conforming, and administrative updates that do not alter how the Clearing Agencies comply with the applicable requirements of Rule 17ad–22(e) under the Act.[9]

## II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

*(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

FICC proposes to amend the Risk Management Framework of the Clearing Agencies. Specifically, the proposed rule change would amend the Risk Management Framework to clarify and update the Framework. The proposed changes would update and clarify the Framework by (1) revising the format and structure of various sections to reflect internal policy and procedure governance requirements, (2) updating the descriptions to reflect that the Risk Management Framework supports the Clearing Agencies' compliance with Rule 17ad–25(j) and Rule 17ad–26; (3) adding a description of the Clearing Agency Framework for Certain Requirements on Governance and Conflicts of Interests, which was adopted by the Clearing Agencies in 2024 and (4) adding clarifying, conforming, and administrative updates that do not alter how the Clearing Agencies comply with the applicable requirements of Rule 17ad–22(e).

Risk Management Framework

The Clearing Agencies adopted the Risk Management Framework [10] to provide an outline for how each of the Clearing Agencies (i) comprehensively manages legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by it; (ii) maintains a well-founded, clear, transparent and enforceable legal basis for each aspect of its activities; (iii) identifies, monitors, and manages risks related to links it establishes with one or more clearing agencies, financial market utilities, or trading markets; (iv) publicly discloses certain information, including market data; (v) meets the requirements of its participants and the markets it serves efficiently and effectively; (vi) uses, or at a minimum accommodates, relevant internationally accepted communication procedures and standards in order to facilitate efficient payment, clearing and settlement; and (vii) conducts an annual review of the Government Securities Division of FICC's access models. In this way, the Risk Management Framework currently supports the Clearing Agencies' compliance with Rules 17ad–22(e)(1), (3), (18), (20), (21), (22), (23), 17ad–25(j) and 17ad–26 under the Act,[11] as described in the Framework Filings.

In addition to setting forth the manner in which each of the Clearing Agencies addresses these requirements, the Risk Management Framework also describes the Framework ownership and the required governance process for review and approval of changes to the Framework. In connection with the annual review and approval of the Framework by the Board of Directors of each of FICC, DTC and NSCC (each a ''Board'' and collectively, the ''Boards''), the Clearing Agencies are proposing to make certain revisions to the Framework.

Proposed Changes

1. Revising Format and Structure

The proposed changes would reformat and reorganize the Framework to align with the Clearing Agencies' internal governance guidelines for policies, procedures and frameworks. Each Clearing Agency maintains guidelines regarding the required structure, organization, and content of such documents which are intended to ensure that the Clearing Agencies' policies, procedures and frameworks are well-written, well-structured, accurate and easy to understand.

The proposed revisions are intended to conform the Framework to those guidelines and include the following changes: [12]

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(4).

[5] *See* Securities Exchange Act Release Nos. 81635 (Sept. 15, 2017), 82 FR 44224 (Sept. 21, 2017) (SR–DTC–2017–013, SR–FICC–2017–016, SR–NSCC–2017–012) (''Initial Filing''); 89271 (July 9, 2020), 85 FR 42933 (July 15, 2020) (SR–NSCC–2020–012); 89269 (July 9, 2020), 85 FR 42954 (July 15, 2020) (SR–DTC–2020–009); 89270 (July 9, 2020), 85 FR 42927 (July 15, 2020) (SR–FICC–2020–007); 96799 (Feb. 03, 2023), 88 FR 8506 (Feb. 9, 2023) (SR–DTC–2023–001); 96800 (Feb. 3, 2023), 88 FR 8491 (Feb. 9, 2023) (SR–FICC–2023–001); 96801 (Feb. 3, 2023), 88 FR 8502 (Feb. 9, 2023) (SR–NSCC–2023–001); 99097 (Dec. 6, 2023), 88 FR 86186 (Dec. 12, 2023) (SR–FICC–2023–016); 99098 (Dec. 6, 2023), 88 FR 86183 (Dec. 12, 2023) (SR–NSCC–2023–012); 99108 (Dec. 07, 2023), 88 FR 86430 (Dec. 13, 2023) (SR–DTC–2023–012); 101685 (Nov. 21, 2024), 89 FR 93689 (Nov. 27, 2024) (SR–DTC–2024–003, SR–FICC–2024–006, SR–NSCC–2024–003); 102652 (Mar. 13, 2025), 90 FR 12858 (Mar. 19, 2025) (SR–DTC–2025–002); 102653 (Mar. 13, 2025), 90 FR 12870 (Mar. 19, 2025) (SR–FICC–2025–004); and 102654 (Mar. 13, 2025), 90 FR 12844 (Mar. 19, 2025) (SR–NSCC–2025–002) (together with the Initial Filing, the ''Framework Filings'').

[6] 17 CFR 240.17ad–25(j) (''Rule 17ad–25(j)'').

[7] 17 CFR 240.17ad–26 (''Rule 17ad–26'').

[8] *See* Securities Exchange Act Release No. 101764 (Nov. 26, 2024), 82 FR 44224 (Dec. 3, 2024) (SR–DTC–2024–009, SR–FICC–2024–010, SR–NSCC–2024–006).

[9] 17 CFR 240.17ad–22(e) (''Rule 17ad–22(e)'').

[10] *Supra* note 5.

[11] 17 CFR 240.17ad–22(e)(1), (3), (18), (20), (21), (22), (23), 17ad–25(j), and 17ad–26.

[12] References to Section numbers herein are referring to Section numbers following the proposed changes.

| Section | Proposed changes |
| --- | --- |
| Section 1 ..... | Rename the section ''Executive Summary'' to ''Purpose'' and revise the accompanying description to articulate the purpose of the Framework. |
| | Delete the sentence defining DTCC and identifying it as the parent of the Clearing Agencies, and relocate that definition to the first reference to DTCC in Section 2. |
| | Delete the four paragraphs describing the Framework, the treatment of risks not addressed by the Framework, supporting documentation, and the meaning of references, and relocate that content to Section 2. |
| Section 2 ..... | Rename the section ''Framework Ownership and Change'' to ''Roles and Responsibilities'' and move language from Section 1 to this Section as described above. |
| | Delete the sentence addressing ownership of the Framework and move it to Section 3. |
| | Delete the paragraph describing ownership of the processes addressed by the Framework and move it to Section 3. |
| | Delete the paragraph describing the approval process for changes to the Framework and move it to Section 8. |
| | Delete the sentence regarding review of the Framework by the General Counsel's Office and move it to Section 3. |
| | Delete the sentence addressing annual Board approval of the Framework and move it to Section 8. |
| | Delete the sentence regarding the legend associated with the Framework and move it to Section 8. |
| Sections 3–6 ..... | Create new Section 3, titled ''Audience'' and move language from Section 2 to this Section as described above. |
| | Renumber the headings and subheadings in current Sections 3 through 5 to reflect the addition of the new Section 3. |
| Section 7 ..... | Create a new Section 7, titled ''Exceptions,'' describing the process for escalating, approving, and documenting exceptions to the Framework in accordance with applicable internal compliance guidelines governing policies, procedures, and frameworks. |
| Section 8 ..... | Create a new Section 8, titled ''Framework Governance'' and relocate the governance-related provisions currently contained in Section 2 to this Section as described above. |

2. Updating Descriptions To Reflect Support of Compliance With Rule 17ad–25(j) and Rule 17ad–26

The proposed changes include additional disclosures intended to address the Clearing Agencies' compliance with the requirements of Rule 17ad–25(j), related to the management of risks presented by core service providers and the solicitation of stakeholder views, and the requirements set forth in Rule 17ad–26, relating to the maintenance of the Clearing Agencies' recovery and wind-down plans.[13]

Specifically, Section 1 would be revised to include references to Rule 17ad–25(j) and Rule 17ad–26, clarifying that the Framework supports compliance with those requirements. Section 5.2.1 would be updated to state that, consistent with Rule 17ad–25(j), the Clearing Agencies have established policies and procedures to manage risks arising from relationships with providers of core services. Section 5.3 would be enhanced to include a description of the Clearing Agencies' advisory councils as part of their compliance with Rule 17ad–25(j). In addition, Section 6 would be revised to reference Rule 17ad–26 and to state that it requires the recovery and wind-down plans to identify the core staffing and providers of core services necessary to support the continued provision of core services.

3. Add Reference to Clearing Agency Framework for Certain Requirements on Governance and Conflicts of Interests

Section 4.3.3 currently lists additional frameworks adopted by the Clearing Agencies that support the Framework. The proposed revision would add the Clearing Agency Framework for Certain Requirements on Governance and Conflicts of Interest, adopted by the Clearing Agencies in 2024,[14] and include a brief description of its purpose and scope.

4. Immaterial Changes for Clarification Purposes

The proposed changes include a number of clarifying, conforming, and administrative updates to improve the accuracy, consistency, and readability of the Framework.

The following changes would be made throughout the Framework: (i) replace references to 17 CFR 240.17ad–22(e) with 17 CFR 240.17ad–22(e), (ii) replace references to the Risk Department with the Group Chief Risk Office to reflect the department's current name; and (iii) update section references to align with the organizational and formatting revisions described above.

Additional revisions would be made to specific sections of the Framework. In Section 4.1.1, a semicolon would be added in two places. In Section 4.1.2, a period would replace a comma in the first bullet point of the renamed Group Chief Risk Office subsection. In Section 4.1.3, the phrase ''independent validation'' would be replaced with ''independent and objective assurance'' to more accurately describe the role of the Internal Audit department. In Section 4.2, the description of the policy governing the establishment and oversight of internal committees and councils would be enhanced to clarify that each committee is periodically reviewed to confirm that it continues to fulfill its intended purpose effectively. In Section 4.3.1, the apostrophe after ''Agencies''' would be removed and ''business person'' would be replaced with ''businessperson'' for grammatical consistency. In Section 4.3.3, definitions that are not used in the Framework would be removed, and the Clearing Agency Securities Valuation Framework would be renamed the Clearing Agency Price and Margin Input Data Framework to reflect its current title.

Further clarifications would be made in Section 5.1, including the removal of the phrase ''among other things'' as unnecessary, clarification that each of FICC and NSCC publishes public guides describing the methodologies used to calculate their respective Clearing Fund components and provides calculators that estimate certain margin requirements as examples of information available to participants, the addition of the word ''with'' for clarity, and the insertion of a comma after ''time'' to improve readability. In Section 5.2.1, a comma would be added after ''time,'' a sentence that was inadvertently presented as a separate bullet would be incorporated into the preceding bullet, and ''third party'' would be revised to ''third-party.'' In Section 5.2.2, the word ''relevant'' would be capitalized because it is the first word of the sentence. Section 5.3 would be updated to more accurately describe the processes and year-end reporting used by the Clearing Agencies to measure and monitor performance against their goals and targets. In Section 5.4, ''its'' would be replaced with ''their'' for grammatical correctness. Finally, Section 6 would be revised to reflect that Board approval of

[13] *See* 17 CFR 240.17ad–25(j) and 17ad–26.

[14] *See supra* note 8.

the Recovery and Wind-down Plans is now required annually, rather than biennially.

2. Statutory Basis

The Clearing Agencies believe that the proposed changes are consistent with Section 17A(b)(3)(F) of the Act [15] for the reasons described below. Section 17A(b)(3)(F) of the Act requires, in part, that the rules of a registered clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions, and to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible.[16]

The proposed changes would clarify and enhance the descriptions in the Risk Management Framework and correct errors in those descriptions by, for example, (1) revising the format and structure of various sections to reflect internal policy and procedure governance requirements, (2) updating the descriptions to reflect that the Risk Management Framework supports the Clearing Agencies' compliance with Rule 17ad–25(j) and Rule 17ad–26; (3) adding a description of Clearing Agency Framework for Certain Requirements on Governance and Conflicts of Interests, and (4) adding clarifying, conforming, and administrative updates that do not alter how the Clearing Agencies comply with the applicable requirements of Rule 17ad–22(e) under the Act.[17] By creating clearer, updated descriptions and correcting errors, the Clearing Agencies believe that the proposed changes would make the Risk Management Framework more effective in providing an overview of the important risk management activities of the Clearing Agencies, as described therein.

As described in the Framework Filings, the risk management functions described in the Risk Management Framework allow the Clearing Agencies to continue to promote the prompt and accurate clearance and settlement of securities transactions and continue to assure the safeguarding of securities and funds which are in their custody or control or for which they are responsible. The proposed changes to improve the clarity and accuracy of the descriptions of risk management functions within the Framework would assist the Clearing Agencies in carrying out these risk management functions. Therefore, the Clearing Agencies believe these proposed changes are consistent with the requirements of Section 17A(b)(3)(F) of the Act.[18]

*(B) Clearing Agency's Statement on Burden on Competition*

The Clearing Agencies do not believe that the proposed changes to the Framework described above would have any impact, or impose any burden, on competition. As described above, the proposed rule changes would improve the comprehensiveness of the Framework by creating clearer, updated descriptions and correcting errors, thereby making the Risk Management Framework more effective in providing an overview of the important risk management activities of the Clearing Agencies. As such, the Clearing Agencies do not believe the proposed rule changes would have any impact on competition.

*(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

The Clearing Agencies have not received or solicited any written comments relating to this proposal. If any written comments are received, they will be publicly filed as an Exhibit 2 to this filing, as required by Form 19b–4 and the General Instructions thereto.

Persons submitting comments are cautioned that, according to Section IV (Solicitation of Comments) of the Exhibit 1A in the General Instructions to Form 19b–4, the Commission does not edit personal identifying information from comment submissions. Commenters should submit only information that they wish to make available publicly, including their name, email address, and any other identifying information.

All prospective commenters should follow the Commission's instructions on how to submit comments, *available at www.sec.gov/rules-regulations/how-submit-comment.* General questions regarding the rule filing process or logistical questions regarding this filing should be directed to the Main Office of the Commission's Division of Trading and Markets at *tradingandmarkets@sec.gov* or 202–551–5777.

The Clearing Agencies reserve the right not to respond to any comments 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) of the Act [19] and paragraph (f) of Rule 19b–4 thereunder.[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.

## 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 (*www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–FICC–2026–010 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to file number SR–FICC–2026–010. 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 FICC and on DTCC's website (*www.dtcc.com/legal/sec-rule-filings*). 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–FICC–2026–010 and should be submitted on or before October 23, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

**Sherry R. Haywood,**

*Assistant Secretary.*

[FR Doc. 2026–20198 Filed 10–1–26; 8:45 am]

**BILLING CODE 8011–01–P**

[15] 15 U.S.C. 78q–1(b)(3)(F).

[16] *Id.*

[17] 17 CFR 240.17ad–22(e).

[18] 15 U.S.C. 78q–1(b)(3)(F).

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f).

[21] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–106520; File No. SR–NasdaqTX–2026–046]**

## Self-Regulatory Organizations; Nasdaq Texas, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the Rule 5000 Series to Transition to a Primary Listing Venue

September 29, 2026.

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 September 17, 2026, Nasdaq Texas, LLC (''Nasdaq Texas'' 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 modify the Rule 5000 Series to align with the Exchange's transition to a primary listing venue. While these amendments are effective upon filing, the proposal will become operative upon an announcement published on the Nasdaq.com website, which is expected in the second quarter of 2027.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaqtx/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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The purpose of the proposed rule change is amend certain Exchange listing rules, specifically, removing Listing Rule IM–5220–1 (Dually-Listed Companies), and establishing new Listing Rules IM–5101–4 (Delisting in Connection with Trading Indicative of Potential Manipulation), 5210(l) (Special Requirements for Companies based in China, Hong Kong and Macau), 5405(b)(3)(A)(ii) (Initial Listing Requirements and Standards for Primary Equity Securities) and IM–5405–1 (Determination of Price-Based Requirements for Direct Listings), to prepare the Exchange to become a primary listing venue during the second quarter of 2027. The proposed changes align with The Nasdaq Stock Market LLC (''Nasdaq'').

The Exchange recently changed its name to Nasdaq Texas and adopted new initial and continued listing standards for equity securities that are substantially similar to those of the Nasdaq Global Market.[3] As explained when Nasdaq Texas adopted the new initial and continued listing standards, the Exchange anticipated subsequent modification of its rules to allow it to serve as a primary listing venue in the future.[4] The proposed rule changes described below are designed to provide additional listing options as a primary listing venue and to also align the Exchange's rules with the corresponding rules of Nasdaq.

The proposal will become operative upon an announcement published on the *Nasdaq.com* website, which is expected in the second quarter of 2027.[5]

Proposed Listing Rule IM–5101–4

Nasdaq Texas is proposing a new Listing Rule IM–5101–4 substantially similar to Nasdaq, which was approved by the Commission.[6] The proposed rule gives the Exchange authority to delist a security where the Commission has previously implemented a temporary trading suspension pursuant to Exchange Act Section 12(k) and Nasdaq Texas determines it appropriate and in the public interest to do so. In addition to the proposed change bringing alignment to its listing rules with Nasdaq rules, the Exchange believes the proposed rule will enable it to address instances where a company satisfies its listing requirements, but there are ongoing concerns about the trading in the company's securities, which the Exchange believes indicates that the security is inappropriate for continued listing.

Proposed Listing Rule 5210(l)

Nasdaq Texas is proposing a new Listing Rule 5210(l), which would add new listing requirements for companies based in the People's Republic of China (''China'') (including the Hong Kong Special Administrative Region and the Macau Special Administrative Region) (collectively, ''Chinese companies''). More specifically, proposed Listing Rule 5210(l) would apply to a Company that is headquartered or incorporated in China (including the Hong Kong Special Administrative Region and the Macau Special Administrative Region) or whose business is principally administered in one of those jurisdictions. A Company's business will be considered to be principally administered in a jurisdiction 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.[7]

[3] *See* Exchange Act Release No. 104907 (Feb. 27, 2026), 91 FR 10657 (Mar. 4, 2026) (Notice of Filing of Amendment Nos. 1 and 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, to Remove Existing Listing Rules and Establish New Listing Standards) (File No. SR–BX–2026–004) (''Listing Rules Approval Order'').

[4] *Id.* at 10658.

[5] The Exchange also expects to file a separate rule proposal establishing listing fees applicable to companies with a primary listing on the Exchange before the proposal becomes operative.

[6] *See* Exchange Act Release No. 105603 (June 3, 2026), 91 FR 34675 (June 8, 2026) (Order Granting Accelerated Approval to Adopt Listing Rule IM–5101–4).

[7] Pursuant to Listing Rule 5005(a), ''Company'' means the issuer of a security listed or applying to list on Nasdaq Texas. For purposes of the Rule 5000 Series, the term ''Company'' includes an issuer that is not incorporated, such as, for example, a limited partnership. The term ''control'' (including the terms ''controlling,'' ''controlled by'' and ''under common control with'') shall have the same meaning as set forth in 17 CFR 240.12b–2(4), which means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether

Continued

Additionally, in the case of an initial public offering, a Chinese company must offer a minimum amount of securities in Firm Commitment Offering in the United States to Public Holders [8] that will result in gross proceeds to the company of at least $25 million.

Nasdaq Texas also proposes adopting comparable changes for companies seeking to list in connection with business combination, and listings that are currently trading on the OTC market or another national securities exchange. In the case of a business combination, as described in Listing Rule 5110(a) or IM–5101–2(b),[9] Nasdaq Texas is proposing to adopt a new Listing Rule 5210(l)(ii) that would impose a similar new requirement as applicable to initial public offerings (''IPOs'') but would reflect that the listing would not typically be accompanied by an offering. Specifically, proposed Listing Rule 5210(l)(ii) would require a company to have a minimum Market Value of Unrestricted Publicly Held Shares following the business combination equal to at least $25 million. 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.[10]

Nasdaq Texas is proposing to adopt Listing Rule 5210(l)(iii) which will prohibit a Chinese company from listing on Nasdaq Texas in connection with a Direct Listing, as defined by Listing Rule IM–5405–1. While Nasdaq only allows Chinese companies to list on the Nasdaq Global Select Market, it does not allow such companies to list on the Nasdaq Global Market (''NGM'') or the Nasdaq Capital Market. Because the Exchange's listing requirements are similar to NGM, the Exchange is also prohibiting Direct Listings by Chinese companies. Additionally, Nasdaq Texas proposes Listing Rule 5210(l)(iv) which would require a Chinese company that transfers its listing from the over-the-counter market or from another national securities exchange to first trade on that other market for at least one year and have a minimum Market Value of Unrestricted Publicly Held Shares of at least $25 million before it is eligible to list on Nasdaq Texas.

A company that falls under proposed Rule 5210(l) will also need to comply with all other applicable listing requirements. Nasdaq Texas is proposing this rule to align with Nasdaq Rule 5210(l), which was approved by the Commission and found to be consistent with the Act. Nasdaq Texas also proposes to renumber current Listing Rules 5210(l) through (m) alphabetically to maintain consistency in the rulebook.

Removal of Listing Rule IM–5220–1

Current Listing Rule IM–5220–1 requires all companies listed on Nasdaq Texas to be listed on another national securities exchange—specifically a primary listing venue. This requirement was necessary because Nasdaq Texas was not established as a primary listing venue. However, once the Exchange transitions becoming a primary listing venue, Listing Rule IM–5220–1 will no longer be applicable. Therefore, the Exchange proposes to remove this provision which will enable companies to list solely on Nasdaq Texas without being required to also list on another national securities exchange. Removing this rule also is consistent with Nasdaq Listing Rules.

Proposed Listing Rule 5405(b)(3)(A)(ii)

Nasdaq Texas is also proposing to modify Listing Rule 5405(b)(3)(A) to increase the minimum Market Value of Listed Securities that a company whose business plan is to complete one or more acquisitions, as described in Listing Rule IM–5101–2 (an ''Acquisition Company''), to at least $100 million.[11] Specifically, proposed Listing Rule 5405(b)(3)(A)(ii) will require Market Value of Listed Securities of at least $100 million (current publicly traded Companies must meet this requirement and the $4 bid price requirement for 90 consecutive trading days prior to applying for listing if qualifying to list only under the Market Value Standard). This increased Market Value of Listed Securities requirement for the listing of an Acquisition Company is the same as the current Market Value of Listed Securities requirement under the Alternative Initial Listing Requirements for Acquisition Companies listing pursuant to Listing Rule 5406 and Section 102.06 of the New York Stock Exchange (''NYSE'') Listed Company Manual.[12] The proposed rule is also substantially similar to Nasdaq's corresponding Listing Rules 5405(b)(3)(A)(ii). However, unlike Acquisition Companies listing under Rule 5406 or the NYSE requirements, which can list with 300 shareholders, an Acquisition Company listing under Rule 5405(b)(3)(A) would continue to be required to have 400 shareholders.

Proposed Listing Rule IM–5405–1

As explained when Nasdaq Texas adopted new initial and continued listing standards, Nasdaq Texas included cross-references to rules relating to Direct Listing, with the intent on proposing the related cross-referenced rules once Nasdaq Texas transitions to a primary listing venue.[13] In preparation for this transition, the Exchange is proposing Listing Rule IM–5405–1 which will allow for the Direct Listing of securities on Nasdaq Texas. More specifically, proposed Listing Rule IM–5405–1 describes when a company whose stock is not previously registered under the Exchange Act may list on the Exchange.

*Proposed Listing Rule IM–5405–1:* (1) describes when a company whose stock is not previously registered under the Exchange Act may list on Nasdaq Texas, where such company is listing without a related underwritten offering upon effectiveness of a registration statement

through the ownership of voting securities, by contract, or otherwise.

[8] Rule 5005(a) 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.''

[9] Rule 5110(a) relates to business combinations with non-Nasdaq entities resulting in a change of control. Rule IM–5101–2(b) relates to a business combination with an acquisition company, which is a company whose business plan at the time of its initial listing is to complete an IPO and engage in a merger or acquisition with one or more unidentified companies within a specific period of time.

[10] Rule 5005(a) defines ''Unrestricted Publicly Held Shares'' as the Publicly Held Shares that are Unrestricted Securities. Rule 5005(a) defines ''Publicly Held Shares'' as shares not held directly or indirectly by an officer, director or any person who is the beneficial owner of more than 10 percent of the total shares outstanding. Rule 5005(a) defines ''Unrestricted Securities'' as securities that are not Restricted Securities and Rule 5005(a) defines ''Restricted Securities'' as securities that are subject to resale restrictions for any reason, including, but not limited to, securities: (1) acquired directly or indirectly from the issuer or an affiliate of the issuer in unregistered offerings such as private placements or Regulation D offerings; (2) acquired through an employee stock benefit plan or as compensation for professional services; (3) acquired in reliance on Regulation S, which cannot be resold within the United States; (4) subject to a lockup agreement or a similar contractual restriction; or (5) considered ''restricted securities'' under Rule 144. Rule 5005(a) defines ''Market Value'' as the consolidated closing bid price multiplied by the measure to be valued (*e.g.,* a Company's Market Value of Publicly Held Shares is equal to the consolidated closing bid price multiplied by a Company's Publicly Held Shares).

[11] All other Companies listing under Listing Rule 5405(b)(3)(A) will continue to be subject to the current Market Value of Listed Securities requirement of $75 million. Rule 5005(a) defines ''Listed Securities'' as securities listed on Nasdaq Texas or another national securities exchange.

[12] *See* Nasdaq Listing Rule 5406; *See also* Section 102.06 of the NYSE Listed Company Manual.

[13] Listing Rules Approval order *supra* n.3 at 10658 n.15.

registering only the resale of shares sold by the company in earlier private placements; (2) sets forth the additional listing requirements for Direct Listings on the Exchange; and (3) describes how the Exchange will determine compliance with initial listing standards related to the requirements based on the price of a security, including the bid price, Market Value of Listed Securities and Market Value of Unrestricted Publicly Held Shares. The proposed rule is substantially similar to the corresponding provisions of Nasdaq Listing Rules IM–5315–1 and 5405–1 which have been approved by the Commission and found to be consistent with the Act.[14]

Except as described in more detail below, under proposed Listing Rule IM–5405–1, Nasdaq Texas would generally require that a company listing on the Exchange through a Direct Listing provide Nasdaq Texas an independent third-party valuation (a ''Valuation''), as defined in the proposed rule, that meets the requirements of proposed Listing Rules IM–5405–1(a)(1)(A) and (a)(1)(B). Under proposed Listing Rule IM–5405–1(a)(1)(A), any Valuation used for this purpose must be provided by an entity that has significant experience and demonstrable competence in the provision of such valuations. The Valuation must be of a recent date as of the time of the approval of the company for listing and the evaluator must have considered, among other factors, the annual financial statements required to be included in the registration statement, along with financial statements for any completed fiscal quarters subsequent to the end of the last year of audited financials included in the registration statement. Nasdaq Texas will consider any market factors or factors particular to the listing applicant that would cause concern that the value of the company had diminished since the date of the Valuation and will continue to monitor the company and the appropriateness of relying on the Valuation up to the time of listing. Nasdaq Texas may withdraw its approval of the listing at any time prior to the listing date if it believes that the Valuation no longer accurately reflects the company's likely market value.[15]

Under proposed Listing Rule IM–5405–1(a)(1)(B), a valuation agent will not be considered independent if:

- At the time it provides such Valuation, the valuation agent or any affiliated person or persons beneficially own in the aggregate as of the date of the valuation, more than 5% of the class of securities to be listed, including any right to receive any such securities exercisable within 60 days.
- The valuation agent or any affiliated entity has provided any investment banking services to the listing applicant within the 12 months preceding the date of the Valuation. For purposes of this provision, ''investment banking services'' includes, without limitation, acting as an underwriter in an offering for the issuer; acting as a financial adviser in a merger or acquisition; providing venture capital, equity lines of credit, PIPEs (private investment, public equity transactions), or similar investments; serving as placement agent for the issuer; or acting as a member of a selling group in a securities underwriting. The valuation agent or any affiliated entity has been engaged to provide investment banking services to the listing applicant in connection with the proposed listing or any related financings or other related transactions.

For a security that has had sustained recent trading in a Private Placement Market[16] prior to listing, Nasdaq Texas will determine a company's price, Market Value of Listed Securities and Market Value of Unrestricted Publicly Held shares based on the lesser of: (i) the value calculable based on the Valuation[17] and (ii) the value calculable based on the most recent trading price in a Private Placement Market.[18]

Under proposed Listing Rule IM–5405–1(a)(5), to determine compliance with the price-based requirements and suitability for listing on the Exchange, Nasdaq Texas will examine the trading price trends for the stock in the Private Placement Market over a period of several months prior to listing and will only rely on a Private Placement Market price if it is consistent with a sustained history over that several month period evidencing a market value in excess of Nasdaq Texas' market value requirement. Nasdaq Texas believes that the price from such sustained trading in a Private Placement Market for the issuer's securities is predictive of the price in the market for the common stock that will develop upon listing of the securities on Nasdaq Texas.

Alternatively, in the absence of any recent sustained trading in a Private Placement Market over a period of several months,[19] to determine that such company has met the applicable price-based initial listing requirements, Nasdaq Texas proposes to require, under proposed Listing Rule IM–5405–1(a)(2) that a Valuation must evidence a price, Market Value of Listed Securities and Market Value of Unrestricted Publicly Held Shares that exceed 200% of the otherwise applicable requirement. Thus, to list on the Exchange, the Valuation must evidence a minimum bid price of at least $8 per share; Market Value of Unrestricted Publicly Held Shares of $30 million under the Income Standard; or Market Value of Unrestricted Publicly Held Shares of $36 million under the Equity Standard; or Market Value of Unrestricted Publicly Held Shares of $40 million and Market Value of Listed Securities of $150 million under the Market Value Standard; or Market Value of Unrestricted Publicly Held Shares of $40 million under the Total Assets/Total Revenue Standard.[20]

Under proposed Listing Rule IM–5405–1(a)(3) Nasdaq Texas may (but is not required to) accept other compelling evidence of the security's price, Market Value of Listed Securities and Market Value of Unrestricted Publicly Held Shares, including, a tender offer for cash by the company or an unaffiliated third party, a sale between unaffiliated third parties involving the company's equity securities, or equity security sales by the company that exceed 250% of the otherwise applicable requirement. To qualify as compelling evidence, transactions under the proposed rule must (1) have been completed within the prior six months, (2) have represented at least 20% of the

[14] *See* Exchange Act Release No. 87648 (Dec. 3, 2019), 84 FR 67308 (Dec. 9, 2019) (Order Granting Accelerated Approval of NASDAQ–2019–001[sic]).

[15] Additionally, under Listing Rule 5101 Nasdaq Texas has broad discretionary authority to deny initial listing, apply additional or more stringent criteria for the initial or continued listing of particular securities, or suspend or delist particular securities based on any event, condition, or circumstance that exists or occurs that makes initial or continued listing of the securities on Nasdaq Texas inadvisable or unwarranted in the opinion of Nasdaq Texas, even though the securities meet all enumerated criteria for initial or continued listing on Nasdaq Texas.

[16] Nasdaq Texas defines ''Private Placement Market'' in Listing Rule 5005(a) as a trading system for unregistered securities operated by a national securities exchange or a registered broker-dealer.

[17] As described in more detail below, under proposed Listing Rules IM–5405–1(a)(3), in lieu of a Valuation, Nasdaq Texas may accept certain other compelling evidence of the security's price, Market Value of Listed Securities and Market Value of Unrestricted Publicly Held Shares.

[18] Proposed Listing Rule IM–5405–1(a)(1).

[19] *See also supra* note 9[sic].

[20] *See* Listing Rules 5405(a) and (b), which generally require minimum bid price of at least $4 per share; Market Value of Unrestricted Publicly Held Shares of $15 million under the Income Standard; or Market Value of Unrestricted Publicly Held Shares of $18 million under the Equity Standard; or Market Value of Unrestricted Publicly Held Shares of $20 million and Market Value of Listed Securities of $75 million under the Market Value Standard; or Market Value of Unrestricted Publicly Held Shares of $20 million under the Total Assets/Total Revenue Standard.

applicable Market Value of Unrestricted Publicly Held Shares requirement and (3) the participation of affiliates of the Company must be de minimis.[21]

For a company transferring from a foreign regulated exchange where there is a broad, liquid market for the company's shares, or listing on Nasdaq Texas while trading on such exchange, Nasdaq Texas will determine that the company has met the applicable price-based requirements based on the recent trading in such market. Listing Rule IM–5405–1(a)(4) will clarify that a company transferring from a foreign regulated exchange where there is a broad, liquid market for the company's shares or listing on the Nasdaq Texas while trading on such exchange is not subject to the new requirements applicable to Direct Listings.

Finally, proposed Listing Rule IM–5405–1(b) require that securities qualified for listing under proposed Listing Rule IM–5405–1(b) must begin trading on Nasdaq Texas following the initial pricing through the crossing mechanism available for IPOs outlined in Rule 4120(c)(8) and Rule 4753.[22] To allow such initial pricing, the company must: (i) in accordance with Rule 4120(c)(9), have a broker-dealer serving in the role of financial advisor to the issuer of the securities being listed, who is willing to perform the functions under Rule 4120(c)(8) that are performed by an underwriter with respect to an initial public offering; and (ii) list upon effectiveness of a Securities Act of 1933 registration statement filed solely for the purpose of allowing existing shareholders to sell their shares.

By proposing Listing Rule IM–5405–1, once Nasdaq Texas becomes a primary listing venue, issuers will have the alternative to list on the Exchange via Direct Listing.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[23] in general, and furthers the objectives of Section 6(b)(5) of the Act,[24] in particular, in that it is designed 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 transaction in securities, to remove impediments 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's proposed Listing Rules at IM–5101–4, IM–5210(l), IM–5405–1 and 5405(b)(3)(A) are substantially similar rules of Nasdaq and by removing Listing Rule IM–5220–1, the Exchange will be enabled to operate as a primary listing venue. The proposed rules are substantially similar to the rules of Nasdaq, which have been approved by the Commission. The Commission has previously found that Nasdaq's rules are consistent with the Act.

The Exchange believes that proposed Listing Rule IM–5101–4 authority would enhance Nasdaq Texas' ability to maintain fair and orderly markets, protect investors from the risks associated with trading in securities that raise significant concerns, and ensure that Nasdaq Texas' listing standards are applied in a manner consistent with investor protection and market integrity. The Exchange also believes that Proposed Rule IM–5101–4 furthers the objectives of Section 6(b)(7) of the Act in that it would provide a fair procedure for denying listing on the Exchange. Further, issuers will continue to be afforded applicable procedural protections in connection with any delisting determination, including notice and an opportunity for review as provided under Nasdaq Texas rules.

By adopting special requirements for companies based in China, Hong Kong and Macau, and requirements for Direct Listings that are substantially similar to those of Nasdaq, in addition to removing the rule requiring issuers to dually list on another exchange, the proposed rule changes will support the Exchange's transition to serve as a primary listing market and protect investors and the public interest in connection with the listing and trading of securities on the Exchange. Further, Nasdaq and U.S. regulators and policymakers have identified specific and serious concerns with companies that principally operate in China which increase the risks to investors and make the protection of investors more difficult.[25] Therefore, the Exchange does not believe that the proposed listing rule is designed to permit unfair discrimination against Chinese companies.

The proposed special requirements for companies based in China, Hong Kong and Macau will help to ensure that the security has sufficient public float, investor base, and trading interest likely to generate depth and liquidity sufficient to promote fair and orderly trading, thereby protecting investors and the public interest. Nasdaq Texas also believes that requiring a $25 million minimum offering size for Chinese companies seeking to list on the Exchange through an IPO, a business combination or transfer from the OTC market or another national securities exchange, as well as prohibiting these companies from direct listing on the Exchange, will ensure that a security to be listed on Nasdaq Texas has adequate liquidity, distribution and U.S. investor interest to support fair and orderly trading in the secondary market, which will reduce trading volatility and price manipulation, thereby protecting investors and the public interest. Moreover, because a Direct Listing does not raise any offering proceeds and typically does not involve an underwriter to market the transaction and help develop distribution and investor interest, Nasdaq Texas does not believe that the minimum of $30 million in Unrestricted Publicly Held Shares is sufficient for China-based Issuers to support meaningful price discovery and fair and orderly trading. The proposed rules are also substantially similar to Nasdaq Listing Rule 5210(l) which was found by the Commission to be consistent with the Act.[26]

Removal of Listing Rule IM–5220–1 eliminates any impediments from issuers listing solely on Nasdaq Texas by eliminating the requirement for issuers to also list on another exchange, which removes an impediment to a free and open market and will enhance competition for listings consistent with Section 6(b)(8) of the Act.[27] Similar to other primary listing venues like Nasdaq, once Nasdaq Texas becomes a primary listing venue, Listing Rule IM–5220–1 is no longer necessary.

Nasdaq believes that the proposal to modify Listing Rule 5405(b)(3)(A) to provide that an Acquisition Company must have a Market Value of Listed Securities of at least $100 million to list on the Global Market is consistent with the protection of investors because this proposed listing requirement raises the existing threshold and is equal to the requirements applicable to Acquisition Companies listing on Nasdaq and NYSE.

[21] See Proposed Listing Rule IM–5405–1(a)(3)(ii)(C).

[22] Rules 4120(c)(8) and 4750 were proposed by Nasdaq on September 3, 2026. *See* Release No. 34–106397 dated September 16, 2026, available at *https://www.sec.gov/files/rules/sro/nasdaqtx/2026/34-106397.pdf.*

[23] 15 U.S.C. 78f(b).

[24] 15 U.S.C. 78f(b)(5).

[25] *See* Exchange Act Release No. 105495 (May 14, 2026), 91 FR 29183, 29190, (May 19, 2026) (Order Granting Accelerated Approval to Adopt Listing Rule 5210(l)).

[26] *Id.*

[27] 15 U.S.C. 78f(b)(8).

Finally, establishing Direct Listing standards pursuant to proposed Listing Rule IM–5405–1 is designed to provide issuers with an alternative mechanism for listing on the Exchange while protecting investors and the public interest by imposing listing standards similar to an IPO. In addition to the proposed new requirements, Direct Listings are subject to all initial listing requirements applicable to equity securities and, subject to applicable exemptions, the corporate governance requirements set forth in the Rule 5600 Series. Nasdaq Texas' existing requirements are designed to protect investors and serve to help assure that securities listed on Nasdaq Texas have sufficient investor interest and will trade in a liquid manner. As such, Nasdaq Texas believes the provisions of proposed Listing Rule IM–5405–1 protect investors and the public interest in accordance with Section 6(b)(5) of the Exchange Act.

By basing the proposed rules on the rules of the Exchange's affiliate—Nasdaq, the proposed rule changes will promote continuity across affiliated exchanges and will ensure that market participants encounter substantially similar rules and trading procedures across both exchanges.

*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.

The proposed rule changes to adopt Listing Rules 5210 and IM–5405–1 is designed to provide transparency to the mechanism of listing securities from Chinese companies and listing securities in connection with a Direct Listing, respectively. These proposed rules, in addition to the removal of Listing Rule IM–5220–1, are appropriately protective of investors and are not designed to limit the ability of the issuers of those securities to list them on any other national securities exchange. The proposed rule changes will align the Exchange's Listing Rules 5210 and IM–5405–1 with substantially similar corresponding rules of Nasdaq, which will support the Exchange in its transition to a primary listing venue. The proposed listing rules will apply equally to all issuers of the Exchange, with the exception of proposed Listing Rule 5210(l). While proposed Listing Rule 5210(l) will apply only to companies primarily operating in China (including the Hong Kong Special Administrative Region and the Macau Special Administrative Region), Nasdaq, Congress, state financial officers and the SEC have identified specific concerns with such companies that make the imposition of additional initial listing criteria on such companies appropriate to enhance investor protection, which is a central purpose of the Act. Any impact on competition, either among listed companies or between exchanges, is incidental to that purpose.[28] Further, China-based issuers may elect to list on other markets that do not have a similar requirement. Further, the proposed rule change will allow the Exchange to operate under listing rules that are substantially similar to those of Nasdaq and other primary listing markets, enabling the Exchange to compete with those markets for listings. The Exchange believes that the proposed rules will promote competition among national securities exchanges by providing issuers with an additional venue for listing their securities on an exchange with trading rules that are consistent with those of other primary listing 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

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 Act[29] and subparagraph (f)(6) of Rule 19b–4 thereunder.[30]

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–NasdaqTX–2026–046 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–NasdaqTX–2026–046. 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–NasdaqTX–2026–046 and should be submitted on or before October 23, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

**Sherry R. Haywood,**

*Assistant Secretary.*

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[28] *See supra* n.26 at 29191.

[29] 15 U.S.C. 78s(b)(3)(A)(iii).

[30] 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.

[31] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–106521; File No. SR–OGM–2026–001]**

## Self-Regulatory Organizations; North American Derivatives Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Rules Governing Contract Specifications for Perpetual Cash-Settled Single Stock Security Futures

September 29, 2026.

Pursuant to Section 19(b)(7) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–7 under the Act,[2] notice is hereby given that on September 24, 2026, the North American Derivatives Exchange Inc. (''Nadex'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change 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. Nadex has submitted the proposed rule change to the Commodity Futures Trading Commission (''CFTC'') for approval under Section 5c(c) of the Commodity Exchange Act (''CEA'') [3] on September 24, 2026. The CFTC has not yet approved the proposed rule change.

### I. Self-Regulatory Organization's Description and Text of the Proposed Rule Change

Nadex is registered with the CFTC as a designated contract market under the Commodity Exchange Act (''CEA''). Nadex is making this filing in its capacity as a national securities exchange for security futures products (''SFPs'') registered pursuant to the notice registration provisions of Section 6(g) of the Act [4] to establish the framework for the listing of the SFPs it plans to list for trading.

Nadex is adopting new Chapter 16 (Perpetual Security Futures Products) governing the listing, trading, margining, clearing, settlement, and adjustment of cash-settled single security futures, including perpetual single-security futures, each of which is a security futures product (each, a ''SFP'' and collectively, ''SFPs''). Each SFP will represent one share of one eligible underlying stock. Unlike a security futures product that provides for a fixed expiration and a scheduled final settlement, the contracts that Nadex proposes to list are perpetual SFPs that have no fixed expiration date; the contract will not provide for delivery of, or convey ownership in, the underlying security. Each SFP will be cash settled and feature periodic real-time pricing mechanism adjustments, through which the contract will be adjusted throughout its existence to align with its underlying, full corporate-actions, and have no fixed expiration date and no scheduled final settlement. Each perpetual SFP may be terminated and settled in cash only upon an event specified in the Exchange's rulebook. Further, the Exchange hereby certifies the listing, under a common set of contract specifications, of cash-settled SFPs on a range of eligible equity securities that meet the applicable Nadex listing standards (including, by way of illustration, large-cap securities such as Alphabet Inc. (''GOOGL''), Amazon.com Inc. (''AMZN''), Apple Inc. (''AAPL''), Meta Platforms, Inc. (''META''), Microsoft Corporation (''MSFT''), Nvidia Corporation (''NVDA''), and Tesla Inc. (''TSLA''), among others). The specific instruments to be listed will be published on Nadex's website or by notice. The Exchange intends to offer SFPs exclusively on its electronic trading platform.

The text of the proposed rule changes is included in Exhibit 4.

### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for the, Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for the, Proposed Rule Change*

1. Purpose

The Exchange proposes to adopt contract specifications governing cash-settled single stock security futures, referred to in this filing as ''SFPs.'' Each SFP is a perpetual future on one share of its underlying stock, with periodic real-time pricing mechanism cash adjustments that keep the contract aligned with the underlying, full corporate-action handling across the tenor, no fixed expiration date and no scheduled final settlement. Further, the Exchange hereby certifies the listing, under the common contract specifications described in this filing, of cash-settled SFPs on a range of eligible equity securities that meet the applicable Nadex listing standards including, by way of illustration, large-cap securities such as Alphabet Inc. Class A Common Stock (''GOOGL''), Amazon.com Inc. (''AMZN''), Apple Inc. (''AAPL''), Meta Platforms, Inc. (''META''), Microsoft Corporation (''MSFT''), Nvidia Corporation (''NVDA''), and Tesla Inc. (''TSLA''), among others. The specific instruments to be listed will be published on Nadex's website or by notice, and a general summary of the terms and conditions of SFPs is below.

SFPs—Summary Terms and Conditions

*Contract Size*—1 share (one unit) of the underlying stock. (Rule 16.02(d))

*Quotation Specification*—Prices are quoted in U.S. dollars to two decimal places, with a minimum tick of $0.01 and a tick value of $0.01 for a one-share contract. (Rule 16.02(e))

*Position Limits*—Position limits will be established and applied in accordance with CFTC Regulation 41.25(b)(3) and the Nadex Rulebook; generally, the position limit for SFPs will be 2,500,000 contracts, and any applicable limit or accountability level will be set forth in the applicable contract specifications or on Nadex's website. This 2,500,000 contract limit with a 1 share contract size is consistent with other currently listed security futures, which have a 25,000 contract limit applicable to a 100 share contract for securities with less than 20 million in estimated deliverable shares. (Rule 16.02(g), (h))

*Underlying Index Price*—Median of the national best bid, national best offer and last sale price published by the securities information processor (''SIP'') for the underlying (and during non-regular market hours, several different

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[1] 15 U.S.C. 78s(b)(7).

[2] 17 CFR 240.19b–7.

[3] 7 U.S.C. 7a–2(c).

[4] 15 U.S.C. 78f(g). On September 14, 2026, Nadex, in its capacity as a designated contract market under the Commodity Exchange Act, submitted a 1–N notice filing to the Commission to register as a national securities exchange for security futures products pursuant to the notice registration provisions of Section 6(g) of the Act. On September 16, 2026, the Commission issued a notice acknowledging receipt of such written notice and effectiveness of Nadex's notice registration as a national securities exchange contemporaneously with Nadex's submission of the 1–N notice. Acknowledgement of Receipt of Notice of Registration as a National Securities Exchange Pursuant to Section 6(g) of the Securities Exchange Act of 1934 by North American Derivatives Exchange Inc. (Sept. 16, 2026) [Release No. 34–106396; File No. 10–255], 91 FR 59823 (published Sept. 21, 2026).

SEC-approved after hour market trading centers and inclusive of a secondary backup data vendor for SIP and non-regular market hours data). (Rule 16.03(a))

*Trading Schedule*—Continuous trading, subject to the trading hours, holiday schedules, underlying-market availability, and other limitations permitted by the Nadex Rulebook and applicable listing standards; the current product specifications contemplate trading pursuant to Nadex Rule 5.18. Notwithstanding Rule 5.18, SFP trading occurs 24 hours a day, 5 days a week. (Rule 16.02(c))

*No Expiration and No Final Settlement*—Perpetual SFPs have no fixed expiration date and no scheduled final settlement and a perpetual SFP may be terminated and settled in cash only upon an event specified in the Rulebook and applicable contract specifications. Convergence between the price of a Contract and the price of the Underlying Security is effected through the funding mechanism described in Rule 16.14 or the applicable contract specification. (Rule 16.02(b)) Nadex plans to use the final settlement price.

*Real-time Pricing Mechanism*—Periodic real-time pricing mechanism cash adjustments, currently contemplated at 00:00, 08:00, and 16:00 UTC, will be exchanged between long and short holders to keep each SFP's price aligned with its underlying stock, as specified in Rule 16.14 or the applicable contract specification. When funding is positive, longs pay shorts; when negative, shorts pay longs.

*Trading Halts*—Trading in a SFP will be halted at all times that a regulatory halt has been instituted for the underlying security, as provided in Rule 16.02(l) and CFTC Regulation 41.25(b)(2),[5] and may be halted or otherwise restricted under the Nadex Rulebook and applicable listing standards. (Rule 16.02(l); Rule 16.12)

*Termination*—Upon termination pursuant to the Rule 16.15, the termination price for a perpetual SFP shall be the official opening price of the underlying security on its primary listing exchange on the Termination Date (as defined below) or, in the event the market for the underlying security closes without any trading activity that would permit the calculation of the termination price, such termination price will be calculated using the most recent regular session price or the next available opening price. This complies with SEC Rule 240.6h–1(b) and CFTC Regulation 41.25(c).[6] The SFP will be terminated in USD cash with no physical delivery. Terminating positions will be settled pursuant to a three-tier waterfall approach. (Rule 16.08(a) and (b)).

*Daily Settlement*—Open positions are settled twice each business day. A midday settlement at 12:00 ET and an end-of-day settlement of 17:00 ET (business days follow the exchange holiday calendar). At each daily settlement, the position's average open price is reset to the settlement price, so any unrealized profit or loss becomes realized. Realized profit is then available for withdrawal. Open positions will be settled daily pursuant to a three-tier waterfall approach. (Rule 16.08(a)).

*Termination Date*—The date on which a participant terminates or otherwise exits its SFP position in accordance with Rule 16.15.

Compliance with Listing Standards—The Exchange will list only SFPs based on eligible equity securities that satisfy the applicable Nadex listing standards, including the requirements in Rule 16.02 and the initial and maintenance listing standards in Rules 16.04 and 16.05. The specific instruments and their contract specifications will be published on Nadex's website or by notice.

The proposed rule changes are described below.

Rule 16.01 provides that Chapter 16 applies to the listing, trading, clearing, pricing, settlement, and adjustment of any Contract listed by Nadex that is a perpetual security future. The rule further provides that, except as expressly provided in Chapter 16, all other Rules of Nadex apply to perpetual security futures. Any change in instructions, order, ruling, directive, or law issued or enacted by any court or agency of the Federal Government of the United States that conflicts with the Rules contained in this Chapter shall take precedence, immediately become a part of these Rules, and be effective for all currently traded and newly listed security futures.

Rule 16.02 provides that each security future based on a single equity security (each, a ''Single Stock Future'' or an ''SSF'') shall be based on an underlying single equity security listed in Schedule A of Chapter 16 (the ''Underlying Security''), which satisfies the requirements set forth in CFTC Rule 41.21(a) and the initial and maintenance listing standards in Rules 16.04 and 16.05, as may be determined from time to time by the Exchange.

Rule 16.02 specifies that each SSF shall have no specified dated tenor, shall remain listed and tradable until otherwise terminated pursuant to the Rulebook, shall be cash-settled based on its opening price, and will not expire. SSF trading occurs 24 hours a day, 5 days a week, and SSFs will not be traded during holidays and other periods when the underlying markets for the securities are not open; however, trading during the market close is permitted based on available liquidity in the order book. SSF trading is subject to any applicable halt, suspension, Emergency Rule, or product-specific restriction, and SSFs settle on a daily basis during market hours.

Rule 16.02 further provides that each SSF represents a contract for 1 share of the Underlying Security, with a minimum trade size of 0.01 contract. Prices shall be quoted in U.S. dollars per share to two decimal places, with a minimum price fluctuation of $0.01 per share. SSFs are not subject to daily price limits unless otherwise specified by Nadex or by notice. Position limits for each SSF shall be 2,500,000 contracts, subject to the cap prescribed by CFTC Regulation 41.25(b)(3).

Rule 16.03 defines ''Underlying Index Price'' to mean the median of the national best bid, national best offer, and last sale price published by the securities information processor (''SIP'') for the Underlying Security (and during non-regular market hours, several different SEC-approved after hour market trading centers and inclusive of a secondary backup data vendor for SIP and non-regular market hours data).

Rule 16.04[7] sets out the standards pursuant to which the Exchange will list Contracts. The proposed listing standards require, among other things, that the Underlying Security must be a common stock registered under Section 12 of the Securities Exchange Act of 1934, listed on a national securities exchange or traded as an NMS security, and must have at least seven million publicly owned shares. Further, the Underlying Security must have at least 2,000 security holders.

Rule 16.04 also includes interpretations addressing the application of these requirements to Restructure Securities, including a Look-Back Test that permits the Exchange to consider the trading volume and market price history of the Original Equity Security prior to the ex-date of the Restructuring Transaction, subject to specified conditions.

Rule 16.05 establishes maintenance standards for the continued listing of SSFs. Under the maintenance standards, the Underlying Security must remain

[5] 17 CFR 41.25(b)(2).

[6] 17 CFR 240.6h–1(b); 17 CFR 41.25(c).

[7] The Exchange notes that Rule 16.04(a)(5), (6), (7), and (9) are marked as ''Reserved.''

registered under Section 12 of the Exchange Act; must have at least 6,300,000 publicly owned shares outstanding; must have at least 1,600 shareholders; must have had a minimum average daily value of transactions of at least $200 million for the prior calendar quarter (or $1 billion for securities listed for less than a quarter); and must have a minimum market capitalization of at least $50 billion. The market price per share of the Underlying Security must not have closed below $3.00 on the previous trading day.

Rule 16.06 provides that SSF orders shall be matched and allocated in accordance with Nadex 's Trading System functionalities and Chapter 5. Crossing transactions and pre-execution communications for SSFs must comply with Nadex 's order handling, exposure, and crossing requirements under Chapter 5.

Rule 16.07 provides that each SSF shall be cleared by the Clearinghouse. Upon acceptance for clearing, Nadex 's and Members' rights and obligations shall be as provided under the applicable clearing arrangements, and novation shall occur in accordance with the rules of the Clearinghouse. Delivery shall be by cash settlement in accordance with the rules and procedures of the Clearinghouse; no physical delivery of the Underlying Security shall occur.

Rule 16.08 provides that the daily settlement price of an SSF shall be determined based upon a three-tier waterfall approach: (1) a 1-minute VWAP of the futures contract; (2) a 1-minute TWAP of the futures contract midpoint of the Bid/Ask; and (3) index net change, where no transaction in the SSF contract occurs within the applicable window and no sampling point is complete, the daily settlement price shall be the prior daily settlement price adjusted by the net change in the Underlying Index Price over the intervening period. The termination price shall be based on the official opening price of the Underlying Security on the Termination Date.

Rule 16.10 [8] provides that, throughout the full tenor of an SSF, Nadex may adjust or settle SSFs in accordance with the Clearinghouse based on its judgment as to what is appropriate for the protection of investors and the public interest. Adjustments to SSFs to account for corporate actions or other events affecting the Underlying Security—including dividends, stock splits, reverse splits, spin-offs, mergers, consolidations, reorganizations, delistings, and other events—shall be made in accordance with the standards set out in the Rule. As a general rule, there will be no adjustments to reflect ordinary cash dividends or distributions.

Rule 16.11 provides that order entry, modification, cancellation, and recordkeeping for SSFs shall comply with Chapter 5 and CFTC Regulation 1.31. The rule establishes cross-market surveillance procedures to detect, investigate, and deter manipulation, insider trading, and other prohibited conduct. Certain persons, including directors and officers of the issuer of the Underlying Security and persons in possession of material non-public information, are prohibited from trading in SSFs.

Rule 16.12 provides that Nadex may halt trading in SSFs to prevent or reduce the risk of price distortions or market disruptions, including where the underlying market is halted or subject to a limit state. Nadex will coordinate regulatory trading halts between the Exchange and the markets on which any Underlying Security is traded.

Rule 16.13 provides that each Member with access to the Trading System to trade SSFs must be registered with the CFTC as an FCM and registered with the Securities and Exchange Commission as either a broker-dealer under Section 15(b)(1) of the Exchange Act or as a notice-registered broker-dealer under Section 15(b)(11) of the Exchange Act. Trading in SSFs is subject to Nadex's market surveillance under Chapter 9, and violations are subject to disciplinary action.

Rule 16.14 provides that the Funding Rate for perpetual SSFs shall be a periodic cash adjustment exchanged directly between Customers of long and short open positions at each Funding Time. When the Funding Rate is positive, Customers with long positions shall pay Customers with short positions; when the Funding Rate is negative, Customers with short positions shall pay Customers with long positions. Funding Times shall be 00:00, 08:00, and 16:00 UTC, or such other times as Nadex may specify by notice. The Funding Rate is calculated using a formula that incorporates the Premium (the time-weighted average premium of the SSF over its Underlying Index Price), an Interest component, Asset Multiplier, Cap, and Floor parameters, with an outer clamp function limiting the Funding Rate within the range established by the Floor and Cap.

Rule 16.14 further provides that perpetual SSFs shall be cash settled in U.S. dollars, and that the Exchange shall list only one perpetual SSF per Underlying Security at any given time. The perpetual SSF shall have no expiration date and no final settlement date. Margin calculations shall follow the Exchange's three-tier approach, with margin at least 15.05% of the position value, or such other amount as specified in the applicable product specifications or as required by CFTC Regulations 41.42 through 41.49 (without exceptions for offsets permitted under those regulations).

Rule 16.15 provides that the procedures for termination of each SSF shall be set out in the final contract specifications.

Rule 16.16 sets forth provisions regarding margin requirements. Rule 16.16(a) provides that customer margin shall be established at levels no lower than those prescribed by SEC Rule 242.403 [9] and CFTC Regulation 41.45 [10] or any successor regulations. Rule 16.16(a) elaborates by establishing the requisite margin level for each long or short position in a perpetual security future product at 15.05% of the current market value of such security futures contract, or such other requirement as may be established by the SEC and CFTC for purposes of SEC Rule 242.403(b)(1) [11] and CFTC Regulation 41.45(b)(1).[12]

Rule 16.16(b)(1) identifies ''exempted persons'' and ''market makers'' as non-customers for purposes of the proposed rule amendments. Those non-customers are, therefore, exempt from the application of such provisions. Exempted persons are specifically identified by reference to applicable SEC and CFTC Regulations.

SEC Rule 242.400(c)(2)(v) [13] and CFTC Regulation 41.42(c)(2)(v) [14] permit exchanges to adopt rules containing specified requirements for security futures dealers, on the basis of which the financial relations between security futures intermediaries, on the one hand, and qualifying security futures dealers, on the other, are excluded from the margin requirements for perpetual security futures. Rules so adopted by an exchange must meet the criteria set forth in Section 7(c)(2)(B) of the Act.[15] Nadex proposes a market maker exclusion in its Rule 16.16(b)(2) consistent with the requirements of those provisions. To qualify for the market maker exclusion, a person must be a member of Nadex

[8] The Exchange notes that Rule 16.09 is marked as ''Reserved.''

[9] 17 CFR 242.403.

[10] 17 CFR 41.45.

[11] 17 CFR 242.403(b)(1).

[12] 17 CFR 41.45(b)(1).

[13] 17 CFR 242.400(c)(2)(v).

[14] 17 CFR 41.42(c)(2)(v).

[15] 15 U.S.C. 78g(c)(2)(B).

and registered as a dealer with the SEC under Section 15(b) of the Act.[16] A proposed market maker must also hold itself out as willing to buy and sell perpetual security futures for its own account on a regular or continuous basis. The proposed market maker exclusion provides three alternative ways for a person to satisfy this requirement. Under the first alternative, the market maker must (1) provide continuous two-sided quotations throughout the trading day for all perpetual security futures contracts representing a meaningful proportion of the total trading volume of security futures contracts on the Exchange, subject to relaxation during unusual market conditions as determined by Nadex (such as a fast market in either a perpetual security futures contract or a security underlying a perpetual security futures contract) at which times the market maker must use its best efforts to quote continuously and competitively; and (2) when providing quotations, quote with a maximum bid/ask spread of no more than the greater of $0.20 or 150% of the bid/ask spread in the primary market for the security underlying each perpetual security futures contract. Beginning on the 181st calendar day after the commencement of trading of security futures contracts on the Exchange, a ''meaningful proportion of the total trading volume of security futures contracts on the Exchange from time to time'' shall mean a minimum of 20% of such trading volume.

Under the second alternative, the market maker must (1) respond to at least 75% of the requests for quotation for all perpetual security futures contracts representing a meaningful proportion of the total trading volume of perpetual security futures contracts on the Exchange, subject to relaxation during unusual market conditions as determined by the Exchange (such as a fast market in either a perpetual security futures contract or a security underlying a perpetual security futures contract) at which times the Market Maker must use its best efforts to quote competitively; and (2) when responding to requests for quotation, quote within five seconds with a maximum bid/ask spread of no more than the greater of $0.20 or 150% of the bid/ask spread in the primary market for the security underlying each security futures contract. As with the first alternative, beginning on the 181st calendar day after the commencement of trading of security futures contracts on the Exchange, a ''meaningful proportion of the total trading volume of security futures contracts on the Exchange from time to time'' shall mean a minimum of 20% of such trading volume.

Under the third alternative, the market maker is assigned to a group of perpetual security futures contracts listed on the Exchange that is either unlimited in nature (''Unlimited Assignment'') or is assigned to no more than 20% of the security futures contracts listed on the Exchange (''Limited Assignment''). In addition, this alternative provides that: (a) At least 75% of the market maker's total trading activity in Exchange perpetual security futures contracts is in its assigned perpetual security futures contracts, measured on a quarterly basis; (b) during at least 50% of the trading day, the market maker has bids or offers in the market that are at or near the best market, except in unusual market conditions (such as a fast market in either a perpetual security futures contract or a security underlying a perpetual security futures contract), with respect to at least 25% (in the case of an Unlimited Assignment) or at least one (in the case of a Limited Assignment) of its assigned security futures contracts; and (c) the first two requirements are satisfied on at least 90% (in the case of an Unlimited Assignment) or 80% (in the case of a Limited Assignment, or in the case of either an Unlimited or Limited Assignment but where the Exchange is listing four or fewer security futures contracts) of the trading days in each calendar quarter.

Under the proposed revisions, market makers are required to maintain books and records including trading statements and other financial records that would evidence compliance with these standards. This recordkeeping requirement includes, without limitation, such trading statements and other financial records as may be necessary specifically to verify compliance. Failure on the part of a market maker to comply with these standards may result in revocation of security futures dealer status or other sanctions provided under Exchange Rules.

Rule 16.16(d)(1)[17] identifies the types of margin that a security futures intermediary may accept from a customer. Consistent with SEC Rule 242.404(b)[18] and CFTC Regulation 41.46(b),[19] acceptable types of margin are limited to: deposits of cash, margin securities (subject to specified restrictions), exempted securities, any other assets permitted under Regulation T of the Board of Governors of the Federal Reserve System to satisfy a margin deficiency in a securities margin account, and any combination of the foregoing. Proposed Rule 16.16(d)(1) further provides that the different types of eligible margin are to be valued in accordance with the applicable principles set forth in SEC Rules 242.404(c)[20] and 242.404(e)[21] and CFTC Regulations 41.46(c)[22] and 41.46(e).[23] Proposed Rule 16.16(d)(2) provides that a security futures intermediary shall not accept as margin from any customer securities that have been issued by that customer or an affiliate of that customer unless the intermediary files a petition with and receives permission from the Exchange for such purpose. Proposed Rule 16.16(d)(3) provides that all assets deposited by a customer to meet margin requirements must be and remain unencumbered by third-party claims against that customer.

Rule 16.16(e)(1) requires a security futures intermediary to take the deduction required with respect to an underfunded account in computing its net capital under applicable SEC and CFTC Regulations if the customer has failed to comply with a required margin call within a reasonable period of time. This requirement is consistent with SEC Rule 242.406(a)[24] and CFTC Regulation 41.48(a).[25] Further, Rule 16.16(e)(2) requires the liquidation of an account where there is a liquidating deficit, in accordance with SEC Rule 242.406(b)[26] and CFTC Regulation 41.48(b).[27]

2. Statutory Basis

Section 6(h)(3) of the Act[28] contains listing standards and conditions for trading SFPs. The Exchange believes that the proposed amendments to Chapter 16 are consistent with Section 6(h)(3),[29] and that they are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and in general to protect investors and the public interest. Below is a summary of each requirement or condition under Section 6(h)(3) of the Act, followed by a brief explanation of how Nadex would comply with it, whether by particular

[16] 15 U.S.C. 78o(b).

[17] The Exchange notes new Rule 16.16(c) is marked as ''Reserved.''

[18] 17 CFR 242.404(b).

[19] 17 CFR 41.46(b).

[20] 17 CFR 242.404(c).

[21] 17 CFR 242.404(e).

[22] 17 CFR 41.46(c).

[23] 17 CFR 41.46(e).

[24] 17 CFR 242.406(a).

[25] 17 CFR 41.48(a).

[26] 17 CFR 242.406(b).

[27] 17 CFR 41.48(b).

[28] 15 U.S.C. 78f(h)(3).

[29] *Id.*

provisions in Nadex's listing standards or otherwise.

Clause (A) of Section 6(h)(3) of the Act[30] requires that any security underlying a SFP be registered pursuant to Section 12 of the Act.[31] This requirement is addressed by Nadex Rule 16.04(a)(2). Further, under Rule 16.02(j), contract specifications will be published on Nadex's website.

Clause (B) of Section 6(h)(3) of the Act[32] requires that a market on which a physically settled SFP is traded, have arrangements in place with a registered clearing agency for the payment and delivery of the securities underlying the SFP. This requirement is applicable only to physically delivered security futures products. Nadex is only offering cash-settled SFPs, and, therefore, the requirement in Section 6(h)(3) of the Act is not germane to the proposed products.

Clause (C) of Section 6(h)(3) of the Act[33] provides that listing standards for SFPs must be no less restrictive than comparable listing standards for options traded on a national securities exchange or national securities association registered pursuant to Section 15A(a) of the Act.[34] Nadex believes that its listing standards for perpetual SFPs are no less restrictive than the sample listing standards (''Sample Listing Standards'') included in the Commission's Staff Legal Bulletin No. 15,[35] which were ''sample security futures listing standards, which the Division of Market Regulation considers to be comparable to listing standards for options,''[36] except that they:

- Provide for the trading of perpetual, cash-settled single security futures contracts for trading as SFPs;
- Include more stringent listing requirements, as described below; and
- Provide for a real-time pricing mechanism intended to align the SFP's price with the price of the underlying security.

Nadex's initial listing standards require that each Underlying Security satisfy the following requirements set forth in Rule 16.04(a):

(1) It must be a common stock.

(2) It must be registered under Section 12 of the Act,[37] and its issuer must be in compliance with any applicable requirements of the Act.

(3) It must be listed on a national securities exchange or traded through the facilities of a national securities association and reported as a ''national market system'' security as set forth in Rule 11Aa3–1 under the Act (''NMS security'').[38]

(4) There must be at least seven million shares or receipts evidencing the Underlying Security outstanding that are owned by persons other than those required to report their security holdings pursuant to Section 16(a) of the Act.[39]

(5) There must be at least 2,000 security holders.

(6) The Exchange will not list for trading any SSF where the Underlying Security is a Restructure Security that is not yet issued and outstanding, regardless of whether the Restructure Security is trading on a ''when issued'' basis or on another basis that is contingent upon the issuance or distribution of securities. In addition, the proposed SFPs are perpetual with no expirations, which are operationally feasible for Nadex.

The Exchange also may prohibit any opening purchase transactions in SFPs already trading to the extent it deems such action necessary or appropriate, unless the underlying security meets each of the maintenance listing requirements for SFPs in Rule 16.05, which meet the maintenance listing standards provided for in the Commission's Staff Legal Bulletin No. 15.

Specifically, the maintenance listing standards in Rule 16.05(a) require that the Underlying Security meet each of the following:

(1) It must be registered under Section 12 of the Act.[40]

(2) There are at least 6,300,000 shares outstanding that are owned by persons other than those who are required to report their security holdings under Section 16(a) of the Act.[41]

(3) There are at least 1,600 shareholders.

(4) It must have had a minimum average daily value of transactions of at least $200 million for the prior calendar quarter, except where the underlying security has been listed for trading for less than a quarter, in which case the underlying security must have had a minimum average daily value of transactions of at least $1 billion over the period traded during the calendar quarter.

(5) It must have a minimum market capitalization of at least $50 billion.

(6) The market price per share or receipt of the Underlying Security has not closed below $3.00 on the previous trading day to the expiration day of the nearest expiring SSF contract on the Underlying Security. The market price per share of the Underlying Security will be measured by the closing price reported in the primary market in which the Underlying Security traded.

Further, Rule 16.14's real-time pricing mechanism with respect to SFPs keeps the applicable SFP aligned with its underlying in the same manner. The real-time pricing mechanism recreates the put-call parity that holds equity options to their underlying by requiring an explicit interest-rate (financing) component in the rate, which mirrors the cost-of-carry term built into option prices. While an option's time decay is slow until expiration approaches, the real-time pricing mechanism is applied every eight hours for the entire life of the SFP, so potential value drift is addressed promptly and repeatedly.

For the reasons discussed herein, notwithstanding specified differences between the Sample Listing Standards and Nadex's listing standards, Nadex believes that the latter are no less restrictive than comparable listing standards for exchange-traded options.

Clause (D) of Section 6(h)(3) of the Act[42] requires that each SFP be based upon common stock and such other equity securities as the Commission and the CFTC jointly determine appropriate. This requirement is addressed in Rule 16.04(a)(1).

Clause (E) of Section 6(h)(3) of the Act[43] requires that each SFP be cleared by a clearing agency that has in place provisions for linked and coordinated clearing with other clearing agencies that clear SFPs. This provision is inapplicable. The SEC and CFTC have not adopted rules implementing this part of the statute, and no other clearing agency currently clears the proposed cash-settled SFPs. Section 6(h)(7) of the Act[44] defers this requirement until the ''compliance date,'' as defined in that Section. Nadex, in its capacity as a registered derivatives clearing organization, will serve as the clearinghouse for SFPs traded through the Exchange's facilities.

Clause (F) of Section 6(h)(3) of the Act[45] requires that only a broker or dealer subject to suitability rules comparable to those of a national

[30] 15 U.S.C. 78f(h)(3)(A).

[31] 15 U.S.C. 78l.

[32] 15 U.S.C. 78f(h)(3)(B).

[33] 15 U.S.C. 78f(h)(3)(C).

[34] 15 U.S.C. 78o–3(a).

[35] Division of Market Regulation: Staff Legal Bulletin No. 15 (Sept. 5, 2001), *available at https://www.sec.gov/interps/legal/mrslb15.htm.*

[36] *Id.*

[37] 15 U.S.C. 78l.

[38] 15 U.S.C. 78k–1; 17 CFR 240.601.

[39] 15 U.S.C. 78p(a)

[40] 15 U.S.C. 78l.

[41] 15 U.S.C. 78p(a)

[42] 15 U.S.C. 78f(h)(3)(D).

[43] 15 U.S.C. 78f(h)(3)(E).

[44] 15 U.S.C. 78f(h)(7).

[45] 15 U.S.C. 78f(h)(3)(F).

securities association registered pursuant to Section 15A(a) of the Act [46] effect transactions in an SFP. An intermediary acting on behalf of customers trading SFPs must be registered with the CFTC as a futures commission merchant (''FCM'') and registered or notice registered with the SEC as a broker-dealer. Any such intermediary that is fully registered as a broker-dealer will be a member of FINRA, which is a national securities association registered pursuant to Section 15A(a) of the Act,[47] and will thus be subject to FINRA's suitability rules. In addition, all Nadex clearing members authorized to handle SFPs and their correspondents are bound by the applicable sales practice rules of National Futures Association (''NFA''), which is a national securities association. As such, the sales practice rules of NFA are generally comparable to those of a national securities association registered pursuant to Section 15A(a) of the Act.[48] Moreover, the application of NFA sales practice rules is extended beyond the Nadex clearing membership to the extent that NFA Bylaw 1101 provides that ''[n]o Member may carry an account, accept an order or handle a transaction in commodity futures contracts for or on behalf of any non-Member of NFA.'' [49]

Clause (G) of Section 6(h)(3) of the Act [50] requires that each SFP be subject to the prohibition against dual trading in Section 4j of the CEA.[51] This prohibition applies to a contract market operating an electronic trading system if such market provides participants with a time or place advantage or the ability to override a predetermined matching algorithm. The Exchange intends to offer SFPs on Nadex exclusively on its electronic trading platform, as described further in Rule 16.11. Because the conditions described above do not exist in Nadex's electronic trading platform system, the Nadex Rulebook contains no specific rule relating to dual trading in an electronic forum.

Further, the prohibition of dual trading in SFPs under Regulation 41.27,[52] adopted pursuant to Section 4j(a) of the CEA,[53] applies to a contract market operating an electronic trading system if such market provides participants with a time or place advantage or the ability to override a predetermined matching algorithm. The Exchange intends to offer SFPs on Nadex exclusively on its electronic trading platform. Because those conditions do not exist in Nadex's electronic trading platform system, the Nadex Rulebook contains no specific rule relating to dual trading in an electronic forum.

Clause (H) of Section 6(h)(3) of the Act [54] provides that trading in a SFP must not be readily susceptible to manipulation of the price of such SFP, nor to causing or being used in the manipulation of the price of any underlying security, option on such security, or option on a group or index including such securities. Nadex believes that its listing and contract specifications in Rule 16.02 are designed to ensure that Nadex SFPs and the underlying securities would not be readily susceptible to price manipulation. Nadex intends initially to list SFPs on highly liquid securities as measured by average daily trading volume, which must meet the listing standards outlined in Rules 16.04 and 16.05. In addition, Rule 5.19 (m) of the Nadex Rulebook states that no participant ''shall engage in any activity that violates any anti-fraud provision, any anti-manipulation provision, or any other provision of the CEA or the Commission's Regulations'' and Chapter 9 of the Nadex Rulebook (Rule Enforcement) will generally apply to all transactions in SFPs.

In addition, under Nadex Rule 5.19(x), ''No Participant shall, intentionally or recklessly, directly or indirectly, engage or attempt to engage in any fraudulent act or intentionally or recklessly, directly or indirectly, use or employ, or attempt to use or employ, any manipulative device, scheme or artifice to defraud, deceive, trick or mislead or intentionally or recklessly, directly or indirectly, engage, or attempt to engage in any other activity prohibited by CFTC Regulation 180.1(a), or (b) engage, or attempt to engage, in any other activity prohibited by CEA section 9(a)(2), in each case of (a) and (b) in connection with or related to any activities on the Exchange or clearinghouse.'' The position limit standards set forth in Rule 16.02(g) are also designed to prevent market manipulation with respect to SFPs, as the position limits will be no greater than those prescribed by CFTC Regulation 41.25.[55]

With respect to termination prices, Rule 16.08(b) establishes how the termination price is determined for cash-settled SFPs. For each SFP, the Termination Price will be the official opening price of the underlying security on its primary listing exchange on the expiration date. If the official opening price is unavailable because the underlying market did not open, remained halted, or otherwise did not publish an opening price, the applicable rule will provide for a reasonable alternative determination, such as the last preceding closing price, the next available opening price, an average of prices during an appropriate period, or another reasonable measure as required by SEC Rule 6h–1(b) and CFTC Regulation 41.25(c).

Rule 16.10 provides that the Clearinghouse will implement adjustments to SFPs when corporate actions or similar events affect the underlying security, pursuant to its established rules and procedures for the entire existence of the SFP position. Depending on the event, adjustments may include modifying the contract multiplier, unit of trading, settlement price, underlying security, or other contract terms.

Consistent with the Exchange's insider-trading controls, Nadex proposes that the following persons be prohibited from trading in the relevant SFPs: (1) any person who is a director or officer subject to Section 16 of the Act of a corporation that is the issuer of an underlying security; and (2) any person in possession of material non-public information regarding such issuer (Rule 16.11(i)). Nadex Rule 5.19(u) already prohibits an Insider with access to material non-public information regarding an Underlying, or a person able to influence the outcome of an Underlying, from attempting to enter into or entering into any trade, directly or indirectly, in the relevant Contracts, and prohibits soliciting or inducing another person to disclose material non-public information.

Clause (I) of Section 6(h)(3) of the Act [56] requires that procedures be in place for coordinated surveillance amongst the market on which a SFP is traded, any market on which any security underlying the SFP is traded, and other markets on which any related security is traded to detect manipulation and insider trading. The Exchange has surveillance procedures in place to detect manipulation on a coordinated basis with other markets. In particular, Nadex is an affiliate member of the Intermarket Surveillance Group (''ISG'') and is party to an affiliate agreement and an agreement to share market surveillance and regulatory information

[46] 15 U.S.C. 78o–3(a).
[47] 15 U.S.C. 78o–3(a).
[48] 15 U.S.C. 78o–3(a).
[49] NFA Bylaw 1101(a).
[50] 15 U.S.C. 78f(h)(3)(G).
[51] 7 U.S.C. 6j
[52] 17 CFR 41.27.
[53] 7 U.S.C. 6j(a).
[54] 15 U.S.C. 78f(h)(3)(H).
[55] 17 CFR 41.25.
[56] 15 U.S.C. 78f(h)(3)(I).

with the other ISG members. Under Rule 16.11(f), Nadex will maintain and implement written procedures for coordinated cross-market surveillance to detect, investigate, and deter manipulation, insider trading, and other prohibited conduct in connection with trading in any SFP listed on the Exchange. Finally, Nadex Rule 3.4(b) notes that Nadex may provide any information about any Member in connection with information sharing agreements or other contractual, regulatory or legal provisions, in addition to sharing information with foreign regulatory or self-regulatory bodies, law enforcement authorities, or judicial tribunals.

Clause (J) of Section 6(h)(3) of the Act[57] requires that a market on which a SFP is traded have in place audit trails necessary or appropriate to facilitate the coordinated surveillance referred to in the preceding paragraph. Under Rule 16.11(g), Nadex will establish an audit trail to facilitate coordinated surveillance among the Exchange and any market on which any underlying security is traded. The Exchange relies upon its Compliance Department and its highly trained staff to actively monitor market participants and their trading practices and to enforce compliance with Nadex rules. Nadex Compliance Department staff is organized into Compliance and Market Surveillance Groups. The Exchange's trading system will capture all audit trail data for trading of SFPs, which is maintained in accordance with Core Principle 10 in CEA Section 5(d)(10)[58] and CFTC Regulations 38.550,[59] 38.551[60] and 38.552.[61] The Exchange retains this highly granular audit trail for a minimum of 5 years, as required by CFTC Regulation 1.31(b).[62]

Nadex Compliance is responsible for enforcing the trading practice rules of the Exchange through detection, investigation, and prosecution of those who may attempt to violate those Nadex Rules. Further, Nadex Compliance is responsible for handling customer complaints, ensuring the integrity of the Exchange's audit trail, and administering an arbitration program for the resolution of disputes. Nadex Compliance employs investigators, attorneys, trading floor investigators, data analysts, and a computer programming and regulatory systems design staff.

Nadex Compliance Department staff investigates possible misconduct and, when appropriate, initiates disciplinary action. Rule 16.13 and Chapter 9 of the Nadex Rulebook address the Exchange's disciplinary process. Further, per Nadex Rule 3.4(a), the Exchange requires its members to ''cooperate promptly and fully'' with Nadex, ''its agents, any appropriate Self-Regulatory Organization, any appropriate Government Agency, and the Commission in any investigation, call for information, inquiry, audit, examination, or proceeding.

Nadex Rule 5.5 requires that certain information be recorded with respect to each order, including: (1) order direction (*i.e.,* buy or sell); (2) order type (*e.g.,* Limit Order or Market Order); (3) duration of the order (*e.g.,* Fill or Kill, Immediate or Cancel, Good 'Til Cancel); (4) the Series of Contract; (5) the limit price at which the Trading Member wants to buy or sell the Contract, in the case of Limit Orders; (6) the number of Contracts the Trading Member want to buy or sell; (7) the Tolerance Protection in the case of Market Orders With Protection; and (8) the user identifier for the Trading Member. As described above, Nadex Rulebook's ''Monitoring the Market'' rule requires Nadex's Trading System to record and store, for a period of not less than 5 years in a searchable, read-only database, all data entered into the Trading System, including the Participant's identity and the information in Rule 5.5.

Clause (K) of Section 6(h)(3) of the Act[63] requires that a market on which an SFP is traded have in place procedures to coordinate trading halts between such market and any market on which any security underlying the SFP is traded and other markets on which any related security is traded. Rule 16.02(l) would provide, in accordance with Regulation 41.25(b)(2) of CEA,[64] that ''[t]rading of an [SFP] shall be halted at all times when a regulatory halt has been instituted for the Underlying Security.'' In addition, Rule 16.12(c) provides that Nadex will coordinate regulatory trading halts between the Exchange and the markets on which any Underlying Security is traded.

Clause (L) of Section 6(h)(3) of the Act[65] requires that the margin requirements for a SFP comply with the regulations prescribed pursuant to Section 7(c)(2)(B) of the Act.[66] Rule 16.16 provides for a minimum margin requirements of not less than 15.05% of the current market value of the security futures,[67] in accordance with Section 6(h)(3) of the Act and 17 CFR 242.403 and CFTC Regulation 41.45.

Thus, Nadex believes that its proposed margin rules are consistent with the requirements of the Act.

For the reasons described above, Nadex believes that its proposal submitted herewith satisfies the requirements set forth in Section 6(h)(3) of the Act.[68] The Exchange also believes that its proposed rule changes are consistent with Section 6(b) of the Act,[69] in general, and furthers the objectives of Section 6(b)(5) of the Act,[70] in particular, in that it is designed to remove impediments to and perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

Nadex does not believe that the proposed rule changes would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule changes will simply allow Nadex to list certain security futures products. Nothing in the filing restricts or impedes another exchange from offering security futures products for trading subject to its compliance with applicable regulatory requirements under the Act, CEA, and respective rules of the Commission and CFTC governing security futures products.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

The proposed rule change would become effective upon approval by the CFTC pursuant to CFTC Regulations.

Within 60 days of the date of effectiveness of the proposed rule change, the Commission, after consultation with the CFTC, may summarily abrogate the proposed rule

[57] 15 U.S.C. 78f(h)(3)(J).
[58] 7 U.S.C. 7(d)(10).
[59] 17 CFR 38.550.
[60] 17 CFR 38.551.
[61] 17 CFR 38.552.
[62] 17 CFR 1.31(b).
[63] 15 U.S.C. 78f(h)(3)(K).
[64] 17 CFR 41.25(b)(2).
[65] 15 U.S.C. 78f(h)(3)(L).
[66] 15 U.S.C. 78g(c)(2)(B).
[67] 17 CFR 242.403; 17 CFR 41.45.
[68] 15 U.S.C. 78f(h)(3).
[69] 15 U.S.C. 78f(b).
[70] 15 U.S.C. 78f(b)(5).

change and require that the proposed rule change be refiled in accordance with the provisions of Section 19(b)(1) of the Act.[71]

## 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–OGM–2026–001 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–OGM–2026–001. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the 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–OGM–2026–001 and should be submitted on or before October 23, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[72]

**Sherry R. Haywood,**

*Assistant Secretary.*

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[71] 15 U.S.C. 78s(b)(1).

[72] 17 CFR 200.30–3(a)(73).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–106522; File No. SR–NYSEAMER–2026–86]**

## Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend NYSE American Rule 903G

September 29, 2026.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on September 16, 2026, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 903G (Terms of Flexible Exchange (''FLEX'') Options). 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 Rule 903G (Terms of FLEX Options) as it relates to FLEX Equity Options where the underlying security is an ETF that is eligible for cash settlement. Specifically, the proposed amendments would: (i) permit newly FLEX-eligible ETFs that satisfy heightened eligibility thresholds of $600 million average daily notional value and 5,616,000 shares ADV, based on the previous one-month period of trading statistics to be eligible for cash settlement as a contract term; (ii) establish tiered criteria governing the treatment of cash-settled FLEX ETF Options where the underlying ETF ceases to satisfy the requirements of Rule 903G(c)(3)(ii) at the time of the Exchange's bi-annual review; and (iii) eliminate the existing provision limiting cash settlement as a contract term to no more than 50 underlying ETFs.

This filing is based on substantially identical proposals by Cboe Exchange, Inc. (''Cboe''),[4] Nasdaq ISE, LLC (''ISE'') [5] and Nasdaq PHLX Exchange (''PHLX'').[6]

Background

Generally, FLEX Equity Options are settled by physical delivery of the underlying security,[7] while all FLEX Index Options are settled in cash.[8] In February 2020, however, the Exchange amended Rule 903G to permit cash settlement for up to 50 FLEX Equity Options with an underlying security that is an ETF meeting certain criteria: an average daily notional value of $500 Million or more and a national average daily volume of 4,680,000 shares, measured over the prior six-month period. Where more than 50 ETFs qualify, the Exchange selects the 50 with the highest average daily volume.[9]

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 105929 (July 16, 2026), 91 FR 45856 (July 21, 2026) (SR–Cboe–2026–035) (Notice of Filing of Amendment No. 1 and Order Approving a Proposed Rule Change, as Modified and Superseded by Amendment No. 1, To Amend Rule 4.21 (Series of FLEX Options) (''Cboe Approval'').

[5] *See* Securities Exchange Act Release No. 106015 (July 30, 2026), 91 FR 49470 (August 4, 2026) (SR–ISE–2026–44) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend FLEX Options Listing Rules) (''ISE Notice'').

[6] *See* Securities Exchange Act Release No. 106016 (July 30, 2026), 91 FR 49476 (August 4, 2026) (SR–PHLX–2026–49) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend FLEX Electronic Options Listing Rules) (''PHLX Notice'').

[7] *See* Rule 903G(c)(3)(i).

[8] *See* Rule 903G(b)(2) and (3). Similarly, pursuant to Exchange rules, Binary Return Derivatives (''ByRDs'') are also settled in cash (*See* Rule 900ByRDS(b)) and, as discussed below, cash settlement is also permitted in the over-the-counter (''OTC'') market.

[9] *See* Rule 903G(c)(3)(ii). *See also* Securities Exchange Release No. 88131 (February 5, 2020), 85 FR 7806 (February 11, 2020) (SR–NYSEAMER–2019–38) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Allow Certain Flexible Equity Options To Be Cash Settled).

The Exchange adopted these specific thresholds to limit cash-settled FLEX ETF Options to the most highly liquid and actively-traded ETFs, thereby mitigating concerns about susceptibility to manipulation at settlement. With respect to the notional value threshold, the Exchange determined that average daily notional value is an appropriate proxy for selecting underlying securities that are not readily susceptible to manipulation for purposes of establishing a settlement price. The Exchange noted that average daily notional value takes into account both the trading activity and the price of an underlying security. As a general matter, the more expensive an underlying security's price, the less cost-effective manipulation could become. Further, manipulation of the price of a security encounters greater difficulty the more volume that is traded.

With respect to the ADV threshold, the Exchange determined that a requirement of 4,680,000 shares per day is appropriate because it represents average trading in the underlying ETF of approximately 200 shares per second, a level of continuous trading activity that the Exchange believes meaningfully limits the ability to influence the ETF's price for purposes of establishing a settlement value. The Exchange acknowledged that no security is immune from all manipulation, but determined that the combination of these two requirements would appropriately limit cash settlement of FLEX ETF Options to underlying securities that are less susceptible to manipulation.

Under this framework, the Exchange conducts a bi-annual review on January 1 and July 1 of each year to identify qualifying ETFs. The rule caps the number of eligible underlying ETFs at 50; if more than 50 ETFs satisfy the criteria, the Exchange selects the top 50 by highest ADV. This cap was designed to prevent the scope of cash-settled FLEX ETF Options from expanding considerably without a corresponding evaluation of whether the level of the requirements remains reasonable, while still providing flexibility to add ETFs given that the initial list of eligible ETFs numbered well below 50 at the time of adoption. In the event a previously eligible ETF fails to satisfy the criteria at the time of a bi-annual review, any new positions overlying that ETF must be physically settled and any existing open cash-settled positions may be traded only to close. This provision was designed to address how to wind down outstanding cash-settled positions in an ETF that no longer qualifies under the liquidity and volume criteria, thereby addressing manipulation concerns while still permitting market participants to exit existing positions.

In connection with the adoption of this framework, the Exchange committed to conducting a five-year review of cash-settled FLEX ETF Option trading activity and furnishing the Commission with five annual reports. Pursuant to this commitment, the Exchange has submitted two annual monitoring reports to the Commission covering the two years of trading. The report assessed trading volume and open interest in cash-settled FLEX ETF options relative to physically settled options on the same underlying ETFs, market maker participation, the liquidity of the market for such options products and the underlying ETF, and any manipulation concerns arising in connection with the trading of cash-settled FLEX ETF Options under the proposed rule. The reports also discuss any recommendations the Exchange may have for enhancements to the listing standards based on its review. The Exchange had no recommendations for enhancements to the listing standards based on its reviews. The Exchange had no open investigation, inquiry, or enforcement matter relating to the manipulation of cash-settled FLEX ETF options or their underlying ETFs.

As discussed in the Cboe Approval, Cboe noted that it submitted two annual monitoring reports to the Commission covering the periods of August 1, 2023 through July 31, 2024 and August 1, 2024 through July 31, 2025, respectively.[10] The reports assessed trading volume and open interest in cash-settled FLEX ETF options relative to physically settled options on the same underlying ETFs, market maker participation, position limit activity, and manipulation concerns.[11] Cboe had no recommendations for enhancements to the listing standards based on either review.[12] Also, Cboe noted that in both review periods, neither Cboe nor any affiliated Cboe securities exchange had an open investigation, inquiry, or enforcement matter relating to the manipulation of cash-settled FLEX ETF options or their underlying ETFs.[13] Financial Industry Regulatory Authority (''FINRA''), acting as Cboe's regulatory services provider for position limit surveillance, confirmed the same finding for both periods.[14] While both of Cboe's reports note that certain regulatory matters arose during each period involving the applicable ETFs or related physically-settled options, Cboe's surveillance and investigatory staff confirmed in each instance that the activity did not appear to relate to manipulation of an ETF for the purpose of benefiting a cash-settled FLEX ETF option position.[15]

The review period reflects broad and stable market maker participation across the eligible underlying ETFs. Cboe stated that the highest levels of FLEX market maker participation were observed in SPY (9 to 12 per month), QQQ (6 to 10 per month), and IWM (3 to 15 per month).[16] Cboe noted that participation in less actively traded eligible ETFs was more limited but consistent across both periods, reflecting a well-supported and liquid product across the eligible universe.[17]

Proposal

The Exchange proposes to amend Rule 903G(c)(3)(ii) to refine two aspects of the framework governing cash-settled FLEX ETF Options and to eliminate the 50- ETF cap. First, the Exchange proposes to permit newly FLEX-eligible ETFs to qualify for cash settlement as a contract term based on one month of trading statistics outside of the Exchange's regular bi-annual review cycle.[18] Second, the Exchange proposes to replace the existing provision governing ETFs that cease to satisfy the eligibility criteria with a tiered framework that more precisely calibrates treatment to the actual state of open interest in cash-settled FLEX ETF Options overlying the affected ETF.[19] Third, the Exchange proposes to eliminate the existing cap limiting cash settlement as a contract term to no more than 50 underlying ETFs.

One-Month Lookback for Newly Eligible ETFs

Under the current rule, the Exchange determines eligible underlying ETFs bi-annually, on January 1 and July 1 of each year, using six months of prior trading statistics, with newly eligible ETFs permitted to list cash-settled FLEX options beginning on February 1 and August 1, respectively. No mechanism currently exists to add newly FLEX-eligible ETFs to the eligible list between bi-annual reviews. As a result, an ETF that becomes FLEX-eligible after a bi-annual review has been conducted may not be considered for cash-settled FLEX

[10] *See* Cboe Approval, *supra* note 4.
[11] *See Id.*
[12] *See Id.*
[13] *See Id.*
[14] *See Id.*
[15] *See Id.*
[16] *See Id.*
[17] *See Id.*
[18] *See* proposed Rule 903G(c)(3)(ii)(A).
[19] *See* proposed Rule 903G(c)(3)(ii)(B).

ETF Option eligibility for up to six months, even if it otherwise satisfies the notional value and ADV requirements of Rule(c)(3)(ii).[20]

The Exchange proposes to address this gap by permitting, outside of the regular bi-annual review, the Exchange to determine that a newly FLEX-eligible ETF satisfies heightened notional value and trading volume requirements of $600 million average daily notional value and 5,616,000 shares ADV based on the previous one-month period of trading statistics. Any ETF satisfying such requirements on that basis shall be eligible for cash settlement as a contract term.

The Exchange believes a one-month lookback is appropriate in this context because an ETF that has newly become FLEX-eligible and simultaneously satisfies both the $600 million average daily notional value threshold and the 5,616,000-share ADV requirement over the prior month has already demonstrated the degree of liquidity and trading activity that the eligibility criteria are designed to capture. These thresholds represent a 20% increase over the standard $500 million and 4,680,000-share thresholds that apply to the bi-annual review, reflecting the Exchange's determination that heightened criteria are appropriate for ETFs seeking to qualify based on a shorter lookback period. The Exchange believes Cboe's and its annual monitoring reports demonstrate that the existing criteria are an effective proxy for identifying ETFs that are not readily susceptible to manipulation. Requiring newly eligible ETFs to await the next bi-annual review before becoming eligible for cash settlement would delay investor access to the product.

Cboe's back-testing analysis of newly listed FLEX ETFs supports the appropriateness of the heightened thresholds.[21] Under the standard eligibility criteria ($500 million average daily notional value and 4,680,000 shares ADV), ten ETFs would have qualified based on one month of trading data. Under the 20% increased thresholds ($600 million average daily notional value and 5,616,000 shares ADV), only eight ETFs qualified. Cboe noted that the two ETFs excluded by the heightened thresholds did not qualify at their next six-month bi-annual review, demonstrating that the heightened thresholds effectively filter out ETFs whose initial trading activity may not be sustained.

The Exchange believes the heightened thresholds for the one-month lookback appropriately address the concern that a newly listed ETF may experience elevated trading activity in its initial period that is not representative of sustained liquidity. By requiring newly eligible ETFs to satisfy thresholds that are 20% above the standard bi-annual review criteria, the Exchange ensures that only those ETFs demonstrating a meaningfully higher level of liquidity and trading activity—beyond what may reflect initial market interest—are eligible for cash settlement based on the shorter lookback period.

Further, the Exchange represents that it will continue to monitor the one-month lookback criteria on an ongoing basis to assess the appropriateness of the threshold. As part of this ongoing monitoring, the Exchange will evaluate whether the heightened criteria continue to effectively identify ETFs with sustained liquidity and trading activity, and will propose adjustments to the threshold if warranted by the Exchange's review.

Tiered Criteria for ETFs Ceasing To Satisfy Eligibility Requirements

Under the current rule, if the Exchange determines at the time of a bi-annual review that an underlying ETF ceases to satisfy the eligibility criteria, any new position overlying that ETF must be physically settled and any existing open cash-settled positions may be traded only to close. While this provision addresses the wind-down of cash-settled activity in a straightforward manner, it does not distinguish between ETFs with active open interest and those with no meaningful cash-settled activity, nor does it account for the possibility that an ETF may temporarily fall below the eligibility thresholds and subsequently recover.

The Exchange proposes to replace this provision with a tiered framework that more precisely calibrates the treatment of an ineligible ETF to the actual state of the market for cash-settled FLEX ETF Options overlying that ETF. Under the proposed framework, if no open interest in cash-settled FLEX Equity Options overlying the ETF exists during the previous six-month period at the time of the bi-annual review determination, the existing treatment will apply: any new position must be physically settled and any open cash-settled positions may be traded only to close. Where open interest in cash-settled FLEX Equity Options overlying the ETF does exist during the previous six-month period, the Exchange will permit the opening of new cash-settled positions in that ETF for a period of one year from the date of the bi-annual review, after which any new position must be physically settled and any remaining open cash-settled positions may be traded only to close. This one-year continuation period is intended to provide market participants holding or seeking to manage existing cash-settled positions with a reasonable and predictable runway to do so, rather than abruptly restricting new position activity at the time of the bi-annual review determination.

The proposed framework also includes a recovery provision: if the underlying ETF satisfies the eligibility criteria at the time of either bi-annual review conducted during the one-year continuation period, that period will terminate and the ETF will resume full eligibility for cash settlement as a contract term. The Exchange believes this provision appropriately accounts for the possibility that an ETF's trading statistics may fluctuate around the eligibility thresholds and prevents an unnecessarily disruptive wind-down in cases where the ETF promptly returns to eligibility.

Elimination of the 50–ETF Cap

The Exchange also proposes to eliminate the existing provision limiting cash settlement as a contract term to no more than 50 underlying ETFs. The cap was adopted at the outset of the program to prevent the scope of cash-settled FLEX ETF Options from expanding considerably without a corresponding evaluation of whether the level of the eligibility requirements remained reasonable. While the number of ETFs satisfying the eligibility criteria remained well below 50 during the initial period of the program's operation, over the two-year period that Cboe monitored the market, the number of qualifying ETFs has grown to exceed that threshold (as of February 1, 2026, 60 ETFs were eligible), such that the cap now operates as an active constraint on the availability of cash-settled FLEX ETF Options on ETFs that otherwise satisfy the established eligibility criteria. The Exchange does not believe this result is consistent with the purpose of the cap, which was intended as a programmatic guardrail rather than a permanent numerical ceiling. As noted above, neither the Exchange nor Cboe identified manipulation concerns in their reviews. Given the same eligibility criteria and position and exercise limits would apply to any cash-settled FLEX ETF option, as would the Exchange's surveillance program, the Exchange believes the 50–ETF cap is no longer necessary. The Exchange believes these

[20] *See* proposed Rule 903G(c)(3)(ii)(A).

[21] For purposes of the back-testing analysis, Cboe reviewed all newly listed FLEX-eligible ETFs from January 1, 2025 through April 6, 2026.

protections and the eligibility criteria themselves sufficiently mitigate any manipulation concerns associated with cash-settled FLEX ETF Options.

The Exchange also notes that, consistent with its commitment in the original proposal, it will continue to furnish the Commission with annual reports for the remainder of the five-year review period. The Exchange believes that the continued reporting commitment, together with the proposed amendments, appropriately positions the cash-settled FLEX ETF Option framework to address the operational gaps identified through the Exchange's review to date while preserving the monitoring mechanisms that allow the Exchange and the Commission to evaluate the ongoing impact of the program.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[22] in general, and furthers the objectives of Section 6(b)(5) of the Act,[23] 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 mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. In addition, the Exchange believes that the proposed rule change is consistent with the Section 6(b)(5)[24] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

One-Month Lookback for Newly Eligible ETFs

The Exchange believes the proposed one-month lookback for newly FLEX-eligible ETFs is consistent with the Act because it removes an impediment to the offering of cash-settled FLEX ETF Options on ETFs that have already demonstrated the liquidity and trading activity that the eligibility criteria are designed to capture, without compromising the manipulation-resistant features of those criteria. Under the current rule, an ETF that becomes FLEX-eligible after a bi-annual review has been conducted must wait up to six months before it may be considered for cash-settled FLEX ETF Option eligibility, even if it satisfies both the $600 million average daily notional value threshold and the 5,616,000-share ADV requirement at the time it becomes FLEX-eligible. The Exchange believes this gap is not necessary to protect against manipulation.

An ETF that satisfies both heightened thresholds over the prior one-month period has demonstrated a degree of liquidity and breadth of trading activity exceeding that which the six-month bi-annual review is designed to identify as indicative of reduced susceptibility to manipulation. The heightened thresholds, which represent a 20% increase over the standard $500 million and 4,680,000-share thresholds applicable to the bi-annual review, are designed to account for the possibility that a newly listed ETF may experience elevated trading activity in its initial period that is not representative of sustained liquidity. As noted above, Cboe's and the Exchange's annual monitoring reports have demonstrated the existing eligibility criteria are an effective and reliable proxy for identifying ETFs that are not readily susceptible to manipulation, and neither Cboe nor the Exchange has identified any manipulation concerns in connection with cash-settled FLEX ETF Options or their underlying ETFs during that period. The Exchange therefore believes that permitting a one-month lookback for newly FLEX-eligible ETFs between bi-annual reviews, subject to the heightened thresholds, removes an impediment to and perfects the mechanism of a free and open market and protects investors and the public interest by providing timely investor access to a cash-settlement alternative on ETFs that satisfy the established eligibility criteria, while maintaining the protections afforded by those criteria.

Cboe's back-testing analysis further supports the consistency of the heightened thresholds with the Act's anti-manipulation objectives. Under the standard criteria, ten newly listed FLEX ETFs would have qualified based on one month of trading data, but under the 20% increased thresholds only 8 qualified. The two names excluded (AMDL and SIVR) did not qualify at their next six-month bi-annual review, confirming that the heightened thresholds effectively identify and exclude ETFs whose initial trading statistics do not reflect sustained market activity. The Exchange believes this empirical evidence demonstrates that the heightened thresholds are reasonably designed to prevent ETFs with potentially transient liquidity from qualifying for cash settlement based on the shorter lookback period.

Tiered Criteria for ETFs Ceasing To Satisfy Eligibility Requirements

The Exchange believes the proposed tiered framework for ETFs that cease to satisfy the eligibility criteria at the time of a bi-annual review is consistent with the Act because it is reasonably designed to prevent fraudulent and manipulative acts and practices while also promoting just and equitable principles of trade and protecting investors. The current rule applies a single, uniform wind-down treatment to any ETF that falls below the eligibility thresholds at bi-annual review, regardless of whether active open interest in cash-settled FLEX ETF Options overlying that ETF exists. The Exchange believes this one-size-fits-all approach does not adequately account for the legitimate interests of market participants that hold existing cash-settled positions or that need the ability to open new positions to manage existing risk exposure in an ETF that has temporarily fallen below the thresholds.

The proposed tiered framework addresses this concern in a manner consistent with the Act's investor protection and anti-manipulation objectives. Where no open interest in cash-settled FLEX ETF Options overlying the affected ETF has existed during the previous six-month period, the current treatment would continue to apply, because the Exchange believes an immediate restriction on new cash-settled positions would not disrupt market participants' activity. Where open interest does exist at the time of the bi-annual review, the proposed one-year continuation period provides market participants with a reasonable and predictable runway to manage existing positions, which the Exchange believes promotes just and equitable principles of trade. The Exchange further believes that the recovery provision, under which the continuation period terminates and full eligibility is restored if the ETF satisfies the criteria at either bi-annual review during the one-year period, is consistent with the Act because it prevents an unnecessarily disruptive wind-down where an ETF's trading statistics temporarily dip below the eligibility thresholds and then recover, and it reinforces the principle that the eligibility criteria, rather than arbitrary timing, are the appropriate determinant of cash-settlement eligibility. Taken together, the Exchange believes the tiered framework is a reasonable means to address manipulation concerns while not unduly burdening market participants with existing cash-settled

[22] 15 U.S.C. 78f(b).

[23] 15 U.S.C. 78f(b)(5).

[24] 15 U.S.C. 78f(b)(5).

positions, as it eliminates the current immediate disruption to their investment strategies.

Elimination of the 50–ETF Cap

The Exchange believes the elimination of the 50–ETF cap is consistent with the Act because the cap is no longer necessary to protect against the concerns it was designed to address and, as currently operative, functions as an impediment to the offering of cash-settled FLEX ETF Options on ETFs that otherwise satisfy the established eligibility criteria. The cap was adopted at the outset of the program to prevent the scope of cash-settled FLEX ETF Options from expanding considerably without a corresponding evaluation of whether the level of the eligibility requirements remained reasonable. While the number of qualifying ETFs remained well below 50 during the initial period of the program's operation, that number has more recently grown to exceed the cap, such that the cap now actively restricts the availability of cash-settled FLEX ETF Options on ETFs that fully satisfy the notional value and ADV requirements of Rule 903G. The Exchange believes that retaining this arbitrary restriction is inconsistent with the Act's objectives because Cboe's two-year monitoring record demonstrates that the eligibility criteria themselves limit the availability of cash settlement to FLEX ETF Options. The liquidity and trading activity requirements mitigate manipulation concerns for any ETF that satisfies those requirements, not just the top 50.

During the first two years that cash-settled FLEX ETF Options were available on Cboe, it identified (and its annual monitoring reports demonstrated) no manipulation concerns in connection with cash-settled FLEX ETF Options or their underlying ETFs. The Exchange did not identify any manipulation in its two years of monitoring. The Exchange believes the eligibility criteria, position and exercise limits, and surveillance program applicable to the 50 ETFs eligible for FLEX options with cash-settlement provide adequate protections against manipulation and market disruption to all ETFs that satisfy the criteria, regardless of the number of qualifying ETFs. The Exchange therefore believes that eliminating the cap removes an impediment to and perfects the mechanism of a free and open market, protects investors and the public interest, and is otherwise consistent with the Act.

*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 this regard and as indicated above, the Exchange notes that the rule change is substantially similar in all material respects to proposals submitted by Cboe, ISE and PHLX.[25]

The Exchange does not believe that the proposed rule change will impose any burden on inter-market competition as the proposal is not competitive in nature. The Exchange expects that all option exchanges have or will adopt substantively similar proposals, such that the Exchange's proposal would benefit competition. For these reasons, 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 Exchange's proposal does not burden intra-market competition because all Members and Member Organizations would be subject to the proposed changes to Rule 903G. The Exchange believes that the proposed rule change will also provide additional opportunities for market participants to continue to efficiently achieve their investment and trading objectives for equity options on the Exchange.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

No written comments were solicited or received with respect to the proposed rule change.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[26] and Rule 19b–4(f)(6) thereunder.[27] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)[28] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[29] 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. Waiver of the 30-day operative delay would allow the Exchange to immediately align its rules with the current rules of Cboe, ISE and PHLX. 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 operative upon filing.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[30] 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–

[25] Cboe Approval Order, ISE Notice and PHLX Notice, *supra* notes 4–6.

[26] 15 U.S.C. 78s(b)(3)(A)(iii).

[27] 17 CFR 240.19b–4(f)(6).

[28] 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.

[29] 17 CFR 240.19b–4(f)(6)(iii).

[30] 15 U.S.C. 78s(b)(2)(B).

NYSEAMER–2026–86 on the subject line.

*Paper Comments*

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSEAMER–2026–86. 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–NYSEAMER–2026–86 and should be submitted on or before October 23, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

**Sherry R. Haywood,**

*Assistant Secretary.*

[FR Doc. 2026–20195 Filed 10–1–26; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[OMB Control No. 3235–0648]**

## Agency Information Collection Activities; Proposed Collection; Comment Request; Extension: Rule 498

*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 collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 498 (17 CFR 230.498) under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) (''Securities Act'') permits open-end management investment companies (''funds'') to satisfy their prospectus delivery obligations under the Securities Act by sending or giving key information directly to investors in the form of a summary prospectus (''Summary Prospectus'') and providing the statutory prospectus on a website. Upon an investor's request, funds are also required to send the statutory prospectus to the investor. In addition, under rule 498, a fund that relies on the rule to meet its statutory prospectus delivery obligations must make available, free of charge, the fund's current Summary Prospectus, statutory prospectus, statement of additional information, and most recent annual and semi-annual reports to shareholders at the website address specified in the required Summary Prospectus legend (17 CFR 270.498(e)(1)). A Summary Prospectus that complies with rule 498 is deemed to be a prospectus that is authorized under Section 10(b) of the Securities Act and Section 24(g) of the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*).

The purpose of rule 498 is to enable a fund to provide investors with a Summary Prospectus containing key information necessary to evaluate an investment in the fund. Unlike many other federal information collections, which are primarily for the use and benefit of the collecting agency, this information collection is primarily for the use and benefit of investors. The information filed with the Commission also permits the verification of compliance with securities law requirements and assures the public availability and dissemination of the information.

Based on an analysis of fund filings, the Commission estimates that approximately 11,699 funds are using a Summary Prospectus. The Commission estimates that the annual hourly burden per fund associated with the compilation of the information required on the cover page or the beginning of the Summary Prospectus is 0.5 hours, and estimates that the annual hourly burden per fund to comply with the website posting requirement is approximately 1 hour, requiring a total of 1.5 hours per fund per year.[1] Thus the total annual hour burden associated with these requirements of the rule is approximately 17,549 hours.[2] The Commission estimates that the annual cost burden is approximately $23,380 per fund, for a total annual cost burden of approximately $273,522,620.[3]

Estimates of average burden hours are made solely for the purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules and forms. Under rule 498, use of the Summary Prospectus is voluntary, but the rule's requirements regarding provision of the statutory prospectus upon investor request are mandatory for funds that elect to send or give a Summary Prospectus in reliance upon rule 498. The information provided under rule 498 will not be kept confidential.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid 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 December 1, 2026.

Dated: September 30, 2026.

**Sherry R. Haywood,**

*Assistant Secretary.*

[FR Doc. 2026–20280 Filed 10–1–26; 8:45 am]

**BILLING CODE 8011–01–P**

[31] 17 CFR 200.30–3(a)(12).

[1] 0.5 hours per fund + 1 hour per fund = 1.5 hours per fund.

[2] 1.5 hours per fund × 11,699 funds = 17,549 hours.

[3] $23,380 per fund × 11,699 funds = $273,522,620.

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–106527; File No. SR–NSCC–2026–010]**

## Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Clearing Agency Risk Management Framework

September 29, 2026.

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 September 18, 2026, National Securities Clearing Corporation (''NSCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. NSCC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(4) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

### I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of amendments to the Clearing Agency Risk Management Framework (''Risk Management Framework'' or ''Framework'') of NSCC and its affiliates, The Depository Trust Company (''DTC'') and Fixed Income Clearing Corporation (''FICC,'' and together with NSCC and DTC, the ''Clearing Agencies'').[5] Specifically, the proposed rule change would amend the Risk Management Framework to clarify and update the Framework. The proposed changes would update and clarify the Framework by (1) revising the format and structure of various sections to reflect internal policy and procedure governance requirements, (2) updating the descriptions to reflect that the Risk Management Framework supports the Clearing Agencies' compliance with Rules 17ad–25(j)[6] and 17ad–26[7] under the Act; (3) adding a description of the Clearing Agency Framework for Certain Requirements on Governance and Conflicts of Interests, which was adopted by the Clearing Agencies in 2024[8] and (4) adding clarifying, conforming, and administrative updates that do not alter how the Clearing Agencies comply with the applicable requirements of Rule 17ad–22(e) under the Act.[9]

### II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

*(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

NSCC proposes to amend the Risk Management Framework of the Clearing Agencies. Specifically, the proposed rule change would amend the Risk Management Framework to clarify and update the Framework. The proposed changes would update and clarify the Framework by (1) revising the format and structure of various sections to reflect internal policy and procedure governance requirements, (2) updating the descriptions to reflect that the Risk Management Framework supports the Clearing Agencies' compliance with Rule 17ad–25(j) and Rule 17ad–26; (3) adding a description of the Clearing Agency Framework for Certain Requirements on Governance and Conflicts of Interests, which was adopted by the Clearing Agencies in 2024 and (4) adding clarifying, conforming, and administrative updates that do not alter how the Clearing Agencies comply with the applicable requirements of Rule 17ad–22(e).

Risk Management Framework

The Clearing Agencies adopted the Risk Management Framework[10] to provide an outline for how each of the Clearing Agencies (i) comprehensively manages legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by it; (ii) maintains a well-founded, clear, transparent and enforceable legal basis for each aspect of its activities; (iii) identifies, monitors, and manages risks related to links it establishes with one or more clearing agencies, financial market utilities, or trading markets; (iv) publicly discloses certain information, including market data; (v) meets the requirements of its participants and the markets it serves efficiently and effectively; (vi) uses, or at a minimum accommodates, relevant internationally accepted communication procedures and standards in order to facilitate efficient payment, clearing and settlement; and (vii) conducts an annual review of the Government Securities Division of FICC's access models. In this way, the Risk Management Framework currently supports the Clearing Agencies' compliance with Rules 17ad–22(e)(1), (3), (18), (20), (21), (22), (23), 17ad–25(j) and 17ad–26 under the Act,[11] as described in the Framework Filings.

In addition to setting forth the manner in which each of the Clearing Agencies addresses these requirements, the Risk Management Framework also describes the Framework ownership and the required governance process for review and approval of changes to the Framework. In connection with the annual review and approval of the Framework by the Board of Directors of each of NSCC, DTC and FICC (each a ''Board'' and collectively, the ''Boards''), the Clearing Agencies are proposing to make certain revisions to the Framework.

Proposed Changes

1. Revising Format and Structure

The proposed changes would reformat and reorganize the Framework to align

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(4).

[5] *See* Securities Exchange Act Release Nos. 81635 (Sept. 15, 2017), 82 FR 44224 (Sept. 21, 2017) (SR–DTC–2017–013, SR–FICC–2017–016, SR–NSCC–2017–012) (''Initial Filing''); 89271 (July 9, 2020), 85 FR 42933 (July 15, 2020) (SR–NSCC–2020–012); 89269 (July 9, 2020), 85 FR 42954 (July 15, 2020) (SR–DTC–2020–009); 89270 (July 9, 2020), 85 FR 42927 (July 15, 2020) (SR–FICC–2020–007); 96799 (Feb. 03, 2023), 88 FR 8506 (Feb. 9, 2023) (SR–DTC–2023–001); 96800 (Feb. 3, 2023), 88 FR 8491 (Feb. 9, 2023) (SR–FICC–2023–001); 96801 (Feb. 3, 2023), 88 FR 8502 (Feb. 9, 2023) (SR–NSCC–2023–001); 99097 (Dec. 6, 2023), 88 FR 86186 (Dec. 12, 2023) (SR–FICC–2023–016); 99098 (Dec. 6, 2023), 88 FR 86183 (Dec. 12, 2023) (SR–NSCC–2023–012); 99108 (Dec. 07, 2023), 88 FR 86430 (Dec. 13, 2023) (SR–DTC–2023–012); 101685 (Nov. 21, 2024), 89 FR 93689 (Nov. 27, 2024) (SR–DTC–2024–003, SR–FICC–2024–006, SR–NSCC–2024–003); 102652 (Mar. 13, 2025), 90 FR 12858 (Mar. 19, 2025) (SR–DTC–2025–002); 102653 (Mar. 13, 2025), 90 FR 12870 (Mar. 19, 2025) (SR–FICC–2025–004); and 102654 (Mar. 13, 2025), 90 FR 12844 (Mar. 19, 2025) (SR–NSCC–2025–002) (together with the Initial Filing, the ''Framework Filings'').

[6] 17 CFR 240.17ad–25(j) (''Rule 17ad–25(j)'').

[7] 17 CFR 240.17ad–26 (''Rule 17ad–26'').

[8] *See* Securities Exchange Act Release No. 101764 (Nov. 26, 2024), 82 FR 44224 (Dec. 3, 2024) (SR–DTC–2024–009, SR–FICC–2024–010, SR–NSCC–2024–006).

[9] 17 CFR 240.17ad–22(e) (''Rule 17ad–22(e)'').

[10] *Supra* note 5.

[11] 17 CFR 240.17ad–22(e)(1), (3), (18), (20), (21), (22), (23), 17ad–25(j), and 17ad–26.

with the Clearing Agencies' internal governance guidelines for policies, procedures and frameworks. Each Clearing Agency maintains guidelines regarding the required structure, organization, and content of such documents which are intended to ensure that the Clearing Agencies' policies, procedures and frameworks are well-written, well-structured, accurate and easy to understand.

The proposed revisions are intended to conform the Framework to those guidelines and include the following changes: [12]

| Section | Proposed changes |
|---|---|
| Section 1 | Rename the section ''Executive Summary'' to ''Purpose'' and revise the accompanying description to articulate the purpose of the Framework.<br>Delete the sentence defining DTCC and identifying it as the parent of the Clearing Agencies, and relocate that definition to the first reference to DTCC in Section 2.<br>Delete the four paragraphs describing the Framework, the treatment of risks not addressed by the Framework, supporting documentation, and the meaning of references, and relocate that content to Section 2. |
| Section 2 | Rename the section ''Framework Ownership and Change'' to ''Roles and Responsibilities'' and move language from Section 1 to this Section as described above.<br>Delete the sentence addressing ownership of the Framework and move it to Section 3.<br>Delete the paragraph describing ownership of the processes addressed by the Framework and move it to Section 3.<br>Delete the paragraph describing the approval process for changes to the Framework and move it to Section 8.<br>Delete the sentence regarding review of the Framework by the General Counsel's Office and move it to Section 3.<br>Delete the sentence addressing annual Board approval of the Framework and move it to Section 8.<br>Delete the sentence regarding the legend associated with the Framework and move it to Section 8. |
| Sections 3–6 | Create new Section 3, titled ''Audience'' and move language from Section 2 to this Section as described above.<br>Renumber the headings and subheadings in current Sections 3 through 5 to reflect the addition of the new Section 3. |
| Section 7 | Create a new Section 7, titled ''Exceptions,'' describing the process for escalating, approving, and documenting exceptions to the Framework in accordance with applicable internal compliance guidelines governing policies, procedures, and frameworks. |
| Section 8 | Create a new Section 8, titled ''Framework Governance'' and relocate the governance-related provisions currently contained in Section 2 to this Section as described above. |

2. Updating Descriptions to Reflect Support of Compliance With Rule 17ad–25(j) and Rule 17ad–26

The proposed changes include additional disclosures intended to address the Clearing Agencies' compliance with the requirements of Rule 17ad–25(j), related to the management of risks presented by core service providers and the solicitation of stakeholder views, and the requirements set forth in Rule 17ad–26, relating to the maintenance of the Clearing Agencies' recovery and wind-down plans.[13]

Specifically, Section 1 would be revised to include references to Rule 17ad–25(j) and Rule 17ad–26, clarifying that the Framework supports compliance with those requirements. Section 5.2.1 would be updated to state that, consistent with Rule 17ad–25(j), the Clearing Agencies have established policies and procedures to manage risks arising from relationships with providers of core services. Section 5.3 would be enhanced to include a description of the Clearing Agencies' advisory councils as part of their compliance with Rule 17ad–25(j). In addition, Section 6 would be revised to reference Rule 17ad–26 and to state that it requires the recovery and wind-down plans to identify the core staffing and providers of core services necessary to support the continued provision of core services.

3. Add Reference to Clearing Agency Framework for Certain Requirements on Governance and Conflicts of Interests

Section 4.3.3 currently lists additional frameworks adopted by the Clearing Agencies that support the Framework. The proposed revision would add the Clearing Agency Framework for Certain Requirements on Governance and Conflicts of Interest, adopted by the Clearing Agencies in 2024,[14] and include a brief description of its purpose and scope.

4. Immaterial Changes for Clarification Purposes

The proposed changes include a number of clarifying, conforming, and administrative updates to improve the accuracy, consistency, and readability of the Framework.

The following changes would be made throughout the Framework: (i) replace references to 17 CFR 240.17Ad–22(e) with 17 CFR 240.17ad–22(e), (ii) replace references to the Risk Department with the Group Chief Risk Office to reflect the department's current name; and (iii) update section references to align with the organizational and formatting revisions described above.

Additional revisions would be made to specific sections of the Framework. In Section 4.1.1, a semicolon would be added in two places. In Section 4.1.2, a period would replace a comma in the first bullet point of the renamed Group Chief Risk Office subsection. In Section 4.1.3, the phrase ''independent validation'' would be replaced with ''independent and objective assurance'' to more accurately describe the role of the Internal Audit department. In Section 4.2, the description of the policy governing the establishment and oversight of internal committees and councils would be enhanced to clarify that each committee is periodically reviewed to confirm that it continues to fulfill its intended purpose effectively. In Section 4.3.1, the apostrophe after ''Agencies''' would be removed and ''business person'' would be replaced

[12] References to Section numbers herein are referring to Section numbers following the proposed changes.

[13] *See* 17 CFR 240.17ad–25(j) and 17ad–26.

[14] *See supra* note 8.

with ''businessperson'' for grammatical consistency. In Section 4.3.3, definitions that are not used in the Framework would be removed, and the Clearing Agency Securities Valuation Framework would be renamed the Clearing Agency Price and Margin Input Data Framework to reflect its current title.

Further clarifications would be made in Section 5.1, including the removal of the phrase ''among other things'' as unnecessary, clarification that each of FICC and NSCC publishes public guides describing the methodologies used to calculate their respective Clearing Fund components and provides calculators that estimate certain margin requirements as examples of information available to participants, the addition of the word ''with'' for clarity, and the insertion of a comma after ''time'' to improve readability. In Section 5.2.1, a comma would be added after ''time,'' a sentence that was inadvertently presented as a separate bullet would be incorporated into the preceding bullet, and ''third party'' would be revised to ''third-party.'' In Section 5.2.2, the word ''relevant'' would be capitalized because it is the first word of the sentence. Section 5.3 would be updated to more accurately describe the processes and year-end reporting used by the Clearing Agencies to measure and monitor performance against their goals and targets. In Section 5.4, ''its'' would be replaced with ''their'' for grammatical correctness. Finally, Section 6 would be revised to reflect that Board approval of the Recovery and Wind-down Plans is now required annually, rather than biennially.

2. Statutory Basis

The Clearing Agencies believe that the proposed changes are consistent with Section 17A(b)(3)(F) of the Act [15] for the reasons described below. Section 17A(b)(3)(F) of the Act requires, in part, that the rules of a registered clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions, and to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible.[16]

The proposed changes would clarify and enhance the descriptions in the Risk Management Framework and correct errors in those descriptions by, for example, (1) revising the format and structure of various sections to reflect internal policy and procedure governance requirements, (2) updating the descriptions to reflect that the Risk Management Framework supports the Clearing Agencies' compliance with Rule 17ad–25(j) and Rule 17ad–26; (3) adding a description of Clearing Agency Framework for Certain Requirements on Governance and Conflicts of Interests, and (4) adding clarifying, conforming, and administrative updates that do not alter how the Clearing Agencies comply with the applicable requirements of Rule 17ad–22(e) under the Act.[17] By creating clearer, updated descriptions and correcting errors, the Clearing Agencies believe that the proposed changes would make the Risk Management Framework more effective in providing an overview of the important risk management activities of the Clearing Agencies, as described therein.

As described in the Framework Filings, the risk management functions described in the Risk Management Framework allow the Clearing Agencies to continue to promote the prompt and accurate clearance and settlement of securities transactions and continue to assure the safeguarding of securities and funds which are in their custody or control or for which they are responsible. The proposed changes to improve the clarity and accuracy of the descriptions of risk management functions within the Framework would assist the Clearing Agencies in carrying out these risk management functions. Therefore, the Clearing Agencies believe these proposed changes are consistent with the requirements of Section 17A(b)(3)(F) of the Act.[18]

*(B) Clearing Agency's Statement on Burden on Competition*

The Clearing Agencies do not believe that the proposed changes to the Framework described above would have any impact, or impose any burden, on competition. As described above, the proposed rule changes would improve the comprehensiveness of the Framework by creating clearer, updated descriptions and correcting errors, thereby making the Risk Management Framework more effective in providing an overview of the important risk management activities of the Clearing Agencies. As such, the Clearing Agencies do not believe the proposed rule changes would have any impact on competition.

*(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

The Clearing Agencies have not received or solicited any written comments relating to this proposal. If any written comments are received, they will be publicly filed as an Exhibit 2 to this filing, as required by Form 19b–4 and the General Instructions thereto.

Persons submitting comments are cautioned that, according to Section IV (Solicitation of Comments) of the Exhibit 1A in the General Instructions to Form 19b–4, the Commission does not edit personal identifying information from comment submissions. Commenters should submit only information that they wish to make available publicly, including their name, email address, and any other identifying information.

All prospective commenters should follow the Commission's instructions on how to submit comments, *available at www.sec.gov/rules-regulations/how-submit-comment.* General questions regarding the rule filing process or logistical questions regarding this filing should be directed to the Main Office of the Commission's Division of Trading and Markets at *tradingandmarkets@sec.gov* or 202–551–5777.

The Clearing Agencies reserve the right not to respond to any comments 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) of the Act [19] and paragraph (f) of Rule 19b–4 thereunder.[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.

## 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:

[15] 15 U.S.C. 78q–1(b)(3)(F).

[16] *Id.*

[17] 17 CFR 240.17ad–22(e).

[18] 15 U.S.C. 78q–1(b)(3)(F).

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f).

*Electronic Comments*

- Use the Commission's internet comment form (*www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NSCC–2026–010 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to file number SR–NSCC–2026–010. 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 NSCC and on DTCC's website (*www.dtcc.com/legal/sec-rule-filings*). 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–NSCC–2026–010 and should be submitted on or before October 23, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

**Sherry R. Haywood,**

*Assistant Secretary.*

[FR Doc. 2026–20199 Filed 10–1–26; 8:45 am]

**BILLING CODE 8011–01–P**

## DEPARTMENT OF STATE

**[Public Notice: 13141]**

### Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Auschwitz. Not Long Ago. Not Far Away.'' 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 ''Auschwitz. Not Long Ago. Not Far Away.'' at the United States Holocaust Memorial Museum, Washington, District of Columbia, 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.

**Sherry C. Keneson-Hall,**

*Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Bureau of Educational and Cultural Affairs, Department of State.*

[FR Doc. 2026–20213 Filed 10–1–26; 8:45 am]

**BILLING CODE 4710–05–P**

## DEPARTMENT OF STATE

**[Delegation of Authority No. 634]**

### Delegation of Authority by the Secretary of State to the Official Performing the Duties of the Administrator of the U.S. Agency for International Development

By virtue of the authority vested in the Secretary of State by the laws of the United States, including section 621 of the Foreign Assistance Act of 1961 (22 U.S.C. 2381), Executive Order 12163 of September 29, 1979, and section 1 of the State Department Basic Authorities Act (22 U.S.C. 2651a), I hereby delegate the following functions to the Official Performing the Duties of the Administrator of the U.S. Agency for International Development to the extent authorized by law:

The functions conferred on the Secretary of State to provide for the approval of funds from the Operating Expenses (OE), Assistance for Eastern Europe and Central Asia (AEECA), Development Assistance (DA), Economic Support Fund (ESF), Global Health Programs (GHP), Democracy Fund (DF), Complex Crises Fund (CCF), International Disaster Assistance (IDA), and Transition Initiative (TI) accounts for Fiscal Years 2018 through 2025, as well as funds in those accounts and predecessor accounts available until expended, made available to USAID to pay costs solely associated with the termination of USAID awards and the wind-down of USAID functions, including the approval of funding allocations, as well as the approval of the obligation and expenditure of such funds for close out and related purposes. This authority shall be exercised subject to at least bi-monthly reporting to the Under Secretary for Foreign Assistance, Humanitarian Assistance, and Religious Freedom on the specific uses of such funds and compliance with Congressional funding earmarks and directives.

This delegation shall remain in effect until June 30, 2027. The Secretary, Deputy Secretary, and Deputy Secretary for Management and Resources, and Under Secretary for Foreign Assistance, Humanitarian Assistance, and Religious Freedom may exercise any function or authority delegated herein. This delegation of authority does not modify any other delegation of authority currently in effect.

This delegation of authority shall be published in the **Federal Register**.

Dated: September 18, 2026.

**Marco Rubio,**

*Secretary of State, U.S. Department of State.*

[FR Doc. 2026–20263 Filed 10–1–26; 8:45 am]

**BILLING CODE 4710–05–P**

## DEPARTMENT OF STATE

**[Public Notice: 13138]**

### Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: Exhibition of ''Four Norwegian Bridal Crowns''

**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 exhibition or display in the European Sculpture and Decorative Arts galleries of 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,

[21] 17 CFR 200.30–3(a)(12).

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.

**Sherry C. Keneson-Hall,**

*Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Bureau of Educational and Cultural Affairs, Department of State.*

[FR Doc. 2026–20214 Filed 10–1–26; 8:45 am]

**BILLING CODE 4710–05–P**

## SURFACE TRANSPORTATION BOARD

**[Docket No. AB 33 (Sub–No. 353X)]**

### Union Pacific Railroad Company—Discontinuance of Service Exemption—in San Bernardino County, Cal.

Union Pacific Railroad Company (UP) has filed a verified notice of exemption under 49 CFR pt. 1152 subpart F—*Exempt Abandonments and Discontinuances of Service* to discontinue UP's freight operating rights over a portion of the Rialto Line of the Baldwin Park Branch extending from milepost 535.5 to milepost 537.74 and from milepost 537.78 to milepost 538.3, a total distance of approximately 2.76 miles in Rialto, San Bernardino County, Cal (the Line). The Line traverses United States Postal Service Zip Code 92376.

UP has certified that: (1) no local or overhead traffic has moved over the Line for at least two years; (2) there is no need to reroute any traffic over other lines; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line is pending either with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the two-year period; and (4) the requirements at 49 CFR 1105.12 (newspaper publication) and 49 CFR 1152.50(d)(1) (notice to governmental 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) [1] has been received, this exemption will be effective on November 1, 2026, unless stayed pending reconsideration.[2] Petitions to stay that do not involve environmental issues and formal expressions of intent to file an OFA to subsidize continued rail service under 49 CFR 1152.27(c)(2), must be filed by October 9, 2026.[3] Petitions for reconsideration must be filed by October 22, 2026.[4]

All pleadings, referring to Docket No. AB 33 (Sub–No. 353X), 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 UP's representative: Christine A. Neuharth, Union Pacific Railroad Company, 1400 Douglas Street, MS 1580, Omaha, NE 68179.

If the verified notice contains false or misleading information, the exemption is void ab initio.

Board decisions and notices are available at *www.stb.gov.*

Decided: September 29, 2026.

By the Board, Anika S. Cooper, Chief Counsel, Office of Chief Counsel.

**Aretha Laws-Byrum,**

*Clearence Clerk.*

[FR Doc. 2026–20206 Filed 10–1–26; 8:45 am]

**BILLING CODE 4915–01–P**

[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] UP states that it intends to consummate the discontinuance of the Line on or after November 3, 2026.

[3] The filing fees for OFAs can be found at 49 CFR 1002.2(f)(25).

[4] Because this is a discontinuance proceeding and not an abandonment, interim trail use/rail banking and public use conditions are not appropriate. UP states that because it is merely discontinuing service covered by reserved freight operating rights, environmental review is not applicable.

## SURFACE TRANSPORTATION BOARD

**[Docket No. FD 36957]**

### Macquarie Infrastructure Partners V GP, LLC, et al.—Control Exemption—Kankakee, Beaverville and Southern Railroad Company

Macquarie Infrastructure Partners V GP, LLC (MIP GP), a noncarrier, filed for the benefit of the MIP Infrastructure Partners V fund vehicle (MIP V), MIP V Rail, LP (MIP Rail), Pinsly Holdco, LLC, and Pinsly Railroad Company, LLC (Pinsly),[1] a verified notice of exemption under 49 CFR 1180.2(d)(2) to acquire control of Kankakee, Beaverville and Southern Railroad Company (KBSR),[2] a Class III common carrier freight railroad. KBSR is currently controlled by Vicki L. Stroo Living Trust, Vicki L. Stroo, Tyler A. Stroo, and Neil A. Stroo (collectively, the Stroo Family).

The verified notice states that, pursuant to a Purchase Agreement dated September 16, 2026,[3] Pinsly has agreed to acquire 100% of the equity interests of KBSR from the Stroo Family. Currently, Pinsly directly controls, and MIP GP, MIP V, and MIP Rail indirectly control, nine rail carriers: Grenada Railroad, LLC; Florida Gulf & Atlantic Railroad, LLC; Camp Chase Rail, LLC; Chesapeake and Indiana Railroad, LLC; Vermilion Valley Railroad Company LLC; Pioneer Valley Railroad Company, LLC; Hondo Railway LLC; North Florida Industrial Railroad, LLC; and Georgiana & Andalusia Railroad, LLC.

MIP GP states that: (1) KBSR does not connect with any of the railroads that would be in the same corporate family following the transaction; (2) the proposed transaction is not part of a series of anticipated transactions that would connect KBSR with any railroad in its corporate family; and (3) the transaction does not involve a Class I rail carrier. Therefore, the proposed transaction is exempt from the prior

[1] The verified notice states that Pinsly is wholly owned by Pinsly Holdco, LLC, which is wholly owned by MIP Rail, which in turn is wholly owned (indirectly) by MIP V. MIP V is controlled by MIP GP.

[2] KBSR operates approximately 159.7 miles of track in Illinois and Indiana comprised of: (1) the Lafayette Subdivision consisting of 74.6± miles between Kankakee, Ill., and Lafayette, Ind.; (2) the Danville Subdivision consisting of 57.4± miles between Hooper and Danville, Ill.; (3) the Boswell Subdivision consisting of 20.7± miles between Cheneyville, Ill. and Templeton, Ind.; and (4) a 7.0± mile spur between Sheff and Free, Ind. KBSR also operates as a contract carrier over approximately 9.5 miles owned by the Bee Line Railroad Company between Handy and Stewart, Ind.

[3] Public and confidential versions of the Purchase Agreement were filed with the verified notice. The confidential version was submitted under seal concurrently with a motion for protective order, which is addressed in a separate decision.

approval requirements of 49 U.S.C. 11323. *See* 49 CFR 1180.2(d)(2).

The earliest this transaction may be consummated is October 17, 2026, the effective date of the exemption (30 days after the verified notice was filed).

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. However, 49 U.S.C. 11326(c) does not provide for labor protection for transactions under 49 U.S.C. 11324 and 11325 that involve only Class III rail carriers. Because this transaction involves Class III rail carriers only, the Board, under the statute, may not impose labor protective conditions for this transaction.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than October 9, 2026 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36957, should be filed with the Surface Transportation Board 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 MIP GP's representative, Terence M. Hynes, Sidley Austin LLP, 1501 K Street NW, Washington, DC 20005.

According to MIP GP, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided:

By the Board, Anika S. Cooper, Chief Counsel, Office of Chief Counsel.

**Regena Smith-Bernard,**

*Clearance Clerk.*

[FR Doc. 2026–20205 Filed 10–1–26; 8:45 am]

**BILLING CODE 4915–01–P**

## SURFACE TRANSPORTATION BOARD

**[Docket No. FD 36946]**

### Alameda Belt Line—Operation Exemption—Board of Harbor Commissioners of the Port of Los Angeles, Board of Harbor Commissioners (Long Beach), Alameda Corridor Transportation Authority, and Union Pacific Railroad Company

Alameda Belt Line (ABL), a Class III railroad, has filed a verified notice of exemption pursuant to 49 CFR 1150.41 to assume common carrier operations over various tracks and terminal facilities in the Los Angeles Basin area (the Lines).[1] The Lines are owned in part by the City of Los Angeles (LA), a municipal corporation, acting through its Board of Harbor Commissioners; in part by the City of Long Beach (LB), a municipal corporation, acting through its Board of Harbor Commissioners; and in part by UP. The Lines are within and proximate to the terminal facilities of POLA and POLB and are composed of: (1) track owned by LA, within and proximate to POLA; (2) track owned or leased by LB, within and adjacent to POLB; (3) track jointly owned by POLA and POLB constituting the south end of the Alameda Corridor between milepost 16.1 at CP West Thenard, Cal., and milepost 18.2 at CP Badger Bridge, Cal., including a connecting segment extending between milepost 16.8 at CP Long Beach Junction, Cal., and milepost 17.7 at CP Gaspur, Cal.; [2] (4) the portion of the Alameda Corridor extending from milepost 0.0 at CP East Redondo, Cal., to milepost 16.1 at CP West Thenard, a triple-tracked main line corridor owned jointly by POLA and POLB; [3] and (5) the UP-owned Northerly Drill Track, also known as the Patata Industrial Lead, extending from milepost 12.8 at CP Tyler, Cal., to milepost 16.1 at CP West Thenard.

According to the verified notice, Pacific Harbor Line, Inc. (PHL), currently operates the Lines, providing terminal service to POLA and POLB. ABL states that it is currently negotiating separate agreements with LA, LB, ACTA, UP, and, as needed, jointly with POLA and POLB. According to the verified notice, ABL anticipates that all agreements essential to the transaction will be finalized in October 2026. ABL further states that pursuant to those agreements, it will replace PHL as the provider of terminal switching service to POLA and POLB. The verified notice does not indicate that PHL has consented to the discontinuance of its operating authority. PHL therefore will retain all existing common carrier authority to operate over the Lines. However, PHL may seek Board authority to discontinue operations over the Lines, or a third party may request that the Board authorize an ''adverse'' discontinuance of PHL's operating authority.

The verified notice states that none of the agreements governing the transaction involves any provision barring or limiting ABL's future interchange with any third-party connecting carrier. ABL further certifies its status as a terminal switching carrier will qualify ABL to be a Class III railroad pursuant to 49 CFR part 1201, General Instruction 1–1(d). Pursuant to 49 CFR 1150.42(e), if a carrier's projected annual revenues will exceed $5 million, it must, at least 60 days before the exemption is to become effective, post a notice of its intent to undertake the proposed transaction at the workplace of the employees on the affected lines, serve a copy of the notice on the national offices of the labor unions with employees on the affected lines, and certify to the Board that it has done so. On July 13, 2026, ABL certified that it posted the required 60-day notice at the workplaces of current PHL employees who work on the Lines and served a copy of the notice on the national offices of the labor union with employees on the Lines.

The earliest this transaction may be consummated is October 16, 2026, the effective date of the exemption. If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than October 9, 2026.

[1] ABL states that it is a privately-held railroad company granted common carrier dispatching authority pursuant to *Alameda Belt Line—Operation Exemption—Board of Harbor Commissioners of the Port of Los Angeles,* FD 36787 (STB served July 22, 2024). ABL further states that it provides dispatching over the trackage known as the Alameda Corridor, which functions as a conduit for BNSF Railway Company and Union Pacific Railroad Company (UP) traffic flowing to and from the Port of Los Angeles (POLA) and the Port of Long Beach (POLB).

[2] ABL states that it will acquire non-exclusive rights over this track.

[3] ABL states that it will acquire non-exclusive rights over this track. According to the verified notice, asset administration for the Alameda Corridor has been delegated to the Alameda Corridor Transportation Authority (ACTA).

All pleadings, referring to Docket No. FD 36946, 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 ABL's representative, Robert A. Wimbish, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606.

According to ABL, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: September 29, 2026.

By the Board, Anika S. Cooper, Chief Counsel, Office of Chief Counsel.

**Aretha Laws-Byrum,**

*Clearence Clerk.*

[FR Doc. 2026–20203 Filed 10–1–26; 8:45 am]

**BILLING CODE 4915–01–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

**[Docket No. FAA–2026–1985]**

### Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Drug and Alcohol Testing Program for Personnel Engaged in Specified Aviation Activities

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on April 24, 2026. The information collected is used to determine program compliance or non-compliance of regulated aviation employers and contractors (including certificated foreign repair stations that must comply with the FAA's final rule, Drug and Alcohol Testing of Certificated Repair Station Employees Located Outside of the United States), conduct oversight planning, determine employers required to provide annual Management Information System (MIS) testing information, and communicate with entities subject to the program regulations.

**DATES:** Written comments should be submitted by November 2, 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:** Latonya Williams by email at: *Latonya.Williams@faa.gov;* phone: 202–267–8442.

**SUPPLEMENTARY INFORMATION:**

*Public Comments Invited:* You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

*OMB Control Number:* 2120–0535

*Title:* Drug and Alcohol Testing Program for Personnel Engaged in Specified Aviation Activities

*Form Numbers:* There are no FAA forms associated with this collection.

*Type of Review:* Renewal

*Background:* The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on April 24, 2026 (91 FR 22215). The FAA mandates specified aviation entities to conduct drug and alcohol testing under its regulations, Drug and Alcohol Testing Program (14 CFR part 120), 49 U.S.C. 31306 (Alcohol and controlled substances testing), the Omnibus Transportation Employee Testing Act of 1991 (the Act), the FAA Modernization and Reform Act of 2012 (the Act), and the FAA final rule (Drug and Alcohol Testing of Certificated Repair Station Employees Located Outside of the United States). The FAA uses information collected for determining program compliance or non-compliance of regulated aviation employers and contractors (including certificated foreign repair stations that must comply with the FAA's final rule, Drug and Alcohol Testing of Certificated Repair Station Employees Located Outside of the United States), oversight planning, determining who must provide annual MIS testing information, and communicating with entities subject to the program regulations. In addition, the information is used to ensure that appropriate action is taken regarding flight crewmembers and other safety-sensitive employees who have tested positive for drugs, engaged in prohibited alcohol related-conduct, or refused to submit to testing.

Information collected includes 15 categories of information for domestically regulated entities (policy promulgation, registration information if required, supervisory training documentation, employee training documentation, reasonable cause and suspicion documentation, post-accident determination documentation, voluntary disclosure information, emergency maintenance reports, scientifically valid random testing process information, medical review officer contract recordkeeping, Substance Abuse Professional return-to-duty requirements, and reporting of refusals to take a drug or alcohol test or positive drug or alcohol test results) and five categories of information for foreign repair stations (information related to the issuance of the Drug and Alcohol Testing Paragraph/A449, parent corporation information collection if combining programs, program development and maintenance information, training records, and testing records). Of the responses, the FAA estimates that most (at least 80%) are submitted electronically. The remaining responses consist of recordkeeping and may be accomplished in any form (electronic or otherwise) that the respondents choose.

*Respondents:* Approximately 7,159 affected entities annually.

*Frequency:* On Occasion.

*Estimated Average Burden per Response:* 1 hour (rounded up from 0.957 hours per response).

*Estimated Total Annual Burden:* 325,181 Hours.

Issued in Washington, DC.

**Nancy Rodriguez Brown,**

*Director, Drug Abatement Division, Aviation Safety, AAM–800.*

[FR Doc. 2026–20207 Filed 10–1–26; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

**[Docket No. FAA–2026–12578]**

### Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Extended Operations (ETOPS) of Multi-Engine Airplanes

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves practices that permitted certificated air carriers to operate two-engine airplanes over long range routes. The FAA uses this information collection to ensure that aircraft for long range flights are equipped to minimize diversions, to preclude and prevent diversions in remote areas, and to ensure that all personnel are trained to minimize any adverse impacts of a diversion.

**DATES:** Written comments should be submitted by December 1, 2026.

**ADDRESSES:** Please send written comments:

*By Electronic Docket: www.regulations.gov* (Enter docket number into search field).

*By Mail:* Sandra Ray, 1187 Thorn Run Road, Suite 200, Coraopolis, PA 15108.

*By Fax:* 412–239–3063.

**FOR FURTHER INFORMATION CONTACT:** Sandra L. Ray by email at: *Sandra.ray@faa.gov;* phone: 412–546–7344.

**SUPPLEMENTARY INFORMATION:**

*Public Comments Invited:* You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

*OMB Control Number:* 2120–0718.

*Title:* Extended Operations (ETOPS) of Multi-Engine Airplanes.

*Form Numbers:* None.

*Type of Review:* Renewal of an information collection.

*Background:* The final rule codified the previous practices that permitted certificated air carriers to operate two-engine airplanes over long-range routes and extended the procedures for extended operations to all passenger-carrying operations on routes beyond 180 minutes from an alternate airport. This option is voluntary for operators and manufacturers. The FAA uses this information collection to ensure that aircraft for long range flights are equipped to minimize diversions, to preclude and prevent diversions in remote areas, and to ensure that all personnel are trained to minimize any adverse impacts of a diversion.

*Respondents:* Approximately 22 current operators, 4 airplane/engine manufacturers or type-certificate holders, and 6 prospective part 121 or part 135 operators.

*Frequency:* Information is collected on occasion.

*Estimated Average Burden per Response:* 1 hour per response.

*Estimated Total Annual Burden:* 41,214 Hours.

Issued in Washington, DC, on September 30, 2026.

**Sandra L. Ray,**

*Aviation Safety Inspector, AFS–260.*

[FR Doc. 2026–20221 Filed 10–1–26; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

**[Docket No. FHWA–2026–0958]**

### Proposed Memorandum of Understanding (MOU) Assigning Certain Federal Environmental Responsibilities to the State of Georgia, Including National Environmental Policy Act (NEPA) Authority for Certain Categorical Exclusions (CEs)

**AGENCY:** Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

**ACTION:** Notice of proposed MOU and request for comments.

**SUMMARY:** This notice announces that FHWA and the State of Georgia, acting by and through its State Department of Transportation, propose a MOU providing participation of the State in the CE Assignment Program. This program allows FHWA to assign its authority and responsibility for determining whether certain designated activities within the geographic boundaries of the State, as specified in the proposed MOU, are categorically excluded from preparation of an environmental assessment or an environmental impact statement under NEPA.

**DATES:** Please submit comments by November 2, 2026.

**ADDRESSES:** To ensure that you do not duplicate your docket submissions, please submit them by only one of the following means:

*Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for submitting comments.

*Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building Ground Floor Room W12–140, Washington, DC 20590.

*Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Ave SE, Washington, DC 20590 between 9:00 a.m. and 5:00 p.m. (E.T.), Monday through Friday, except Federal holidays.

*Instructions:* You must include the Agency name and docket number at the beginning of your comments. All comments received will be posted without change to *www.regulations.gov,* including any personal information provided.

**FOR FURTHER INFORMATION CONTACT:**

*For FHWA:* Sabrina David by email at *Sabrina.David@dot.gov,* by telephone at 404–562–3630. FHWA Georgia Division Office's normal business hours are 7:30 a.m. to 4:00 p.m. (E.T.), Monday–Friday, except for Federal holidays.

*For GDOT:* Amber Phillips by email at *aphillips@dot.ga.gov* or by telephone at 404–631–1100. State business hours are 8:00 a.m. to 5:00 p.m. (E.T.), Monday–Friday, except Federal and State holidays, although State holidays may not completely coincide with Federal holidays.

**SUPPLEMENTARY INFORMATION:**

#### Electronic Access

You may submit or retrieve comments online through the Federal eRulemaking portal at: *www.regulations.gov.* The website is available 24 hours each day, 365 days each year. Please follow the instructions. Electronic submission and retrieval help and guidelines are available under the help section of the website.

An electronic copy of this document may also be downloaded from the Office of the Federal Register's home page at: *www.federalregister.gov* and the U.S. Government Publishing Office's web page at: *www.govinfo.gov.*

#### Background

On October 24, 2025, FHWA received a request from the State of Georgia,

acting by and through its State Department of Transportation, to participate in the CE Assignment Program. The CE Assignment Program, pursuant to Section 326 of Title 23, United States Code (U.S.C.), is a program that allows the Secretary of the U.S. Department of Transportation (Secretary), to assign, and a State to assume, responsibility for determining whether certain highway projects are included within classes of action that are categorically excluded from requirements for environmental assessments or environmental impact statements pursuant to NEPA, 42 U.S.C. 4321 *et seq.* In addition, this program allows the assignment of other environmental review requirements applicable to Federal highway projects. FHWA is authorized to act on behalf of the Secretary with respect to these matters.

FHWA would execute Georgia's participation in this program through an MOU. statewide decisionmaking responsibility would be assigned for all activities identified in the MOU within the categories listed in 23 Code of Federal Regulations (CFR) 771.117(c) and those listed as examples in 23 CFR 771.111(d), and any activities added through FHWA rulemaking to those listed in 23 CFR 771.117(c) or example activities listed in 23 CFR 771.117(d) after the date of the execution of this MOU. In addition to the NEPA CE determination responsibilities, the MOU would assign to the State the responsibility for conducting Federal environmental review, consultation, and other related activities for projects that are subject to the MOU with respect to the following laws and requirements:

*Air Quality*

- Clean Air Act, 42 U.S.C. 7401–7671q, *Including determinations for project-level conformity if required for the project, except as specified in Stipulation II.B.2 of the MOU*

*Noise*

- Noise Control Act of 1972, 42 U.S.C. 4901–4918
- FHWA noise regulations in 23 CFR part 772

*Fisheries and Wildlife*

- Endangered Species Act of 1973, 16 U.S.C. 1531–1544
- Marine Mammal Protection Act, 16 U.S.C. 1361–1423h
- Anadromous Fish Conservation Act, 16 U.S.C. 757a–757f
- Fish and Wildlife Coordination Act, 16 U.S.C. 661–667d
- Migratory Bird Treaty Act, 16 U.S.C. 703–712
- Bald and Golden Eagle Protection Act, 16 U.S.C. 668–668d
- Magnuson-Stevens Fishery Conservation and Management Act of 1976, as amended, 16 U.S.C. 1801–1891d, with Essential Fish Habitat requirements at 16 U.S.C. 1855(b)(2)

*Historic and Cultural Resources*

- National Historic Preservation Act of 1966, as amended, 54 U.S.C. 300101 *et seq.*
- Section 4(f) of the Department of Transportation Act of 1966 [Section 4(f)], 23 U.S.C. 138, 49 U.S.C. 303 and implementing regulations at 23 CFR part 774
- Archeological Resources Protection Act of 1979, 16 U.S.C. 470(aa)–470(mm)
- Native American Grave Protection and Repatriation Act, 25 U.S.C. 3001–3013; 18 U.S.C. 1170
- Archeological and Historic Preservation Act, 54 U.S.C. 312501–312508

*Social and Economic Impacts*

- American Indian Religious Freedom Act, 42 U.S.C. 1996
- Farmland Protection Policy Act, 7 U.S.C. 4201–4209

*Water Resources and Wetlands*

- Clean Water Act, 33 U.S.C. 1251–1387
- Coastal Barrier Resources Act, 16 U.S.C. 3501–3510
- Coastal Zone Management Act, 16 U.S.C. 1451–1466
- Safe Drinking Water Act, 42 U.S.C. 300f–300j–26
- General Bridge Act of 1946, 33 U.S.C. 525–533
- 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. 3901 and 3921
- Wetlands Mitigation, 23 U.S.C. 119(g), 133(b)(14)
- Flood Disaster Protection Act, 42 U.S.C. 4001–4130
- FHWA wetland and natural habitat mitigation regulations, 23 CFR part 777

*Parklands and Other Special Uses*

- Section 4(f) of the Department of Transportation Act of 1966 [Section 4(f)], 23 U.S.C. 138, 49 U.S.C. 303 and implementing regulations at 23 CFR Part 774
- Land and Water Conservation Fund Act, 54 U.S.C. 200302–200310

*FHWA-Specific*

- Planning and Environmental Linkages, 23 U.S.C. 168, with the exception of those FHWA responsibilities associated with 23 U.S.C. 134 and 135
- Programmatic Mitigation Plans, 23 U.S.C. 169, with the exception of those FHWA responsibilities associated with 23 U.S.C. 134 and 135

The MOU allows the State to act in the place of FHWA in carrying out the functions described above, except with respect to government-to-government consultations with federally recognized Indian Tribes. FHWA will retain responsibility for conducting formal government-to-government consultation with federally recognized Indian Tribes, which is required under some of the above-listed laws. The State may also assist FHWA with formal consultations, with consent of a Tribe, but FHWA remains responsible for the consultation.

This assignment includes transfer to the State of Georgia the obligation to fulfill the assigned environmental responsibilities on any proposed projects meeting the criteria in Stipulation 1(B) of the MOU that were determined to be CEs prior to the effective date of the proposed MOU but that have not been completed as of the effective date of the MOU.

The assignment under this part does not alter the scope and terms of the proposed Surface Transportation Project Delivery Program Assignment MOU under 23 U.S.C. 327 between GDOT and FHWA published in the **Federal Register** for public review and comment concurrently with this MOU. As applicable, GDOT will conduct all environmental reviews authorized under the terms of that MOU when fully executed.

A copy of the proposed MOU may be viewed on the docket at *www.regulations.gov,* as described above, or may be obtained by contacting FHWA or the State at the addresses provided above. A copy also may be viewed on GDOT's website at *www.dot.ga.gov/GDOT/Pages/NEPAAssignment.aspx.*

FHWA will consider the comments submitted on the proposed MOU when making its decision on whether to execute this MOU. FHWA will make the final, executed MOU publicly available.

(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. 326; 42 U.S.C. 4331, 4332; 23 CFR 771.117.

**Sean McMaster,**

*Administrator, Federal Highway Administration.*

[FR Doc. 2026–20209 Filed 10–1–26; 8:45 am]

**BILLING CODE 4910–22–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

**[Docket No. FHWA–2026–0959]**

### Application From the State of Georgia to the Surface Transportation Project Delivery Program and Proposed Memorandum of Understanding (MOU) Assigning Environmental Responsibilities to the State

**AGENCY:** Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

**ACTION:** Notice of proposed MOU and request for comments.

**SUMMARY:** This notice announces that FHWA received and reviewed an application from the Georgia Department of Transportation (GDOT) requesting participation in the Surface Transportation Project Delivery Program (Program). This Program allows for FHWA to assign, and States to assume, responsibilities under the National Environmental Policy Act of 1969 (NEPA), and all or part of FHWA's responsibilities for environmental review, consultation, or other actions required under any Federal environmental law with respect to one or more Federal highway projects within the State. FHWA has determined the application to be complete and developed a draft MOU with GDOT outlining how the State would implement the Program with FHWA oversight. FHWA invites the public to comment on GDOT's request, including its application and the proposed MOU, which includes the proposed assignments and assumptions of environmental review, consultation, and other activities.

**DATES:** Please submit comments by November 2, 2026.

**ADDRESSES:** To ensure you do not duplicate your docket submissions, please submit them by only one of the following means:

*Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for submitting comments.

*Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building Ground Floor Room W12–140, Washington, DC 20590.

*Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Ave. SE, Washington, DC 20590 between 9:00 a.m. and 5:00 p.m. (E.T.), Monday through Friday, except Federal holidays.

*Instructions:* You must include the Agency name and docket number at the beginning of your comments. All comments received will be posted without change to *www.regulations.gov,* including any personal information provided.

**FOR FURTHER INFORMATION CONTACT:**

*For FHWA:* Sabrina David by email at *Sabrina.David@dot.gov,* by telephone at 404–562–3630. FHWA Georgia Division Office's normal business hours are 7:30 a.m. to 4:00 p.m. (E. T.), Monday–Friday, except for Federal holidays.

*For GDOT:* Amber Phillips by email at *aphillips@dot.ga.gov* or by telephone at 404–631–1100. State business hours are 8:00 a.m. to 5:00 p.m. (E. T.), Monday–Friday, except Federal and State holidays, although State holidays may not completely coincide with Federal holidays.

**SUPPLEMENTARY INFORMATION:**

#### Electronic Access

You may submit or retrieve comments online through the Federal eRulemaking portal at: *www.regulations.gov.* The website is available 24 hours each day, 365 days each year. Please follow the instructions. Electronic submission and retrieval help and guidelines are available under the help section of the website.

An electronic copy of this document may also be downloaded from the Office of the Federal Register's home page at: *www.federalregister.gov* and the U.S. Government Publishing Office's web page at: *www.govinfo.gov.*

#### Background

On September 2, 2026, FHWA received an application and supplementary materials from GDOT requesting participation in the Program. Under the Program, pursuant to Section 327 of Title 23, United States Code (U.S.C.), the Secretary of the DOT is allowed to assign, and a State to assume, the responsibilities under the NEPA (42 U.S.C. 4321 *et seq.*) and all or part of the responsibilities for environmental review, consultation, or other actions required under certain Federal environmental laws with respect to one or more Federal-aid highway projects within the State. FHWA is authorized to act on behalf of the Secretary with respect to these matters and implements this authority through execution of a MOU with the State.

Under the proposed initial MOU with the State of Georgia, FHWA would assign to the State, through GDOT, its responsibility of making project-level decisions in relation to NEPA on highway projects within the State of Georgia that are proposed to be funded with Title 23 funds or otherwise require FHWA approval, and that require preparation of a categorical exclusion (CE) determination, environmental assessment, or environmental impact statement with the exception of the following: (1) Federal Lands Highway projects authorized under 23 U.S.C. 202, 203, or 204, unless such projects will be designed and constructed by GDOT; (2) projects that cross State boundaries; (3) projects that cross or are adjacent to international boundaries; (4) Recreational Trails projects under 23 U.S.C. 206; (5) Project DeRenne which includes the following Project Identifier (PI): (i) PI 0008358; West DeRenne/Hampstead Avenue Connector, (ii) PI 0008359; East DeRenne from Abercorn Street to Harry S. Truman Parkway, (iii) PI 0010236; State Route (SR) 21 From CS 346/Mildred Street to SR 204; (6) Projects advanced by direct recipients of Federal aid highway funds other than GDOT, including but not limited to: (i) Competitive grant programs, (ii) Direct recipient Tribal project, and (iii) Transportation Infrastructure Finance and Innovation Act Credit Program.

The assignment would give the State the responsibility to conduct environmental review, consultation, and other related activities for project delivery including, but not limited to the following laws and requirements:

*Air Quality*

- Clean Air Act (CAA), 42 U.S.C. 7401–7671q, with the exception of any project level conformity determinations (42 U.S.C. 7506)

*Noise*

- Noise Control Act of 1972, 42 U.S.C. 4901–4918
- FHWA noise regulations in 23 CFR Part 772

*Fisheries and Wildlife*

- Endangered Species Act of 1973, 16 U.S.C. 1531–1544
- Marine Mammal Protection Act, 16 U.S.C. 1361–1423h
- Anadromous Fish Conservation Act, 16 U.S.C. 757a–757f
- Fish and Wildlife Coordination Act, 16 U.S.C. 661–667d
- Migratory Bird Treaty Act, 16 U.S.C. 703–712

- Bald and Golden Eagle Protection Act, 16 U.S.C. 668–668d
- Magnuson-Stevens Fishery Conservation and Management Act of 1976, as amended, 16 U.S.C. 1801–1891d, with Essential Fish Habitat requirements at 16 U.S.C. 1855(b)(2)

*Historic and Cultural Resources*

- National Historic Preservation Act of 1966, as amended, 54 U.S.C. 300101 *et seq.*
- Section 4(f) of the Department of Transportation Act of 1966 [Section 4(f)], 23 U.S.C. 138, 49 U.S.C. 303 and implementing regulations at 23 CFR Part 774
- Archeological Resources Protection Act of 1979, 16 U.S.C. 470(aa)–470(mm)
- Native American Grave Protection and Repatriation Act, 25 U.S.C. 3001–3013; 18 U.S.C. 1170
- Archeological and Historic Preservation Act, 54 U.S.C. 312501–312508

*Social and Economic Impacts*

- American Indian Religious Freedom Act, 42 U.S.C. 1996
- Farmland Protection Policy Act, 7 U.S.C. 4201–4209

*Water Resources and Wetlands*

- Clean Water Act, 33 U.S.C. 1251–1387
- Coastal Barrier Resources Act, 16 U.S.C. 3501–3510
- Coastal Zone Management Act, 16 U.S.C. 1451–1466
- Safe Drinking Water Act, 42 U.S.C. 300f–300j–26
- General Bridge Act of 1946, 33 U.S.C. 525–533
- 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. 3901 and 3921
- Wetlands Mitigation, 23 U.S.C. 119(g), 133(b)(14)
- Flood Disaster Protection Act, 42 U.S.C. 4001–4130
- FHWA wetland and natural habitat mitigation regulations, 23 CFR Part 777

*Parklands and Other Special Uses*

- Section 4(f) of the Department of Transportation Act of 1966 [Section 4(f)], 23 U.S.C. 138, 49 U.S.C. 303 and implementing regulations at 23 CFR Part 774
- Land and Water Conservation Fund Act, 54 U.S.C. 200302–200310

*FHWA-Specific*

- Planning and Environmental Linkages, 23 U.S.C. 168, with the exception of those FHWA responsibilities associated with 23 U.S.C. 134 and 135
- Programmatic Mitigation Plans, 23 U.S.C. 169 with the exception of those FHWA responsibilities associated with 23 U.S.C. 134 and 135

The Secretary's responsibilities for government-to-government consultation with Indian Tribes, as defined in 36 CFR 800.16(m), are not assigned to or assumed by GDOT under the proposed MOU. FHWA will retain responsibility for conducting formal government-to-government consultation with federally recognized Indian Tribes. GDOT will conduct routine consultation with Indian Tribes and understands that an Indian Tribe has the right for government-to-government consultation with FHWA upon request.

Nothing in the proposed MOU shall be construed to permit GDOT's assumption of the Secretary's responsibilities for conformity determinations required by Section 176 of the CAA (42 U.S.C. 7506) or any responsibility under 23 U.S.C. 134 or 135, or under 49 U.S.C. 5303 or 5304.

The assignment under this part does not alter the scope and terms of the proposed CE Assignment MOU under 23 U.S.C. 326 between GDOT and FHWA published in the **Federal Register** for public review and comment concurrently with this MOU. As applicable, GDOT will conduct all environmental reviews authorized under the terms of that MOU when fully executed.

On the cover page of all environmental analyses prepared under the authority granted by this MOU, GDOT shall insert the following language in a way that is conspicuous to the reader, or include it in a CE project record: The environmental review, consultation, and other actions required by applicable Federal environmental laws for this project are being, or have been, carried out by GDOT pursuant to 23 U.S.C. 327 and a MOU dated [MMDDYYY] and executed by FHWA and GDOT.

GDOT will also disclose to the public, agencies and Tribes as part of agency outreach and public involvement procedures, the above disclosure.

GDOT will not make any determination that an action constitutes a constructive use of a Section 4(f) property under 49 U.S.C. 303 and 23 U.S.C. 138 without first consulting with FHWA and obtaining FHWA's approval of such determination.

A copy of the proposed MOU may be viewed on the docket at *www.regulations.gov,* as described above, or may be obtained by contacting FHWA or the State at the addresses provided above. A copy also may be viewed on GDOT's website at *www.dot.ga.gov/GDOT/Pages/NEPAAssignment.aspx.*

FHWA Georgia Division, in consultation with FHWA Headquarters, will consider the comments submitted when making its decision on the proposed MOU. FHWA and GDOT may revise the MOU based on substantive comments and will make the final MOU available to the public.

(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. 327; 42 U.S.C. 4331, 4332; 23 CFR 771.117.

**Sean McMaster,**

*Administrator, Federal Highway Administration.*

[FR Doc. 2026–20210 Filed 10–1–26; 8:45 am]

**BILLING CODE 4910–22–P**

## DEPARTMENT OF THE TREASURY

### Office of Foreign Assets Control

### Notice of OFAC Sanctions Action

**AGENCY:** Office of Foreign Assets Control, Treasury.

**ACTION:** Notice.

**SUMMARY:** The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

**DATES:** This action was issued on September 29, 2026. See **SUPPLEMENTARY INFORMATION** for relevant dates.

**FOR FURTHER INFORMATION CONTACT:** *OFAC:* Associate Director for Global Targeting, 202–622–2420; Assistant Director for Licensing, 202–622–2480; Assistant Director for Sanctions Compliance, 202–622–2490 or *https://ofac.treasury.gov/contact-ofac.*

**SUPPLEMENTARY INFORMATION:**

#### Electronic Availability

The SDN List and additional information concerning OFAC sanctions

programs are available on OFAC's website: *https://ofac.treasury.gov.*

**Notice of OFAC Actions**

On September 29, 2026, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

**BILLING CODE 4810–AL–P**

**Individuals**

1. AHMADY, Ali Fotowat (a.k.a. AHMADI, Ali Fotovat; a.k.a. AHMADI, Ali Fotowat), Tehran, Iran; DOB 22 Sep 1958; POB Shemiran, Iran; nationality Iran; alt. nationality United States; citizen United States; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport 642906027 (United States) expires 17 Dec 2028; alt. Passport F42549387 (Iran) expires 12 Aug 2022; National ID No. 0451991923 (Iran) (individual) [NPWMD] [IFSR] (Linked To: KAVOSHCOM ASIA R AND D GROUP).

   Designated pursuant to section 1(a)(iv) of Executive Order (E.O.) 13382 of June 28, 2005, "Blocking Property of Weapons of Mass Destruction Proliferators and Their Supporters," 70 FR 38567, 3 CFR, 2005 Comp., p. 170 (E.O. 13382), for acting or purporting to act for or on behalf of, directly or indirectly, KAVOSHCOM ASIA R AND D GROUP, a person whose property and interests in property are blocked pursuant to E.O. 13382.

2. LALI, Parisa (a.k.a. LAALI, Parisa; a.k.a. LA'LI, Parisa), Tehran, Iran; DOB 31 Aug 1991; POB Tehran, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Female; Passport U48889102 (Iran) expires 28 May 2024; National ID No. 0013751425 (Iran) (individual) [NPWMD] [IFSR] (Linked To: KAVOSHCOM ASIA R AND D GROUP).

   Designated pursuant to section 1(a)(iii) of E.O. 13382 for having provided, or attempted to provide, financial, material, technological or other support for, or goods or services in support of, KAVOSHCOM ASIA R AND D GROUP, a person whose property and interests in property are blocked pursuant to E.O. 13382.

3. LI, Fen (Chinese Simplified: 李芬) (a.k.a. "LEE, Kirah"), Foshan, Guangdong, China; DOB 23 Apr 1987; POB Xian, China; nationality China; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Female; National ID No. 362523198704231627 (China) (individual) [NPWMD] [IFSR] (Linked To: KAVOSHCOM ASIA R AND D GROUP).

   Designated pursuant to section 1(a)(iii) of E.O. 13382 for having provided, or attempted to provide, financial, material, technological or other support for, or goods or services in support of, KAVOSHCOM ASIA R AND D GROUP, a person whose property and interests in property are blocked pursuant to E.O. 13382.

4. TABATABAI, Seyyed Asghar Alizadeh (a.k.a. TABATABAEI, Seyed Asghar Alizadeh), Beijing, China; DOB 21 Sep 1978; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport B65348644 (Iran) expires 01 Oct 2028; National ID No. 1239538677 (Iran) (individual) [NPWMD] [IFSR] (Linked To: MINISTRY OF DEFENSE AND ARMED FORCES LOGISTICS).

Designated pursuant to section 1(a)(iv) of E.O. 13382 for acting or purporting to act for or on behalf of, directly or indirectly, MINISTRY OF DEFENSE AND ARMED FORCES LOGISTICS, a person whose property and interests in property are blocked pursuant to E.O. 13382.

5. TAJAMMAL, Waseem Pasha, Rawalpindi, Punjab, Pakistan; DOB 22 Dec 1967; POB Chakwal, Pakistan; nationality Pakistan; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport AA7550196 (Pakistan) expires 23 May 2027; National ID No. 3740563500191 (Pakistan) (individual) [NPWMD] [IFSR] (Linked To: MINISTRY OF DEFENSE AND ARMED FORCES LOGISTICS).

   Designated pursuant to section 1(a)(iii) of E.O. 13382 for having provided, or attempted to provide, financial, material, technological or other support for, or goods or services in support of, MINISTRY OF DEFENSE AND ARMED FORCES LOGISTICS, a person whose property and interests in property are blocked pursuant to E.O. 13382.</PHOTO>

**Entities**

1. CAVALIER DYNAMICS FOR TECHNOLOGIES COMPANY (Arabic: شركة كافالييز ديناميكس للتقنيات) (a.k.a. CAVALIER DYNAMICS TECHNOLOGIES COMPANY), Riyadh, Riyadh, Saudi Arabia; Additional Sanctions Information - Subject to Secondary Sanctions; Organization Established Date 03 Mar 2025; Company Number 7049238244 (Saudi Arabia); Registration Number 1009205388 (Saudi Arabia) [NPWMD] [IFSR] (Linked To: TAJAMMAL, Waseem Pasha).

   Designated pursuant to section 1(a)(iv) of E.O. 13382 for being owned or controlled by, or acting or purporting to act for or on behalf of, directly or indirectly, TAJAMMAL, Waseem Pasha, a person whose property and interests in property are blocked pursuant to E.O. 13382.

2. CAVALIER DYNAMICS PRIVATE LIMITED, Plot 101-103, Humak Industrial Area, Sihala Road, Islamabad, Pakistan; Additional Sanctions Information - Subject to Secondary Sanctions; Organization Established Date 24 Nov 2021; Registration Number 0188815 (Pakistan) [NPWMD] [IFSR] (Linked To: TAJAMMAL, Waseem Pasha).

   Designated pursuant to section 1(a)(iv) of E.O. 13382 for being owned or controlled by, or acting or purporting to act for or on behalf of, directly or indirectly, TAJAMMAL, Waseem Pasha, a person whose property and interests in property are blocked pursuant to E.O. 13382.

3. CAVALIER DYNAMICS TEKNOLOJI TICARET ANONIM SIRKETI (Latin: CAVALIER DYNAMICS TEKNOLOJI TICARET ANONIM ŞIRKETI), Block No: 2, Aos 55th Street, 42 Maslak Neighborhood A Door No: 25, Maslak, Sariyer, Istanbul, Marmara, Turkey; Additional Sanctions Information - Subject to Secondary Sanctions; Organization Established Date 18 Jun 2025; Company Number 0203089983700001 (Turkey); Chamber of Commerce Number 1587488

(Turkey); Registration Number 1086476 (Turkey) [NPWMD] [IFSR] (Linked To: TAJAMMAL, Waseem Pasha).

Designated pursuant to section 1(a)(iv) of E.O. 13382 for being owned or controlled by, or acting or purporting to act for or on behalf of, directly or indirectly, TAJAMMAL, Waseem Pasha, a person whose property and interests in property are blocked pursuant to E.O. 13382.

4. EC MOJO TECHNOLOGY CO LIMITED (Chinese Traditional: 昴雋電訊有限公司) (a.k.a. CHENGZI TRADING CO LTD; a.k.a. SUNRISE ELECTRONICS CO LTD), Rm 811, Beverley Commercial Centre, 87-105 Chatham Rd S, Tsim Sha Tsui, Hong Kong, China; Additional Sanctions Information - Subject to Secondary Sanctions; Organization Established Date 11 Jun 2019; Company Number 2839430 (Hong Kong); Business Registration Number 70820781 (Hong Kong) [NPWMD] [IFSR] (Linked To: KAVOSHCOM ASIA R AND D GROUP).

Designated pursuant to section 1(a)(iii) of E.O. 13382 for having provided, or attempted to provide, financial, material, technological or other support for, or goods or services in support of, KAVOSHCOM ASIA R AND D GROUP, a person whose property and interests in property are blocked pursuant to E.O. 13382.

5. KAVOSHCOM ASIA R AND D GROUP (Arabic: گروه تحقیقات خدمات مخابراتی کاوشکام آسیا) (a.k.a. KAVOSHCOM R AND D GROUP), No. 22, 4th Alley, Qanbarzadeh Street, Shahid Beheshti Street, Tehran, Iran; No. 281, Mottahari Ave, Tehran 1586717911, Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Organization Established Date 25 May 2005; National ID No. 10102875382 (Iran); Chamber of Commerce Number 117710 (Iran); Registration Number 246906 (Iran) [NPWMD] [IFSR] (Linked To: MINISTRY OF DEFENSE AND ARMED FORCES LOGISTICS).

Designated pursuant to section 1(a)(iii) of E.O. 13382 for having provided, or attempted to provide, financial, material, technological or other support for, or goods or services in support of, MINISTRY OF DEFENSE AND ARMED FORCES LOGISTICS, a person whose property and interests in property are blocked pursuant to E.O. 13382.

(Authority: E.O. 13382.)

**Bradley T. Smith,**

*Director, Office of Foreign Assets Control.*

[FR Doc. 2026–20215 Filed 10–1–26; 8:45 am]

**BILLING CODE 4810–AL–C**

**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

## Agency Information Collection Activities; Comment Request on Application to Participate in the IRS Acceptance Agent Program

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of information collection; request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, the IRS is inviting comments on the information collection request outlined in this notice.

**DATES:** Written comments should be received on or before December 1, 2026 to be assured of consideration.

**ADDRESSES:** Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.*

Include ''OMB Control No. 1545–1896'' in the subject line of the message.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of this collection should be directed to Kerry Dennis, (202) 317–5751.

**SUPPLEMENTARY INFORMATION:** The IRS, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the IRS assess the impact and minimize the burden of its information collection requirements. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record, and viewable on relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information. 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.

*Title:* Application to Participate in the IRS Acceptance Agent Program.

*OMB Control Number:* 1545–1896.

*Form Number:* 13551.

*Abstract:* This form is ONLY for Foreign participants who don't have a TIN but want to apply to participate in the IRS Acceptance Agent Program. They will need to apply, renew, and update their application using the AA Document Upload Tool (DUT). Domestic participants should NOT use this form. They should go to *IRS.gov* and fill out an application using e-services.

*Current Actions:* There is no change to the previously approved information collection.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Individuals and households, Businesses or other for-profit organizations, not-for-profit institutions, and Federal, state, local or tribal government.

*Estimated Number of Respondents:* 4,422.

*Estimated Time per Response:* 30 minutes.

*Estimated Total Annual Burden Hours:* 2,211.

Dated: September 29, 2026.

**Kerry Dennis,**

*Tax Analyst.*

[FR Doc. 2026–20189 Filed 10–1–26; 8:45 am]

**BILLING CODE 4831–GV–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Agency Information Collection Activities; Comment Request on Discharge From or Subordination of Federal Lax Lien

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of information collection; request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, the IRS is inviting comments on the information collection request outlined in this notice.

**DATES:** Written comments should be received on or before December 1, 2026 to be assured of consideration.

**ADDRESSES:** Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Include ''OMB Control No. 1545–2174'' in the subject line of the message.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of this collection should be directed to Kerry Dennis, (202) 317–5751.

**SUPPLEMENTARY INFORMATION:** The IRS, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the IRS assess the impact and minimize the burden of its information collection requirements. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record, and viewable on relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information. 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.

*Title:* Discharge from or Subordination of Federal Lax Lien.

*OMB Control Number:* 1545–2174.

*Form Numbers:* 14134 and 14135.

*Abstract:* Form 14134 is used to apply for a Certificate of Subordination under Internal Revenue Code (IRC) sections 6325(d)(1) and 6325(d)(2) to allow a named creditor to move their junior creditor position ahead of the United States' position for the property named in the certificate. Form 14135 is used to apply for a Certificate of Discharge under IRC section 6325(b) to remove the United States' lien from the property named in the certificate.

*Current Actions:* There is no change to the previously approved information collection.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Individuals and households, Businesses or other for-profit organizations, not-for-profit institutions, Farms, and Federal, state, local or tribal government.

*Estimated Number of Respondents:* 10,362.

*Estimated Time per Response:* 2 hours, 11 minutes.

*Estimated Total Annual Burden Hours:* 22,665.

Dated: September 29, 2026.

**Kerry Dennis,**

*Tax Analyst.*

[FR Doc. 2026–20190 Filed 10–1–26; 8:45 am]

**BILLING CODE 4831–GV–P**

## DEPARTMENT OF THE TREASURY

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Bureau of the Fiscal Service 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 November 2, 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:**

**Bureau of the Fiscal Service (BFS)**

*1. Title: Certificate of Identity*

*OMB Control Number:* 1530–0026.
*Type of Request:* Extension of a currently approved collection.
*Description:* The information on the completed form is used to establish an individual's identity in a claim for payment of United States savings and retirement securities.
*Forms:* FS Form 0385.
*Affected Public:* Individuals or Households.
*Estimated Number of Respondents:* 330.
*Frequency of Response:* On occasion.
*Estimated Time per Response:* 10 minutes.
*Estimated Total Annual Burden Hours:* 55 hours.

*2. Title: Special Form of Request for Payment of US Savings and Retirement Securities Where Use of a Detached Request Is Authorized*

*OMB Control Number:* 1530–0028.
*Type of Request:* Extension of a currently approved collection.
*Description:* The information on the completed form is submitted by the owner, co-owner, surviving beneficiary, or legal representative of the estate of a deceased or incompetent owner, persons entitled to the estate of a deceased registrant, or such other persons to request payment of United States Savings Bonds, Savings Notes, Retirement Plan Bonds, and Individual Retirement Bonds.
*Forms:* FS Form 1522.
*Affected Public:* Individuals or Households.
*Estimated Number of Respondents:* 14,000.
*Frequency of Response:* On occasion.
*Estimated Time per Response:* 15 minutes.
*Estimated Total Annual Burden Hours:* 3,500 hours.

*3. Title: Treasury Direct System*

*OMB Control Number:* 1530–0071.
*Type of Request:* Extension of a currently approved collection.
*Description:* The information collected in the electronic system is requested to establish a new account and process any associated transactions.
*Forms:* FS Form 5444, FS Form 5446, FS Form 5511, FS Form 5512.
*Affected Public:* Individuals or Households.
*Estimated Number of Respondents:* 3,875,552.
*Frequency of Response:* On occasion.
*Estimated Time per Response:* 30 minutes.
*Estimated Total Annual Burden Hours:* 193,230 hours.
*Authority:* 44 U.S.C. 3501 et seq.

**Juliana L. Pearson,**
*Treasury PRA Clearance Officer.*

[FR Doc. 2026–20232 Filed 10–1–26; 8:45 am]
**BILLING CODE 4810–AS–P**

## UNIFIED CARRIER REGISTRATION PLAN

### Sunshine Act Meetings

**TIME AND DATE:** October 7, 2026, 10:30 a.m.–2:30 p.m., Eastern time.

**PLACE:** This meeting will be held at the Residence Inn Downtown Hotel, 100 Sabin Street, Providence, RI 02903.

**STATUS:** This meeting will be open to the public.

**MATTERS TO BE CONSIDERED:** The Unified Carrier Registration Plan Governance Task Force (the ''Task Force'') will conduct a meeting to continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

**Proposed Agenda**

**I. Call to Order—UCR Plan Governance Task Force Chair**

The UCR Governance Task Force Chair will welcome attendees, call the meeting to order, call roll for the task force, confirm whether a quorum is present, and facilitate self-introductions.

**II. Verification of Publication of Meeting Notice—UCR Executive Director**

The UCR Executive Director will verify the publication of the meeting notice on the UCR website and distribution to the UCR contact list via email followed by the subsequent publication of the notice in the **Federal Register**.

**III. Review and Approval of Task Force Agenda and Setting of Ground Rules—UCR Plan Governance Task Force Chair**

*For Discussion and Possible Task Force Action*

The Governance Task Force Agenda will be reviewed, and the Task Force will consider adoption.

Ground Rules

➢ Task Force action only to be taken in designated areas on agenda

**IV. Approval of Minutes of the August 5, 2026, Task Force Meeting—UCR Governance Task Force Chair**

*For Discussion and Possible Task Force Action*

Draft Minutes from the August 5, 2026 UCR Task Force meeting will be reviewed. The Task Force will consider action to approve.

**V. Conflict of Interest Acknowledgement Form Discussion—UCR Governance Task Force Chair**

*For Discussion and Possible Task Force Action*

The UCR Governance Task Force Chair will lead a discussion on a proposed UCR Plan Board member Conflict of Interest Acknowledgement Form. The Task Force may take action to recommend to the UCR Plan Board a specific Conflict of Interest form and that the Board require each individual Board member to read, complete, and sign such form.

**VI. UCR Plan Subcommittee Charters—UCR Governance Task Force Chair**

*For Discussion and Possible Task Force Action*

The UCR Governance Task Force Chair will lead a discussion on proposed charters for all UCR Plan Subcommittees. The Task Force may take action to recommend to the UCR Plan Board proposed charter language for all UCR Plan Subcommittees.

**VII. Long-Term Strategic Planning for UCR Plan Partners—UCR Governance Task Force Chair**

*For Discussion and Possible Task Force Action*

The UCR Governance Task Force Chair will lead a discussion regarding the long-term evolution of the UCR Plan's key vendor partnerships, including the Executive Director role, Seikosoft and the next iteration of the National Registration System, DSL's service model, Kellen, and other strategic partners. The Task Force may identify opportunities for further evaluation and recommend future planning activities to support continuity, innovation, and the UCR Plan's evolving needs.

**VIII. Other Business—UCR Plan Governance Task Force Chair**

The UCR Plan Governance Task Force Chair will call for any other business, old or new, from the floor, including items from the previous Task Force meeting.

**IX. Adjournment—UCR Plan Governance Task Force Chair**

The UCR Plan Governance Task Force Chair will adjourn the meeting.

The agenda will be available no later than 5:00 p.m. Eastern time, September 29, 2026 at: *https://plan.ucr.gov*.

**CONTACT PERSON FOR MORE INFORMATION:** Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305–3783, *eleaman@board.ucr.gov*.

**Alex B. Leath,**

*Chief Legal Officer, Unified Carrier Registration Plan.*

[FR Doc. 2026–20285 Filed 9–30–26; 4:15 pm]

**BILLING CODE 4910–YL–P**

## DEPARTMENT OF VETERANS AFFAIRS

**[OMB Control No. 2900–0655]**

## Agency Information Collection Activity: Residency Verification Report—Veterans and Survivors

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice.

**DATES:** Comments must be received on or before December 1, 2026.

**ADDRESSES:** Comments must be submitted through *www.regulations.gov*.

**FOR FURTHER INFORMATION CONTACT:**

*Program-Specific information:* Kendra Mccleave, 202–461–9568, *kendra.mccleave@va.gov*.

*VA PRA information:* Dorothy Glasgow, 202–461–1084, *VAPRA@va.gov*.

**SUPPLEMENTARY INFORMATION:** Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

*Title:* Residency Verification Report—Veterans and Survivors (VA Form Letter 21–914).

*OMB Control Number:* 2900–0655. *https://www.reginfo.gov/public/do/PRASearch* (Once at this link, you can enter the OMB Control Number to find the historical versions of this Information Collection).

*Type of Review:* Revision of a currently approved collection.

*Abstract:* VA Form Letter 21–914 is used to gather the necessary information which is necessary to verify whether a veteran or beneficiary who is receiving benefits at the full-dollar rate based on U.S. residency continues to meet the residency requirements. Continued eligibility to benefits at the full-dollar rate cannot be determined without complete information about a veteran's or beneficiary's residency. This is a revision due to the burden increase since the previous approval resulting from the estimated number of receivables averaged over the past year for both Veterans and beneficiaries.

*Affected Public:* Individuals or Households.

*Estimated Annual Burden:* 1,216 hours.

*Estimated Average Burden per Respondent:* 5 minutes.

*Frequency of Response:* One time.

*Estimated Number of Respondents:* 14,593 per year.

*Authority:* 44 U.S.C. 3501 *et seq.*

**Shunda Willis,**

*Alternate, VA PRA Clearance Officer, Office of Information and Technology/Office of Data Governance and Analytics, Department of Veterans Affairs.*

[FR Doc. 2026–20218 Filed 10–1–26; 8:45 am]

**BILLING CODE 8320–01–P**




# FEDERAL REGISTER

Vol. 91 Friday,
No. 190 October 2, 2026

Part II

## Department of the Treasury

Internal Revenue Service

26 CFR Part 1
Federal Scholarship Tax Credit; Proposed Rule

**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 1**

**[REG–117199–25]**

**RIN 1545–BR97**

## Federal Scholarship Tax Credit

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking and public hearing.

**SUMMARY:** This document contains proposed regulations regarding the nonrefundable Federal tax credit for qualified contributions to scholarship granting organizations to fund qualified elementary and secondary school education scholarships. The proposed regulations would affect taxpayers who make such qualified contributions, States that elect to participate by certifying organizations as scholarship granting organizations, and the organizations that have been certified as scholarship granting organizations by one or more electing States. This document also provides notice of a public hearing on the proposed regulations.

**DATES:** Written or electronic comments must be received by December 1, 2026. The public hearing is being held on Tuesday, December 15, 2026, at 10 a.m. Eastern Time (ET). Requests to speak and outlines of topics to be discussed at the public hearing must be received by December 1, 2026. If no outlines are received by December 1, 2026, the public hearing will be cancelled. Requests to attend the public hearing must be received by 5 p.m. ET on Thursday, December 10, 2026.

**ADDRESSES:** Commenters are strongly encouraged to submit public comments electronically via the Federal eRulemaking Portal at *https://www.regulations.gov* (indicate IRS and REG–117199–25) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of the Treasury (Treasury Department) and the IRS will publish for public availability any comments submitted to the IRS's public docket. Send paper submissions to: CC:PA:01:PR (REG–117199–25), Room 5503, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

**FOR FURTHER INFORMATION CONTACT:** Concerning the proposed regulations, Constance Chien, (202) 317–7002, or Andrew Fahmy, (202) 317–3840; concerning the submission of comments, the public hearing, and to be placed on the building access list to attend the public hearing, Publications and Regulations Section, (202) 317–6901 (not toll-free numbers) or by email at *publichearings@irs.gov* (preferred).

**SUPPLEMENTARY INFORMATION:**

### Authority

This document contains proposed additions to 26 CFR part 1 (Income Tax Regulations) addressing the application of the credit available for qualified contributions under section 25F of the Internal Revenue Code (Code),[1] as added by section 70411 of Public Law 119–21, 139 Stat. 72 (July 4, 2025), commonly known as the One, Big, Beautiful Bill Act (OBBBA).

The proposed regulations are issued under section 25F(h), which expressly delegates authority to the Secretary of the Treasury or the Secretary's delegate (Secretary) to issue such regulations or other guidance as the Secretary determines necessary to carry out the purposes of section 25F, including regulations or other guidance (1) providing for enforcement of the requirements under section 25F(d) and (g), and (2) with respect to recordkeeping or information reporting for purposes of administering the requirements of section 25F. The proposed regulations also are issued under the express delegation of authority in section 7805(a) of the Code, which authorizes the Secretary to prescribe all needful rules and regulations for the enforcement of the Code, including all rules and regulations as may be necessary by reason of any alteration of law in relation to internal revenue.

### Background

### I. Overview

As added by section 70411(a) of the OBBBA, the nonrefundable income tax credit under section 25F (section 25F credit) is allowed to an individual who is a citizen or resident of the United States (within the meaning of section 7701(a)(9)) who makes qualified contributions to scholarship granting organizations. For purposes of the section 25F credit, section 25F(c)(5) defines a ''scholarship granting organization'' (SGO) as any organization that (1) is a public charity, (2) prevents the co-mingling of qualified contributions with other amounts by maintaining separate accounts, (3) satisfies each of the requirements of section 25F(d), and (4) is included on the list submitted for the applicable covered State under section 25F(g) for the applicable year. Section 25F(c)(3) defines a ''qualified contribution'' as a charitable contribution of cash to an SGO that uses the contribution to fund scholarships for eligible students (as defined in section 25F(c)(2)) solely within the covered State in which the SGO is listed pursuant to section 25F(g). Section 25F(c)(1) defines a ''covered State'' as ''one of the States, or the District of Columbia,'' that, for a calendar year, voluntarily elects to participate under section 25F and to identify the SGOs located in the State, in accordance with section 25F(g). In order for a contribution made by a taxpayer to an organization in a covered State to be a qualified contribution eligible for a section 25F credit, among other requirements, section 25F requires the State to have identified the organization as an SGO that satisfies the requirements of section 25F(c)(5) for the applicable calendar year. Pursuant to section 70411(c)(1) of the OBBBA, the provisions of section 25F apply to taxable years ending after December 31, 2026.

Additionally, for taxable years ending after December 31, 2026, section 139K, as added by section 70411(b) of the OBBBA, excludes from the gross income of individuals or their dependents any amounts received after December 31, 2026, pursuant to SGO-provided scholarships for qualified elementary or secondary education expenses of eligible students. *See* section 70411(c)(2) of the OBBBA.

### II. Amount of Section 25F Credit

Section 25F(a) provides that an individual's credit against the tax imposed by chapter 1 for the taxable year is an amount equal to the aggregate amount of qualified contributions made by the taxpayer during the taxable year. Section 25F(b) provides that the amount of the section 25F credit allowed to a taxpayer for a taxable year is subject to a reduction and limitation. Section 25F(b)(2) provides that the amount allowed as a section 25F credit for a taxable year is reduced by the amount allowed as a credit on any State tax return of the taxpayer for qualified contributions made by the taxpayer during the taxable year. Section 25F(b)(1) provides that the amount of the section 25F credit allowed to any taxpayer for any taxable year may not exceed $1,700. In addition, section 25F(e) prohibits a double benefit to a taxpayer by providing that any qualified

[1] Unless otherwise indicated, all section references are to the Internal Revenue Code or the Treasury Regulations issued thereunder.

contribution for which a section 25F credit is allowed cannot be taken into account as a charitable contribution for purposes of section 170.

Section 25F(f) provides for the carryforward of unused section 25F credit amounts. Section 25F(f)(1) provides that, if the section 25F credit allowable for any taxable year exceeds the limitation imposed by section 26(a) for such taxable year reduced by the sum of the credits allowable under sections 21, 22, 24, 25, 25A, 25B, 25C, and 25E, such excess is carried to the succeeding taxable year and added to the credit allowable under section 25F(a) for such taxable year. However, section 25F(f)(2) provides that no credit may be carried forward under section 25F(f) to any taxable year following the fifth taxable year after the taxable year in which the credit arose. For this purpose, section 25F(f) provides that section 25F credits are treated as used on a first-in, first-out basis.

## III. Requirements for Scholarship Granting Organizations

An organization can qualify as an SGO only if it satisfies each requirement in section 25F(c)(5). Under section 25F(c)(5), the organization must:

(1) Be described in section 501(c)(3), be exempt from tax under section 501(a), and not be a private foundation;

(2) Prevent the co-mingling of qualified contributions with other amounts by maintaining one or more separate accounts exclusively for qualified contributions;

(3) Satisfy each of the requirements of section 25F(d); and

(4) Be included on the list submitted under section 25F(g) for the applicable year by the covered State in which the organization is located.

The requirements in section 25F(d) referred to in section 25F(c)(5)(C) that an SGO also must satisfy are as follows:

(1) Provide scholarships to 10 or more students who do not all attend the same school;

(2) Spend not less than 90 percent of its income on scholarships for eligible students (90 percent of income spending requirement);

(3) Provide scholarships only for qualified elementary or secondary education expenses described in section 530(b)(3)(A) (relating to Coverdell education savings accounts) of an eligible student;

(4) Provide scholarships to eligible students with a priority for:

(a) Students awarded a scholarship the previous school year, and thereafter;

(b) Any eligible students who have a sibling who was awarded a scholarship from such organization;

(5) Not earmark or set aside contributions for scholarships on behalf of any particular student;

(6) Verify the annual household income and family size of eligible students who apply for scholarships to ensure such students meet the area median gross income requirement of section 25F(c)(2)(A) (defining area median gross income ''as such term is used in section 42''), and limit the awarding of scholarships to eligible students who are members of a household for which the income does not exceed the amount established under section 25F(c)(2)(A); and

(7) Not award a scholarship to any disqualified person, as determined pursuant to rules similar to the rules of section 4946 (relating to private foundations).

## IV. State List of Scholarship Granting Organizations

Section 25F(g)(1)(A) provides that, not later than January 1 of each calendar year (or, with respect to the 2027 calendar year, as early as practicable), a State that voluntarily elects to participate under section 25F must provide to the Secretary a list of the SGOs that meet the requirements described in section 25F(c)(5) and are located in the State. A State's participation under section 25F allows SGOs located in the State and therefore included on the State SGO list to receive qualified contributions for which individuals may be eligible to claim a section 25F credit.

Section 25F(g)(1)(B) provides that the election under section 25F(g) must be made by the Governor of the State or by such other individual, agency, or entity as is designated under State law to make such elections on behalf of the State with respect to Federal tax benefits.

Section 25F(g)(2) provides that the State SGO list submitted under section 25F(g)(1)(A) must include a certification that the individual, agency, or entity submitting such list on behalf of the State has the authority to perform this function.

## V. Prior Guidance Relating to the Section 25F Credit

The Treasury Department and the IRS have issued preliminary guidance with respect to the section 25F credit. On November 25, 2025, the Treasury Department and the IRS issued Notice 2025–70, 2025–50 I.R.B. 773, to request comments regarding issues arising under section 25F that should be addressed in guidance, including issues on which guidance is most quickly needed, such as issues relating to the annual certification by a State as well as SGO requirements.

On December 12, 2025, the Treasury Department and the IRS issued Rev. Proc. 2026–6, 2026–2 I.R.B. 314, to provide the exclusive procedure for a State to make an election during 2026 to be a ''covered State'' prior to identifying SGOs in the State in accordance with section 25F(g).

## VI. Public Feedback Received

The Treasury Department and the IRS have received feedback from taxpayers, tax professionals, and other stakeholders regarding section 25F, including feedback received in response to Notice 2025–70. These proposed regulations are informed by these responses. The major areas with respect to which public stakeholders provided feedback are discussed in the following Explanation of Provisions.

## Explanation of Provisions

### I. Definitions

Proposed § 1.25F–1(a) would provide definitions of terms generally applicable for purposes of applying section 25F and §§ 1.25F–0 through 1.25F–5 (section 25F regulations), including certain defined terms for which additional context is provided in this part of the Explanation of Provisions.

As noted in part IV of the Background section of this preamble, section 25F(g)(1)(A) states that an electing State must provide a list of the SGOs that meet the requirements described in section 25F(c)(5) and are located in the State. Many stakeholders suggested that ''located in the State'' should mean registered to do business in the State and in compliance with otherwise applicable State laws for nonprofit organizations. Some of these stakeholders stated that requiring physical headquarters or in-State staff would be unnecessary, inconsistent with existing State tax credit programs, and would significantly hinder effective multistate SGOs that are well-positioned to deliver scholarships at scale.

Other stakeholders stated that an SGO should be required to have a physical presence in the State if required by State law, arguing that ''located in the State'' straightforwardly means headquartered in the State, rather than simply being authorized or registered to solicit donations there. These stakeholders stated that the phrase ''located in the State'' appears in more than 90 sections of the U.S. Code and that none could be read to mean ''authorized to operate.'' Many of these stakeholders expressed the concern that allowing large multistate SGOs to be located in a State

where they did not have a physical presence might limit a State's ability to implement its educational policies.

Proposed § 1.25F–1(a)(10) would, for purposes of section 25F, define an organization as ''located in a State'' if the organization is authorized to do business in the State and is in compliance with the generally applicable State laws and requirements for charitable organizations in the State, including provisions for transparency, accountability, and fraud prevention.[2] The Treasury Department and the IRS have determined that this definition is consistent with the legislative purpose of section 25F to increase access to scholarship funds.

Proposed § 1.25F–1(a)(12) would provide that a ''qualified contribution'' is a charitable cash contribution made by an individual to an SGO to the extent it is designated as such by the donor at the time of contribution. If the SGO provides any goods or services as consideration for any part of the contribution, then the value of those goods and services must be subtracted from the amount of the charitable contribution to arrive at the amount of the qualified contribution.

For this purpose, the term ''cash'' would mean physical currency, check, money order, electronic transfer (including, for example, by credit or debit card), after-tax payroll deduction, or other similar method, in each case all in U.S. dollars, but would not include any digital assets.

Under this proposed rule, the donor would be required to designate to the recipient SGO, at the time of making the contribution, that the contribution is intended to be a qualified contribution, which would require the SGO to deposit the contribution into the SGO's section 25F segregated account as part of the SGO's compliance with sections 25F(c)(3) and 25F(c)(5)(B) and proposed § 1.25F–3(b)(2) or (c)(3) (as applicable, for single-State SGOs and multistate SGOs, respectively). If the SGO is a multistate SGO, the donor would be able to direct the recipient SGO to allocate the qualified contribution to the multistate SGO's section 25F segregated account for any of the covered States on whose State SGO list the SGO appears. Once a qualified contribution has been deposited into an SGO's section 25F segregated account, the SGO must use the funds in accordance with the operational requirements in section 25F(d) and proposed § 1.25F–3(c) to maintain its status as an SGO.

In response to Notice 2025–70, stakeholders asked that SGOs be allowed to verify that scholarships are spent on qualified elementary or secondary education expenses by using a third-party vendor that verifies the expenses and prevents duplication, which stakeholders referred to as a digital wallet. These proposed regulations would allow the use of a qualified digital wallet to establish that the SGO verified that scholarships are spent on qualified elementary or secondary education expenses. Proposed § 1.25F–1(a)(13) would define a ''qualified digital wallet'' as an electronic payment platform in which a third-party provider provides a streamlined interface for managing the administration of section 25F scholarships by having eligible students and their families submit purchase requests, by tracking approved expenses, and by maintaining controls to ensure that all payments are made for qualified elementary or secondary education expenses by pre-approving vendors and paying vendors directly or requiring timely submission of receipts. The Treasury Department and the IRS request comments on this definition of qualified digital wallet and whether additional safe harbors for verification that scholarships are spent on qualified elementary or secondary education expenses should be included in the final regulations.

Section 25F(c)(4) provides that a ''qualified elementary or secondary education expense'' is any expense of an eligible student that is described in section 530(b)(3)(A), which describes such qualified expenses as being related to elementary or secondary school enrollment or attendance. Section 530(b)(3)(B) provides that the term ''school'' means any school that provides elementary education or secondary education (kindergarten through grade 12), as determined under State law. In addition, section 25F(c)(2) states that an ''eligible student'' must, among other things, be eligible to enroll in a public elementary or secondary school, and section 25F(d) requires an SGO to provide scholarships to 10 or more students who do not all attend the same school.

Section 25F(c)(5) provides that a scholarship granting organization is any organization described in section 501(c)(3), exempt from tax under section 501(a), and not a private foundation, which prevents the co-mingling of qualified contributions with other amounts by maintaining one or more separate accounts exclusively for qualified contributions; satisfies each of the requirements of section 25F(d); and is included on the list submitted under section 25F(g) for a particular calendar year by the covered State in which the organization is located.

Proposed § 1.25F–1(a)(16) would provide that a ''scholarship granting organization'' or ''SGO'' is an organization as defined in section 25F(c)(5) and proposed § 1.25F–3(b). Accordingly, donations made to an organization that generates State tax credits may or may not give rise to a section 25F credit, depending on whether the organization separately satisfies the Federal tax law requirements to be an SGO for purposes of the section 25F credit. For example, a contribution to an organization that qualifies for State tax credits but is not included on the State SGO list, as would be defined in proposed § 1.25F–1(a)(24), of one or more covered States in which the SGO is located, does not give rise to the section 25F credit.

Notice 2025–70 recognized that organizations may fundraise and award scholarships in more than one State and distinguished an organization that is located in only one State (single-State organization) from one that is located in more than one State (multistate organization). The proposed regulations would continue this distinction in proposed § 1.25F–1(a)(20), defining a ''single-State SGO'' as an organization that is included on the State SGO list of only one covered State, and proposed § 1.25F–1(a)(11), defining a ''multistate SGO'' as an SGO that is included on the State SGO list of more than one covered State.

Although proposed § 1.25F–5(e)(2) would clarify that a State may not narrow the required elements of an SGO as described in section 25F(c)(5) and proposed § 1.25F–3(b) and (c), any particular SGO may narrow its own focus and adopt more stringent requirements than those applicable under section 25F. For example, an SGO may choose to limit its scholarships for qualified elementary and secondary education expenses to specific subject matter areas such as science or foreign languages, or to students whose household income is less than 80 percent of the area median gross income, provided that the SGO meets the statutory and regulatory requirements for SGOs. The Treasury Department and the IRS assume that SGOs will publicize their particular missions, the scope of their scholarships for eligible students, and their successes in achieving better student outcomes in order to attract more qualified

[2] However, proposed § 1.25F–5(e)(2) would prohibit covered States from imposing requirements on SGOs that are more restrictive than the requirements in section 25F(c)(5).

contributions from taxpayers supportive of their mission.

Stakeholders requested clarification regarding the meaning of the term ''school'' for purposes of section 25F. Section 25F does not define the term ''school'' or separately cross-reference the definition in section 530(b)(3)(B). Section 25F(c)(4), however, defines a ''qualified elementary or secondary education expense'' as any expense of an eligible student that is described in section 530(b)(3)(A). Each of the three categories of expenses described in section 530(b)(3)(A) depends on the student's enrollment or attendance at, or otherwise being in, a school. For purposes of section 530(b)(3), section 530(b)(3)(B) defines ''school'' as any school that provides elementary education or secondary education (kindergarten through grade 12), as determined under state law. Accordingly, the definition in section 530(b)(3)(B) applies in determining whether an expense is described in section 530(b)(3)(A) and therefore is a qualified elementary or secondary education expense under section 25F(c)(4).

Section 25F(d)(1)(A) also uses the term ''school'' in requiring an SGO to provide scholarships to 10 or more students who do not all attend the same school. To provide a consistent rule for purposes of both section 25F(c)(4) and section 25F(d)(1)(A), these proposed regulations provide that the term ''school'' has the meaning given in section 530(b)(3)(B).

The requirement in section 25F(c)(2)(B) that an eligible student be eligible to enroll in a public elementary or secondary school is distinct from the requirement that an SGO provide scholarships only for qualified elementary or secondary education expenses. The definition of eligible student does not itself require that the student be enrolled in or attending a school at the time of the scholarship application or award. However, an expense is a qualified elementary or secondary education expense only if it satisfies section 530(b)(3)(A), including the applicable connection to a school described in section 530(b)(3)(B). For example, a student who is eligible to enroll in a public school may receive a scholarship during the summer before the school year begins and incur qualified elementary or secondary education expenses in connection with enrollment in a school later that year.

The Treasury Department and the IRS have received many comments requesting guidance under section 530(b)(3) that will clarify the meaning of qualified expenses and schools and intend to issue that guidance as soon as possible so that taxpayers may rely on it.

## II. Federal Scholarship Tax Credit for Qualified Contributions

### *A. In General*

Generally, an individual taxpayer who is a United States citizen or a resident of the United States (as would be defined in proposed § 1.25F–1(a)(15)) is allowed a nonrefundable credit against the tax imposed for the taxable year by sections 1 and 55(a) for qualified contributions made by the taxpayer to an SGO during that taxable year. The amount of the credit allowed for a taxable year generally is equal to the aggregate amount of qualified contributions made by the taxpayer during any period of that taxable year in which the taxpayer is a United States citizen or resident of the United States, reduced (but not below zero) by the amount of any State credits claimed for such qualified contributions, and subject to a cap of $1,700. As a nonrefundable credit, the section 25F credit claimed in a particular year cannot exceed the tax liability of the individual taxpayer for that year. Any unused credit may be carried forward for up to five years. In addition, any qualified contribution for which a credit is allowed under section 25F may not be taken into account as a charitable contribution for purposes of section 170.

In making a contribution to claim a credit under section 25F, a taxpayer may contribute to any SGO without regard to the taxpayer's residence and may rely on the donee organization's presence on the IRS SGO list (and not listed as removed from that list) at the time of the contribution to establish that the organization is an SGO, regardless of which covered States included the organization on their respective State SGO lists. For example, a taxpayer residing in State X may contribute to an SGO in State Y so long as the SGO is on State Y's SGO list. *See* proposed § 1.25F–2(b), described in part II.E. of this Explanation of Provisions.

### *B. Meaning of the Word ''Taxpayer'' in Section 25F(a) and (b)*

Section 25F(a) provides that an ''individual'' who is a citizen or resident of the United States may claim a credit based on an amount equal to the aggregate amount of qualified contributions ''made by the taxpayer.'' Section 25F(b) further provides that (1) the section 25F credit allowed to ''any taxpayer'' for any taxable year ''shall not exceed $1,700'' and (2) the amount of the allowed section 25F credit ''shall be reduced by the amount allowed as a credit on any State tax return of the taxpayer for qualified contributions made by the taxpayer during the taxable year.''

### *C. Married Taxpayers Filing Jointly*

A significant number of stakeholders requested that the term ''taxpayer'' in section 25F(a) and (b) be applied separately to each spouse filing a joint return, which the stakeholders asserted would allow a married couple a combined section 25F credit of up to $3,400 on a joint return.

These stakeholders observed that the Code and regulations thereunder have long recognized that a joint return consists of two taxpayers, absent express statutory language to the contrary. Generally, the Code specifies whether a dollar limitation for a credit or deduction differs based on filing status. *See, e.g.,* sections 22(c) (specifying credit amounts for single individuals, joint filers, and married taxpayers filing separately), 36(b)(1) (providing a first-time homebuyer credit of up to $8,000 or $4,000 for married taxpayers filing separately), and 164(h)(6)(B) (2018) (limiting the deduction for State and local taxes to $10,000 or $5,000 for married filing separately). However, the Code does not always provide for a dollar limitation based on filing status. Moreover, the term taxpayer for purposes of the Code is defined as ''any person subject to any internal revenue tax,'' and person is defined to include ''an individual.'' Section 7701(a)(1) and (14).

The Treasury Department and the IRS interpret section 25F to limit the credit amount that may be claimed to $1,700 per individual taxpayer, allowing married couples filing jointly to potentially claim up to $3,400 on their joint tax return provided that each spouse has made qualified contributions of up to $1,700. This interpretation is consistent with other instances in which a joint return is treated as consisting of two individual taxpayers. *See, e.g.,* Treas. Reg. § 1.151–1(b) (''Since, in the case of a joint return, there are two taxpayers (although under section 6013 there is only one income for the two taxpayers on such return, *i.e.,* their aggregate income), two exemptions are allowed on such return, one for each taxpayer spouse.''); § 1.6013–4(b) (''Although there are two taxpayers on a joint return, there is only one taxable income.''). The statutory language of ''any taxpayer'' without any limitation in section 25F also implies the broadest interpretation and is consistent with how the term taxpayer is defined in section 7701(a).

*D. Contributions From Partnerships and S Corporations*

The Treasury Department and the IRS interpret the language of section 25F(a) to limit the section 25F credit to individuals making qualified contributions directly to one or more SGOs, rather than through one or more entities. The language used in section 25F(a), including the references to both ''individual'' and later ''taxpayer,'' is consistent with the language used in other individual income tax credit provisions in the Code and does not mean that the person making the qualified contribution is intended to differ from the person claiming the credit. *See* sections 23(a)(1), 25C(a), and 25D(a). This interpretation is consistent with the purpose of section 25F, which is to provide a credit for qualified contributions made by individuals. Thus, proposed § 1.25F–2(a)(3) would provide that, although a partnership or S corporation's contribution to an SGO may be treated as a separately stated charitable contribution under section 170 and deductible under section 170 by the partner or S corporation shareholder, that contribution is not a qualified contribution made by the partner or S corporation shareholder for purposes of section 25F. Therefore, a partner may not take into account such partner's distributive share of the partnership's charitable contributions to an SGO in determining the amount of the partner's qualified contributions under section 25F. Similarly, a shareholder of an S corporation may not take into account such shareholder's pro rata share of the S corporation's charitable contributions to an SGO in determining the amount of the shareholder's qualified contributions under section 25F.

*E. Reliance on SGO Status*

Section 25F(c)(3) requires a qualified contribution to be, among other things, made to a ''scholarship granting organization.'' Proposed § 1.25F–2(b) would establish a reliance rule, providing that, in order to ensure that a taxpayer's contribution is being made to an SGO, the taxpayer generally may rely on the IRS SGO list at the time the qualified contribution is made. However, to prevent situations in which a taxpayer could abuse this grant of reliance, proposed § 1.25F–2(b) also would provide that such reliance is not available to a taxpayer if the taxpayer (1) had knowledge that the recipient organization did not satisfy the requirements of section 25F(c)(5) and § 1.25F–3(b) at the time of the contribution; or (2) was at least in part responsible for, or was aware of, the act, the failure to act, or the substantial and material change on the part of the organization that gave rise to the removal of the organization from the IRS SGO list after the date of the taxpayer's contribution.

*F. Calculation of the Section 25F Credit*

Section 25F(b) limits the section 25F credit allowed by both the amount allowed as a credit on any State tax return of the taxpayer for qualified contributions made by the taxpayer during the taxable year and by a $1,700 annual limitation.

Many stakeholders requested guidance on how to apply the reduction for the amount allowed as a State tax credit for such contributions. Stakeholders identified various possible options, including requiring taxpayers to make separate contributions for State and Federal credits. Some stakeholders requested that taxpayers be allowed to take advantage of both State and Federal tax credits in a way that would not reduce the benefit of either credit.

Section 25F(a) describes the taxpayer's credit allowed as the total ''amount of qualified contributions made by the taxpayer during the taxable year,'' before the application of any limitations under section 25F(b). Although the statute includes the $1,700 limitation in section 25F(b)(1) and the State credit reduction in section 25F(b)(2), the Treasury Department and the IRS do not interpret this ordering of the provisions as reflecting an intent to apply the $1,700 limitation to the amount of a taxpayer's qualified contributions before application of the State credit reduction. Such an interpretation would, for example, limit a taxpayer's section 25F credit for a $2,500 qualified contribution for which the taxpayer claims a $500 State credit to $1,200 (that is, $1,700 in creditable qualified contributions after application of the section 25F(b)(1) limitation less the $500 State credit after the subsequent application of the State credit reduction in section 25F(b)(2)).

The Treasury Department and the IRS view the State credit reduction as intended to prevent a taxpayer from receiving combined Federal and State tax benefits exceeding the value of the taxpayer's qualified contributions. It is not otherwise intended to limit the section 25F credit for taxpayers in States that currently provide State credits for their qualified contributions, which would discourage those States from continuing to provide a State tax incentive that would significantly reduce an available Federal tax incentive. Because the Treasury Department and the IRS interpret section 25F(b) as limiting the credit to $1,700 only after applying the State credit reduction, proposed § 1.25F–2(a) and (c)(1) would clarify that the amount of the taxpayer's qualified contributions is reduced by the amount of State credits for such qualified contributions before applying the $1,700 limitation.

Proposed § 1.25F–2(c)(1) would provide that the section 25F credit for qualified contributions is the lesser of the following two amounts:

(1) The aggregate amount of the taxpayer's qualified contributions for the taxable year made while the taxpayer was a United States citizen or a resident of the United States reduced (but not to below zero) by the sum of any State credits with regard to those qualified contributions; or

(2) $1,700.

In general, the following steps would be performed to calculate a taxpayer's section 25F credit: first, the taxpayer determines the aggregate amount of the taxpayer's qualified contributions for the taxable year; second, subtract from that amount the sum of any State credits that were allowed with regard to those qualified contributions; and third, determine the lesser of $1,700 or the amount computed in the second step. In computing the State credits in the second step described in the preceding sentence, only the credits allowed based on qualified contributions would be taken into account; any credit allowed for a contribution that is not a qualified contribution would not be taken into account.

Because a taxpayer may be allowed a State credit for a contribution that includes both a qualified contribution and an amount that is not designated as a qualified contribution, proposed § 1.25F–2(c)(2) would provide that, for purposes of that second step, a State credit is treated as being allowed first from the donor's contributions that are not qualified contributions, and only thereafter from the donor's qualified contributions. This ordering rule preserves the maximum amount of qualified contributions available for a section 25F credit.

Because proposed § 1.25F–1(a)(22) would define a State credit as any tax credit offered by a State for making a contribution to an SGO that is allowed (as defined in § 1.25F–1(a)(22)) on the taxpayer's State tax return, the allowance of a deduction (as opposed to a credit) for State income tax purposes generally would not affect the amount of the section 25F credit.

Although section 25F(e) and proposed § 1.25F–2(f) provide that a qualified contribution for which a credit is

allowed under section 25F may not be taken into account as a charitable contribution for purposes of section 170, the portion of a qualified contribution not taken into account in determining the section 25F credit may be deductible as a charitable contribution if such contribution meets the requirements of section 170 and the regulations thereunder.

*G. Tax Liability Limitation*

Section 25F(a) provides that the section 25F credit is allowed against ''the tax imposed by this chapter for the taxable year,'' and section 25F(f) clarifies that the credit allowable for any taxable year may not exceed the limitation imposed by section 26(a) for such taxable year, reduced by the sum of the credits allowable under subpart A (other than sections 25F, 23, and 25D).

Proposed § 1.25F–2(d) would clarify that the credit allowed under section 25F for a taxable year may not exceed the taxpayer's tax liability as defined in section 26(a), based on the tax imposed for such taxable year as reduced by the sum of the nonrefundable personal credits that may not be carried forward (specifically, the credits allowed under sections 21, 22, 24, 25, 25A, 25B, 25C, and 25E).

*H. Carryforward of Unused Credits*

Similar to sections 23(c) (adoption credit carryforward) and 25D(c) (residential clean energy credit carryforward), section 25F(f) provides for a carryforward of the unused section 25F credit to enable taxpayers to claim the unused section 25F credit against a future tax liability. Although a taxpayer cannot claim a section 25F credit of more than $1,700 for any taxable year, the cumulative amount of section 25F(f) credit carryforwards can be used against a tax liability of more than $1,700 for a single taxable year. *See* proposed § 1.25F–2(h) (*Example 5*).

Proposed § 1.25F–2(e) would provide rules on the application of this carryforward provision, including a prohibition on carrying forward any credit to a taxable year following the fifth taxable year after the taxable year in which the credit arose. This provision also would provide that credits carried forward to a taxable year would be used on a first-in, first-out basis and would be used prior to current year credits.

*I. Reporting and Substantiation of Qualified Contributions*

Section 25F(h) provides that the Secretary shall issue such regulations or other guidance as the Secretary determines necessary to carry out the purposes of section 25F, including with respect to recordkeeping or information reporting for purposes of administering the requirements of section 25F.

Notice 2025–70 solicited comments regarding reporting and recordkeeping requirements for SGOs, including requirements relating to qualified contributions. In response, stakeholders and commenters asked that SGOs be required to provide electronically a written statement to the donor about the contribution. Moreover, several expressed concerns with collecting and reporting a donor's taxpayer identification number (TIN). The Treasury Department and the IRS share the stakeholders' concern that requiring taxpayers to provide TINs to SGOs when making a qualified contribution would be burdensome, could chill an individual's desire to make contributions to an SGO, and might result in unnecessary exposure of sensitive taxpayer information. At the same time, the ability to match contribution information provided by SGOs with that provided by individual taxpayers is important both to ensure effective administration of the section 25F credit and to facilitate the States' monitoring of SGO compliance with the operational requirements under section 25F(d) and § 1.25F–3(c), including the 90 percent of income spending requirement.

Thus, proposed § 1.25F–4(c)(1), also discussed in part IV.C. of this Explanation of Provisions, would provide special rules relating to the reporting of qualified contributions to SGOs that would include the use of a unique donor number provided by the SGO. Proposed § 1.25F–4(c)(1) would require an SGO to generate a unique donor number and to provide it to the donor as part of a timely written acknowledgement no later than January 31 of the calendar year following the calendar year in which the donor made a qualified contribution to the SGO. Because each SGO will be generating its own unique donor numbers, a taxpayer making qualified contributions to more than one SGO would receive a different donor number from each SGO. Proposed § 1.25F–2(g)(1) would require a taxpayer who is attempting to claim a section 25F credit to substantiate the taxpayer's credit on Form 8525, *Federal Scholarship Tax Credit* (or successor form), by reporting such information as may be required in the form instructions, including, for each SGO to which the taxpayer has made a qualified contribution during the taxable year, the unique donor number that the SGO was required to provide as part of a timely written acknowledgement.

If the taxpayer fails to report the required unique donor number on the taxpayer's Form 8525, *Federal Scholarship Tax Credit* (or successor form), proposed § 1.25F–2(g)(2) would create a presumption that the taxpayer did not make a qualified contribution to that SGO. However, this presumption may be rebutted by the taxpayer's submission of the timely written acknowledgement from the SGO that includes such unique donor number or other evidence satisfactory to the Commissioner of the amount of the contribution(s) from the taxpayer and the fact that the contributions were designated as qualified contributions, all within the response time prescribed in a written request from the IRS.

*J. Examples*

Many stakeholders requested that the proposed regulations provide examples of the calculation of the section 25F credit. Proposed § 1.25F–2(h) would provide five such examples.

## III. Scholarship Granting Organizations

*A. Overview*

Section 25F(c)(5) defines the term ''scholarship granting organization'' and requires compliance with the operational requirements in section 25F(d). Proposed § 1.25F–3(a) would provide a roadmap for the rules in proposed § 1.25F–3; proposed § 1.25F–3(b) would define the term SGO; proposed § 1.25F–3(c) would provide operational requirements for SGOs; and proposed § 1.25F–3(d) would define disqualified persons with respect to an SGO.

*B. Definition of Scholarship Granting Organization*

As provided in section 25F, proposed § 1.25F–3(b) would define a ''scholarship granting organization'' as an organization that: (1) is described in section 501(c)(3), is exempt from tax under section 501(a), and not a private foundation, as defined in section 509(a);[3] (2) prevents the co-mingling of qualified contributions with other amounts by maintaining a section 25F segregated account; (3) satisfies the operational requirements of section 25F(d)(1) and proposed § 1.25F–3(c); (4) does not award scholarships to any disqualified person; (5) is included on the State SGO list of one or more covered States in which the SGO is located; and (6) satisfies the reporting

[3] One way to search such organizations is the Tax Exempt Organization Search Tool on the IRS website at *https://www.irs.gov/charities-non-profits/search-for-tax-exempt-organizations.*

and recordkeeping requirements in § 1.25F–4.

Proposed § 1.25F–3(b)(2) would require each SGO to prevent the co-mingling of qualified contributions with other amounts by depositing all qualified contributions into a section 25F segregated account and would require the SGO to maintain a complete set of books and records for the section 25F segregated account. A contribution designated by a donor as a qualified contribution would need to be deposited in this section 25F segregated account regardless of whether the donor ultimately receives a tax credit for the qualified contribution. Once a qualified contribution is designated as such by a donor, neither the donor nor the recipient organization would be permitted to revoke such designation to reduce administrative burden and provide certainty.

*C. Operational Requirements for Scholarship Granting Organizations*

Proposed § 1.25F–3(c)(1) would provide operational requirements for SGOs, proposed § 1.25F–3(c)(2) would provide a safe harbor for a single-State SGO whose activities are 85 percent scholarship granting activities (operational requirement safe harbor), and proposed § 1.25F–3(c)(3) would provide the operational requirements that multistate SGOs would need to satisfy.

Proposed § 1.25F–3(c)(1) would provide that the organization would need to: (1) provide scholarships to 10 or more students who do not all attend the same school; (2) satisfy the 90 percent of income spending requirement described in part III.D of this Explanation of Provisions; (3) verify that scholarships are used solely for qualified elementary or secondary education expenses; (4) verify that scholarships are awarded only to eligible students; (5) verify that the recipient eligible students are solely within the State; (6) award scholarships with a priority for eligible students awarded a scholarship for the previous school year and, thereafter, for any eligible students who have a sibling who was awarded a scholarship from such SGO; and (7) not earmark or set aside contributions for scholarships on behalf of any particular student.

Proposed § 1.25F–3(c)(2) would provide an operational requirement safe harbor. If at least 85 percent of a single-State SGO's activities consist of scholarship granting activities (whether pursuant to section 25F, in accordance with State tax credit scholarship rules, or any other scholarship granting activities), then the SGO may apply the operational requirements to the organization's section 25F segregated account, rather than to the organization as a whole. For example, for a single-State SGO using the operational requirement safe harbor, the requirement that an SGO verify that scholarships are used solely for qualified elementary and secondary education expenses would apply only to scholarships granted with funds disbursed from the SGO's section 25F segregated account.

For purposes of this activity test, administrative, fundraising, governance, investment, compliance, outreach, and other activities are treated as scholarship granting activities to the extent each such activity is conducted in support of scholarship granting activities. This activity test, applied to the organization as a whole, is intended to measure the organization's mission and purpose, and is separate from the 90 percent of income spending requirement, for which only expenditures on scholarships for eligible students are taken into account.

While section 25F(b)(2) contemplates that an SGO may be conducting activities giving rise to a State credit for qualified contributions received during the taxable year, section 25F(d) contemplates that an SGO meets the operational requirements organization-wide. To allow SGOs to conduct section 25F scholarship activities alongside State scholarship activities giving rise to a State credit, and to allow SGOs to raise funds for administrative costs that would not count toward the 90 percent of income spending requirement, the operational requirement safe harbor would be a narrow administrative accommodation for organizations whose overall operations overwhelmingly consist of granting scholarships.

If at least 85 percent of the organization's activities are scholarship granting activities, then the organization's overall mission and operations would be considered aligned with the statutory scholarship purpose behind the section 25F credit. The operational requirement safe harbor would be limited to organizations whose activities are at least 85 percent scholarship granting activities because, for organizations with more than 15 percent of non-scholarship activities, the section 25F segregated account would not be a reliable proxy for the statutory phrase ''organization.'' The Treasury Department and the IRS have determined that such a result would be inconsistent with section 25F(d)(1), which applies the SGO requirements at the organization level.

Recognizing that the proposed operational requirement safe harbor may require the formation of new organizations to conduct section 25F activities, these proposed regulations provide relief for tax-exempt entities whose exempt status is pending with the IRS, as discussed in part V.D. of this Explanation of Provisions.

Proposed § 1.25F–3(c)(3) would provide operational requirements for multistate SGOs. Because section 25F(c)(5)(B) requires an SGO to maintain one or more separate accounts exclusively for qualified contributions, a multistate SGO would be required to maintain a separate section 25F segregated account for each covered State on whose State SGO list the organization appears, and would need to meet the requirements of proposed § 1.25F–3(c)(1) separately for its section 25F segregated account for each covered State on whose State SGO list the SGO appears. The SGO must allow donors to designate how their qualified contribution should be allocated among one or more of the covered States on whose State SGO list the SGO appears and all qualified contributions must be deposited in accordance with donor designations. Consistent with the intent of the statute that the organization be a scholarship granting organization, at least 85 percent of a multistate SGO's activities would be required to be scholarship granting activities.

The Treasury Department and the IRS request comments as to whether further guidance is needed regarding how an organization measures its scholarship-granting activities, including whether the determination should be based on receipts, expenditures, staff time, program-service activity, or another administrable metric, as well as whether 85 percent is a reasonable threshold to ensure that the organization's overall mission and operations are aligned with the statutory scholarship purpose behind the section 25F credit.

*D. 90 Percent of Income Spending Requirement*

Section 25F(d)(1)(B) provides that an SGO must spend not less than 90 percent of ''the income of the organization'' on scholarships for eligible students.

1. Definition of Income

Many stakeholders advocated that the term ''income of the organization'' apply only to qualified contributions, citing concerns that an SGO might not be able to operate if its overhead was limited to 10 percent of the organization's entire income.

The Treasury Department and the IRS have determined that the best reading of the statutory term ''income of the organization'' is the total gross receipts of the organization from all sources, computed using the cash receipts and disbursements method of accounting during its annual accounting period, unreduced by any expenses, regardless of the overall method used by the organization in its books and records, and proposed § 1.25F–3(c)(4)(ii)(A) would adopt this definition. The separate account requirement found in section 25F(c)(5)(B) is a tracing and anti-commingling rule for qualified contributions; it does not limit the income denominator in section 25F(d)(1)(B) to qualified contributions or earnings on those contributions.

However, in response to stakeholder concerns, and consistent with the purpose of section 25F that an SGO should be using the vast majority of its income for awarding scholarships, proposed § 1.25F–3(c)(4)(ii)(B) would provide that, for a single-State SGO using the operational requirement safe harbor, income of the organization, for purposes of the spending requirement, means the total amount of qualified contributions received by, and earnings credited to, the section 25F segregated account during the taxable year. For a multistate SGO, income of the organization, for purposes of this spending requirement, means the total amount of qualified contributions received by, and earnings credited to, the section 25F segregated account during the taxable year and is determined separately for each section 25F segregated account in each covered State.

2. Timing of 90 Percent of Income Spending Requirement

Stakeholders noted that the statute does not provide a timeframe for this spending requirement and asked that the proposed regulations provide that the income may be spent over more than one year. Stakeholders said that the 90 percent rule may pose a challenge for SGOs in the startup phase, as many administrative costs will be fixed. Stakeholders also pointed out that, although the SGO list is based on a calendar year, many SGOs operate on a fiscal year. Some stakeholders suggested permitting timely spending to occur during the ''current or next fiscal year'' of the nonprofit entity; be calculated on a rolling average; or be subject to a phase-in period to accommodate start-up costs. Other stakeholders stated that regulations should not provide special accommodation for income or expense fluctuations, including start-up costs or multi-year smoothing.

In response to this feedback, proposed § 1.25F–3(c)(4)(iii)(A) would require an organization to meet the 90 percent of income spending requirement as of the last day of the taxable year following the taxable year in which such income is received. Thus, although the 90 percent of income spending requirement ultimately would need to be met for an SGO's first year of operation, that requirement may be satisfied, from a timing perspective, by the end of the SGO's second year of operation.

3. Accounting for the 90 Percent of Income Spending Requirement

To simplify calculations and increase administrative efficiency, proposed § 1.25F–3(c)(4)(iii)(B) would provide that amounts are treated as spent when paid under the cash method of accounting.

Given this cash method of accounting requirement, funds allocated for future disbursements (for example, multi-year scholarships) would not be considered ''spent'' until they are paid. Thus, any award for a future year would only count toward satisfaction of the 90 percent of income spending requirement for the year in which it is paid. This is consistent with the annual accounting and eligibility principles reflected in the statutory requirements of section 25F, including the requirement that the SGO determine the ''annual'' household income and family size of eligible students and that the scholarship recipient be an eligible student located in the State, in each case as of the time when the scholarship is paid.

Further, provided an SGO does not retain ownership of funds transferred to a third party for disbursement through a qualified digital wallet, the SGO will be treated as having spent the transferred funds as of the date of transfer for purposes of the 90 percent of income spending requirement.

Proposed § 1.25F–3(c)(4)(iii)(C) would provide that amounts are treated as paid from contributions and other income received in the earliest year first, and then from subsequent years in chronological order; and proposed § 1.25F–3(c)(4)(iii)(D) would provide that, if an SGO receives a return of any payments made to a school or vendor that are in excess of the student's costs or that were disbursed in error, the return would be treated as income received in the year of the return and would need to be spent by the end of the taxable year following the year of the return.

Finally, proposed § 1.25F–3(c)(4)(iii)(E) would provide that in no event would any amount spent by an SGO be treated as spent in more than one year.

*E. Verification That Scholarships Are Used Solely for Qualified Elementary or Secondary Education Expenses*

Many stakeholders noted that waste, fraud, and abuse have been found in some existing State-level scholarship credit programs and said that States need to be able to implement safeguards designed to prevent, identify, and address such behaviors. Stakeholders stated that the primary sources of fraud and abuse in existing scholarship programs are the awarding of more than one scholarship to the same student for the same qualified elementary or secondary education expense if the total of the awards exceeds the expense and the misuse of scholarships for unqualified expenses or for extravagant expenses that are only nominally related to the student's educational needs.

Accordingly, proposed § 1.25F–3(c)(5) would require SGOs to implement reasonable procedures for the prevention and detection of fraud and abuse, including systems to prevent and detect the duplication of scholarship awards to the same student for the same qualified elementary or secondary education expense. In addition, proposed § 1.25F–3(c)(5) would require an SGO to verify that scholarship funds are used exclusively for qualified elementary or secondary education expenses in accordance with the allowable methods of payment described in proposed § 1.25F–3(c)(5)(ii) through (v).

First, proposed § 1.25F–3(c)(5)(ii) would provide that no money may be paid to the family of the eligible student other than as qualified reimbursements. A qualified reimbursement would be a reimbursement of an expense for which the family of the eligible student provides a receipt, and the SGO verifies that the payment was made, that the expense is a qualified elementary or secondary education expense, and that the reimbursement satisfies the SGO's procedures to prevent a single expense from being reimbursed for more than the total cost by more than one source.

Proposed § 1.25F–3(c)(5)(iii) would require that tuition, fees, room and board, and other similar expenses described in section 530(b)(3)(A) that are charged by the school must be paid directly to the school. Proposed § 1.25F–3(c)(5)(iii) would further require the SGO to require the school to return any payments from the SGO that are in excess of the student's costs, or that are disbursed by the SGO in error.

Proposed § 1.25F–3(c)(5)(iv) would allow an SGO to pay other vendors directly if the vendor has been verified as an appropriate provider of such services or items; is not related, directly or indirectly, to the scholarship recipient; and is required to return any payments from the SGO that are in excess of the student's costs or that were disbursed by the SGO in error.

Proposed § 1.25F–3(c)(5)(v) would allow an SGO to use a ''qualified digital wallet,'' as defined in proposed § 1.25F–1(a)(13), to pay qualified elementary or secondary education expenses.

The Treasury Department and the IRS note that section 25F(c)(5)(A) requires that an SGO must be a public charity under section 501(c)(3) (section 501(c)(3) public charity); therefore, scholarships provided by an SGO must further exempt purposes. Section 25F(c)(4) defines a qualified elementary or secondary education expense as any expense of an eligible student that is described in section 530(b)(3)(A), providing the outer boundaries of qualified expenses; however an SGO must award scholarships only for those expenses that are reasonably necessary to further the organization's charitable exempt purposes.

In addition, an organization is not described in section 501(c)(3) if it provides goods or services that confer more than incidental private benefit or otherwise exceed what is reasonably necessary to accomplish those purposes. For example, Rev. Rul. 69–175, 1969–1 C.B. 149, concluded that a nonprofit organization, formed by parents of pupils attending a private school that provides school bus transportation for its members' children, serves a private rather than a public interest and does not qualify for exemption under section 501(c)(3).

Section 501(c)(3) organizations that make distributions of their funds to individuals must establish that such distributions are made on a true charitable basis in furtherance of the purposes for which they are organized. *See, e.g.,* Rev. Rul. 56–304, 1956–2 C.B. 306. In the context of private foundation scholarships, § 53.4945–4(c) requires grant procedures that are reasonably calculated to ensure the funds are used for the intended charitable purpose and tie scholarship expenditures to the purpose of the grant. In the context of private foundation grants under an employer-related scholarship program, Rev. Proc. 76–47 provides that a scholarship must be motivated by a disinterested educational purpose, not by private or business interests.

The Treasury Department and the IRS request comments on how section 501(c)(3) requirements interact with section 25F and whether any clarifications are needed in the final regulations.

Multiple stakeholders requested clarification regarding the scope of the category of education expenses allowed to be paid for with scholarships provided from qualified contributions to SGOs, and they offered many suggestions of the types of expenses that would be beneficial to eligible students. Section 25F defines these permissible expenses by reference to qualified elementary or secondary education expenses as described in section 530(b)(3)(A). The Treasury Department and the IRS recognize that guidance describing the types of expenses permitted is critical to States, SGOs, eligible students, and other stakeholders. Such guidance will be issued separately under section 530. As indicated previously, the Treasury Department and the IRS are working on the development of that guidance and are treating the issuance of that guidance as a high priority.

*F. Method of Verifying That a Student's Household Income Is Not Greater Than 300 Percent of Area Median Gross Income*

Section 25F(d)(1)(F) requires an SGO to verify the annual household income of eligible students who apply for scholarships. This includes verifying that the student is an individual who is a member of a household with an income that, for the calendar year prior to the date of the application for a scholarship, is not greater than 300 percent of the area median gross income.

Many stakeholders addressed how income should be measured for these purposes. One stakeholder suggested that the forthcoming regulations clarify the relevant timeframe for measuring the student's household income. Some stakeholders suggested using information reported on Form 1040 and identifying members of the student's household based on who claims the eligible student as a dependent. Other stakeholders expressed concern with using section 42, the statutory provision for determining the Federal low-income housing credit, for determining income and family size because the section 42 definition encompasses all individuals who might be living in the same residence, including multiple generations of a family or unrelated individuals living together in the same location. Moreover, certain stakeholders suggested allowing SGOs to rely on eligibility determinations from other means-tested, public assistance programs. Other stakeholders suggested allowing SGOs to rely on a combination of tax returns, wage statements, and similar information in order to verify student eligibility.

In defining an eligible student, section 25F(c)(2)(A) incorporates the term ''area median gross income (as such term is used in section 42).'' Proposed § 1.25F–3(c)(6) would define area median gross income in a manner consistent with the rules applicable to section 42. Additionally, these proposed rules would define household income based on the rules applicable to section 42, but with a slight modification as explained in part III.F.1 of this Explanation of Provisions. Under section 42(g)(4), the rules in section 142(d)(2)(B) are applicable to these income determinations. Section 142(d)(2)(B)(i) then refers to Section 8 of the United States Housing Act of 1937 (Public Law 75–896) for determinations of annual income and area median gross income. Accordingly, proposed § 1.25F–3(c)(6) would require determining area median gross income and household income in a manner that generally is consistent with determinations under Section 8, including adjustments for family size. To assist SGOs in verification of household income, the IRS anticipates publishing the applicable limitations by geographic area and family size annually in guidance published in the Internal Revenue Bulletin.

Stakeholders asked that the proposed regulations clarify that an SGO is not required to give scholarships to students in a household with income up to 300 percent of area median gross income. The statute allows an SGO to give scholarships up to that income limit, but an SGO may focus on students below that limit. For example, an SGO that limits scholarships to students that are members of households with an income not greater than 50% of area median gross income, and that otherwise meets all the requirements under section 25F to be an eligible SGO, would be an eligible SGO for purposes of section 25F.

1. Household Income

The regulations issued by the Department of Housing and Urban Development relating to Section 8 are found in 24 CFR part 5. The definition of ''household income'' used in 24 CFR 5.609 is broader than the Federal tax definition of ''income'' and includes items such as child support, alimony received, and the imputed returns on assets (based on the current passbook savings rate) if the value of a family's net assets exceeds $50,000 and the actual returns from a given asset cannot

be calculated. Thus, the definition includes certain items not received in the form of cash, including unrealized appreciation in a home.

Although this Section 8 definition forms the basis of the definition in the proposed regulations to determine the income limit specified in section 25F(c)(2)(A), in the interest of sound Federal tax administration, the proposed regulations would modify this definition for purposes of measuring a particular household's income against the 300 percent statutory limit. Specifically, in determining the household income of an eligible student, the proposed regulations would disregard items not received in cash by a member of the household because such items are unlikely to be documented and verifiable. The proposed regulations, therefore, would disregard the amount of a Section 8 housing allowance, any imputed return on assets, and other items not received in cash. The Treasury Department and the IRS have proposed this approach after consideration of the purpose of section 25F and the fact that approximately 95 percent of the children in the United States are in households with income below the 300 percent of area median gross income limit provided in section 25F(c)(2)(A). This proposed definition of a particular household's income would be expected to simplify the income verification process for families and SGOs by disregarding non-cash items (such as imputed returns on home equity) that generally would not be shown on any tax or financial documents and may be dependent on current valuations.

2. Household

The Section 8 regulations at 24 CFR 5.100 define the term ''household'' as ''family, foster children and adults, and PHA-approved live-in aide.'' This definition then refers to 24 CFR 5.403 for the definition of ''family,'' which focuses on who is living together; it could be a single person or ''a group of persons residing together.'' Accordingly, for purposes of proposed § 1.25F–3(c)(6), proposed § 1.25F–1(a)(4)(iii) would define ''household'' as including the individual seeking to be an eligible student and the group of persons residing with that individual.

For purposes of determining the number of members of the student's household in situations in which the student resides in more than one household during the year (for example, in cases of shared custody), proposed § 1.25F–3(c)(6)(ii)(B) would identify the relevant household as the one in which the student resides for the longest period of time during the year. If the time spent by the student in each residence is equal, then the household of the taxpayer with the highest household income would be the relevant household for purposes of section 25F.

3. Verification of Household Income

For purposes of verifying that a scholarship recipient satisfies the household income requirement, proposed § 1.25F–3(c)(6) would require SGOs to use either the direct income verification method, the categorical eligibility verification method, or one of two safe harbors: the low-income-area tutoring and special-needs safe harbor, and the foster-child safe harbor. The categorical eligibility method, the low-income-area tutoring and special-needs safe harbor, and the foster-child safe harbor are intended to reduce burdens for families and SGOs by not requiring SGOs to collect more sensitive household-income information than is necessary if other reliable indicators of household income are present, while including administrable documentation and audit safeguards that will allow for the appropriate administration of section 25F.

Under the direct income verification method, an SGO would verify income through review of written documentation provided by scholarship applicants, including pay stubs, prior year Federal or State tax returns, IRS transcripts, Forms W–2, evidence of other income not reflected on such documents (such as child support and alimony not reported as income), or a certification that would verify income through other relevant data sources.

Under the categorical eligibility verification method, an SGO would verify that the household income did not exceed 300 percent of area median gross income through review of written documentation, such as an award letter, dated within the last 12 months, documenting that an individual in the student's household currently is approved for assistance from or participation in Supplemental Nutrition Assistance Program (SNAP), Temporary Assistance for Needy Families (TANF), the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), Section 8 housing, or Supplemental Security Income (SSI)). This safe harbor responds to comments requesting a streamlined eligibility method for eligible students who are highly unlikely to be members of a household with income above 300 percent of area median gross income, thus reducing administrative burden by relying upon eligibility determinations that have already been made by government agencies. Because the statute requires that this determination be made on a household basis, eligibility for participation in reduced-price or free lunch programs that apply to an entire school, rather than on an individual level, is not considered adequate verification for this purpose.

The Treasury Department and the IRS request comments on other needs-based programs, such as State or Tribal programs, that also should be included in this categorical eligibility verification method.

Additionally, proposed § 1.25F–3(c)(6)(iii)(C) would provide a safe harbor for SGOs awarding individual scholarships for academic tutoring or special needs services at schools in low-income areas. Pursuant to this safe harbor, if an SGO provides scholarships to individual students at schools in a low-income area for individual academic tutoring, or for special needs services in the case of a special needs student, and the individual students receiving those services are selected by the school on the basis of the particular student's academic or special need, the recipient students would be treated as meeting the household income requirement regardless of whether the student's household income is verified. These proposed regulations would provide two situations where the safe harbor could be used to streamline verification of household income. First, if the school is located in a qualified census tract, as identified at *https://www.huduser.gov/portal/sadda/sadda_qct.html* (or successor website), or in guidance published in the **Federal Register** or Internal Revenue Bulletin (*see* §§ 601.601(d)(2) and 601.602 of this chapter) or, as appropriate, in forms, instructions, and publications available on *https://www.irs.gov*. Second, if the school certifies that at least 80 percent of its students reside in such a qualified census tract, regardless of the location of the school.

In order to avail itself of this safe harbor, however, proposed § 1.25F–3(c)(6)(iii)(C) would require that the SGO annually obtain and provide to the covered State a third-party audit addressing the SGO's compliance with the safe harbor requirements. The auditor's report would be required to include several certifications, including that the school meets one of the two qualified census tract eligibility requirements described above; that the scholarship recipients were selected by the school based on academic or other need; that tutors or other providers were qualified to render the services obtained with scholarship funds; that the

student's need for the services, including the nature and extent of the services needed, is independently diagnosed by a professional not associated with the provider or vendor of the services; and that the services met appropriate quality standards, were provided with a duration and frequency commonly required to produce benefit, and their impact on each individual scholarship recipient was assessed.

Finally, proposed § 1.25F–3(c)(6)(iii)(D) would provide a safe harbor for foster children. Specifically, eligible students who are foster children would be treated as meeting the household income requirement regardless of whether the student's household income is verified. For this purpose, proposed § 1.25F–1(a)(5) would define a ''foster child'' as a child who has been removed from the custody of a parent or legal guardian and placed under the care or placement authority of, or has become the legal responsibility of, a child welfare agency, regardless of whether the child has been or will be placed with a person by an authorized placement agency or by judgment, decree, custody order, or any other order of any court of competent jurisdiction (other than an order appointing a legal guardian of the child). The term ''authorized placement agency'' would mean a State, the District of Columbia, a possession of the United States, a foreign country, an Indian Tribal government (as defined in section 7701(a)(40)), or an agency or organization that is authorized by a State (including a non-federally recognized Tribe that otherwise is authorized to act on such matters under applicable State law), or a political subdivision of any of the foregoing, to place children for legal adoption or in foster care.

*G. Students Solely Within the State*

Section 25F(c)(3) defines a qualified contribution as a charitable contribution of cash to an SGO ''that uses the contribution to fund scholarships for eligible students solely within the State in which the organization is listed pursuant to subsection (g).'' However, it is unclear whether ''solely within the State'' limits the eligible students who may receive scholarships, the use of the scholarships, or both. This distinction is consequential: if the phrase modifies eligible students, contributions may qualify so long as the scholarships benefit only students residing in the State in which the SGO is listed. On the other hand, if it instead modifies the scholarships, only expenses incurred in the State in which the SGO is listed would qualify, regardless of the residence of the eligible student.

Some stakeholders have suggested that the proposed regulations allow scholarships to be awarded to students residing within the State in which the SGO is listed, even if the student is attending school in another State. Other stakeholders suggested allowing scholarships to be awarded to students attending school within the State in which the SGO is listed, even if they reside in a different State. These stakeholders stated that Congress intended the provisions of section 25F to be broadly applied to benefit the highest number of eligible students. These stakeholders also cited a desire for maximum flexibility for children in military families, children attending boarding schools, and children living near a State border and attending school in a State bordering the State of their residence.

Some stakeholders suggested that the intent of the statute appears to be focused on where students attend school, rather than where students reside, or that a school located outside of a covered State should not be able to receive section 25F scholarship funds, regardless of where the SGO is located.

Another stakeholder proposed that, once a scholarship is awarded by an SGO, the scholarship funds should ''attach'' to the student and not be restricted with regard to the State in which the funds are used, consistent with West Virginia's Hope Scholarship and with Indiana's voucher program, for example.

The Treasury Department and the IRS interpret the statutory language ''eligible students solely within the State in which the organization is listed'' to refer to the residence of the student, rather than where a school is located. Accordingly, proposed § 1.25F–3(c)(7) would provide that a contribution is considered used to fund scholarships for eligible students solely within the State in which the organization is listed pursuant to proposed § 1.25F–3(g) only if the students receiving scholarships reside in that State as determined under State law. Exceptions to this rule would be provided for students who are dependents of a member of the Armed Forces of the United States, as well as for students who are dependents of an individual residing on Indian Lands (as defined in 25 U.S.C. 3501(2)).

Proposed § 1.25F–3(c)(7) also would provide examples illustrating the application of these rules.

*H. Priority in Awarding Scholarships*

Section 25F(d)(1)(D) requires that SGOs, in their award selections, give priority consideration to students awarded a scholarship the previous year, and then to any eligible student who had a sibling who was awarded a scholarship by that SGO.

Proposed § 1.25F–3(c)(8) would provide that an SGO has flexibility to consider the particular needs of potential scholarship recipients and the type of expenses for which the scholarship is being awarded. For example, a prior scholarship recipient should be given priority with regard to an award for tuition, fees, and room and board, to ensure that the eligible student is able to continue attending the same school. Similarly, the siblings of such an award recipient should be given priority so that siblings are able to attend the same school. However, if a scholarship is awarded based on need for individual academic tutoring or special needs services, the fact that a student was a previous scholarship recipient, or that a student has a sibling who was a previous scholarship recipient, may not be relevant and priority instead can be based on need for the services.

*I. Disqualified Persons*

Notice 2025–70 requested comments on the definition of a disqualified person for purposes of section 25F(d)(2). Stakeholders generally supported treating SGO officers and directors as disqualified persons, but some suggested that family members of such officers and directors should remain eligible for scholarships. Some stakeholders specifically suggested that exceptions should be permitted if the SGO employs uniform, blind, or anonymized scholarship selection procedures.

The Treasury Department and the IRS have determined that such an exception is inconsistent with section 25F. Section 25F(d)(2)(B)'s incorporation of the term ''rules similar to'' those of section 4946 reflects the same Congressional choice embodied in the self-dealing rules of section 4941: categorical prohibitions are preferred to exceptions relying on inquiries into procedural safeguards or benign intent. Allowing for ''blind'' or ''anonymized'' selection procedures to modify the otherwise categorical prohibitions would present a significant and unjustified deviation from the rules set forth in section 4946. Moreover, section 25F requires that SGOs prioritize students awarded a scholarship the previous year and students with a sibling who was awarded a scholarship by such organization, meaning that truly ''blind'' or ''anonymized'' selection procedures are impossible.

Some stakeholders suggested that selection committee members or anyone with influence over the awarding of scholarships should be considered disqualified persons. Others suggested that selection committee members should not be disqualified if they are not compensated or have no material financial interest in the SGO.

The Treasury Department and the IRS have determined that individuals who participate in the awarding of scholarships by the SGO should be treated as disqualified persons and that an exception for uncompensated members with no financial interest in the SGO is unwarranted. The relevant concern is not whether an individual has a financial interest in or compensation from the SGO, but whether such individual has the ability to confer a financial benefit on themselves or a family member by influencing scholarship awards.

Several stakeholders addressed how to define ''substantial contributor'' for purposes of section 25F. Many recommended that the definition be consistent with section 4946, under which a substantial contributor is generally any person who contributed an aggregate amount of more than $5,000, if such amount is more than 2 percent of the total contributions the organization received before the end of the taxable year in which that person's contributions were received. Notice 2025–70 requested comments on whether to exclude the $5,000 threshold and rely solely on the 2 percent threshold, the aim of which would be to prevent the development of small organizations intended to benefit small groups of related people without explicitly violating the earmarking prohibition. Stakeholders suggested this approach could disproportionately harm small or start-up SGOs and reduce scholarship availability.

Upon further consideration, the Treasury Department and the IRS have concluded that the stated concern is addressed by the existing private benefit doctrine, which would prevent such an organization from properly being recognized as described in section 501(c)(3), thus causing it to be unable to qualify as an SGO. Accordingly, proposed § 1.25F–3(d)(2)(i) adopts the 2 percent and $5,000 thresholds, consistent with section 4946.

However, consistent with the operational requirement safe harbor, which allows SGOs to simplify compliance with the section 25F operational requirements by measuring them at the section 25F segregated account level, these proposed regulations also would apply the disqualified person requirement at the section 25F segregated account level. Application at the section 25F segregated account level ensures that scholarships are not awarded to disqualified persons measured at the same operational level at which the SGO otherwise satisfies section 25F(d). Thus, proposed § 1.25F–3(d)(2) would provide that a substantial contributor means any person who contributed an aggregate amount of more than $5,000 to a section 25F segregated account during the taxable year, if such amount is more than 2 percent of the total contributions received by that section 25F segregated account during the taxable year.

One stakeholder recommended removal of the substantial contributor rule altogether or alternatively incorporating a higher threshold to be considered a disqualified person. The proposed regulations would not eliminate the substantial contributor rule or increase the dollar threshold, as substantial contributors may be able to exercise influence over an SGO by virtue of the size of their contribution relative to the size of total contributions.

Some stakeholders suggested that the substantial contributor calculation should be considered each year based on contributions from that year only, rather than cumulative contributions from the organization's inception. The proposed regulations would adopt this approach based on the view that it better reflects the expected giving patterns to SGOs and more accurately identifies those donors whose current level of contributions may give them meaningful influence. Accordingly, proposed § 1.25F–3(d)(2) would determine substantial contributor status based on contributions received during the taxable year.

A few stakeholders suggested a rule completely prohibiting SGOs from providing scholarships to the family members of any donors. The proposed regulations do not adopt the recommendation. The substantial contributor framework already addresses this concern by identifying those donors who may have meaningful influence over the SGO. Extending this status to all donors regardless of contribution size would sweep in contributors with no meaningful influence and could deter contributions in a manner inconsistent with section 25F's broader goals.

For purposes of determining persons who are substantial contributors, a person would be treated as making all contributions made by his or her spouse. A person's status as a substantial contributor is determined as of the close of each taxable year. Further, proposed § 1.25F–3(d)(4) would provide that once an individual is treated as a substantial contributor for a given taxable year of the SGO, such individual will be treated as a substantial contributor for that taxable year as well as the immediately succeeding taxable year of the SGO.

Evaluating substantial contributor status at taxable year end could result in an SGO unknowingly awarding scholarships to individuals who become disqualified persons by virtue of contributions made after the award of the scholarship. To reduce the risk of an SGO losing its SGO status by inadvertently awarding a scholarship to a disqualified person, proposed § 1.25F–3(d)(2)(ii) would indicate that a scholarship awarded to a disqualified person will not be treated as such if, at the time the scholarship was awarded, two requirements are met for that taxable year. First, the recipient would not have been a disqualified person had the substantial contributor determination been made as of the date of the award based on contributions received by the organization through that date. Second, the SGO did not know or reasonably expect that the recipient would become a disqualified person. Proposed § 1.25F–3(d)(5) would provide examples illustrating the rules addressing disqualified persons.

One stakeholder proposed a rule prohibiting board members, officers, and substantial contributors from having financial interests in recipient schools. The Treasury Department and the IRS have determined that such a prohibition is not required by section 25F. Board members, officers, and substantial contributors would be defined as disqualified persons and conflicts that may arise as a result of their relationships with recipient schools would be subject to scrutiny under other provisions of the Code, such as sections 501(c)(3) and 4958.

Accordingly, proposed § 1.25F–3(d)(1) provides the following list of those included in the definition of a disqualified person for purposes of section 25F: substantial contributors to the SGO or to the 25F segregated account; officers, directors, or trustees of the SGO (or individuals with similar powers and responsibilities); any individual participating in the selection of scholarship recipients, including as a member of a committee; and members of the families of any such person. Proposed § 1.25F–3(d) would clarify that, for these purposes, members of one's family include only spouses, ancestors and descendants of the individual or the individual's spouse, siblings of the individual or the

individual's spouse, the descendants of siblings, and the spouse of any of these individuals. Descendants would be defined to include legally adopted children and stepchildren of any individual.

## IV. Reporting and Recordkeeping Requirements for SGOs

### *A. Overview*

Proposed § 1.25F–4 would provide reporting and recordkeeping requirements for organizations for purposes of section 25F that supplement the general recordkeeping requirements under section 6001 imposed on all persons liable for a tax imposed under Title 26. Proposed § 1.25F–4(b) would describe the mandatory registration process for organizations through the IRS SGO portal. Proposed § 1.25F–4(c) would provide the requirements for an organization's acknowledgement, recordkeeping and reporting for the receipt of amounts designated as qualified contributions. Proposed § 1.25F–4(d) would describe the rules relating to an SGO's annual reporting requirements. Proposed § 1.25F–4(e) would describe an organization's annual financial and programmatic audit requirement.

### *B. Mandatory Registration Through IRS SGO Portal*

In determining how to enforce and administer the requirements of section 25F, the Treasury Department and the IRS considered paper or electronic communications and determined that an IRS SGO portal would provide the most efficient way to timely interact with SGOs. Proposed § 1.25F–4(b) would require an organization to register electronically through the IRS SGO portal, which will allow each organization to obtain instructions for creating a unique donor number, based on a uniform format to be used by all SGOs, and report qualified contribution information to the IRS. The organization also would use the IRS SGO portal to periodically authorize disclosure of the organization's name and identifying information on the IRS SGO list for a calendar year, available on *https://www.irs.gov.* An organization must authorize such disclosure if it wants the IRS to publish such information on the IRS SGO list.

Because an organization would not be able to generate the unique donor number to provide it to a donor until the organization registers in the IRS SGO portal, and because a donor would need that unique donor number to substantiate a qualified contribution, proposed § 1.25F–4(b)(2) would require an organization to complete the registration process with the IRS as soon as possible and preferably before the organization appears on any State SGO list. Until the organization has registered in the IRS SGO portal, the organization will not be able to comply with the acknowledgement and reporting requirements, and that compliance is a necessary part of substantiating that a donor's qualified contribution is eligible for the credit allowed under section 25F.

Proposed § 1.25F–4(b)(3) would describe the information required to register, specifically: the organization's name, IRS employer identification number (EIN), address, telephone number, and year of formation; the name of a person whom the IRS may contact if there is an issue with the organization's registration; the organization's taxable year; and any other information the IRS deems necessary for purposes of administering the requirements of section 25F as provided in guidance. Proposed § 1.25F–4(b)(4) would provide that the IRS will review the information provided to verify that all the required information has been submitted and will provide instructions to the organization for creating a unique donor number in a uniform format to be used by all SGOs, for each donor who has designated at least one payment to the organization as a qualified contribution to the SGO during the calendar year.

### *C. Donor Acknowledgement and Reporting of Qualified Contributions Received by SGOs*

Notice 2025–70 asked what information SGOs should be required to provide to their donors, including whether SGOs should be required to provide the donor with written substantiation in order for the donor to take the section 25F credit. Many stakeholders recommended that SGOs provide a standardized donor acknowledgement form to taxpayers that would include the donor's name and address, the name of the SGO and its EIN, and the amount of the qualified contribution. Other stakeholders suggested that SGOs should not be responsible for reporting the particulars of a donation, other than informing donors that the donation could be eligible for the section 25F credit.

Proposed § 1.25F–4(c)(1) would require the organization to transmit a timely written acknowledgement to each donor with respect to qualified contributions made by such donor during the calendar year. Proposed § 1.25F–4(c)(1)(i) would require the timely written acknowledgement to include: the organization's EIN; the total amount of contributions made by the donor to the organization during the calendar year that the donor designated as qualified contributions; the unique donor number provided to the donor; a statement as to whether the organization provided any goods or services in consideration for any qualified contributions made by the donor; and a description and good faith estimate of the value of any such goods or services. Proposed § 1.25F–4(c)(1)(ii) would require organizations to provide the timely written acknowledgement to the donor no later than January 31 of the calendar year following the calendar year in which the donor made a qualified contribution. The timely written acknowledgement may be provided in writing or in any other form acceptable to the donor, including by electronic delivery if the donor consents to receiving the statement electronically and has not withdrawn the consent before the statement is furnished.

Proposed § 1.25F–4(c)(2) would require organizations to report information about qualified contributions to the IRS. Proposed § 1.25F–4(c)(2)(i) would require the following information to be reported with respect to each unique donor number assigned by the organization: the donor's name and address, the aggregate amount of qualified contributions made by the donor to the organization during the calendar year; and any other information the IRS deems necessary for purposes of administering the requirements of section 25F, as may be described in further guidance. Proposed § 1.25F–4(c)(2)(ii) would require organizations to report this information no later than February 28 of the year following the calendar year in which such qualified contributions were made. Unless otherwise provided in guidance, the reporting would be required to be done through the IRS SGO portal in accordance with the instructions provided therein.

### *D. Reporting Operational Information to the IRS*

Some stakeholders had suggested relying on an SGO's ''sworn compliance affidavit'' in determining whether an organization meets the criteria and requirements of being an SGO. Other stakeholders insisted that an SGO's self-attestation alone should not be sufficient, but suggested that an individual responsible for the operation of the SGO, or an approved third party, could attest that the SGO complied with all statutory requirements.

Other stakeholders advocated for the regulations to provide a ''standard Federal checklist,'' as States vary in their capacity to review nonprofit organizations and many have no existing SGO oversight programs.

In accordance with the concept of such a checklist, these proposed regulations would provide that SGOs must annually certify that they meet the criteria and requirements of being an SGO. Stakeholders stated that, absent a standard Federal checklist, allowing each State to interpret and enforce Federal eligibility requirements would likely result in a patchwork of standards, procedures, and reporting obligations that would significantly increase administrative complexity and compliance costs, particularly for SGOs operating in multiple States.

Thus, proposed § 1.25F–4(d) would require an organization that was an SGO for any part of its taxable year to provide an annual certification to the IRS. Proposed § 1.25F–4(d)(2)(i) would require the organization to annually certify, with respect to its taxable year or the period within its taxable year during which it was an SGO, that such organization: was described in section 501(c)(3) and exempt from tax pursuant to section 501(a), and not a private foundation, as defined in section 509; prevented the co-mingling of qualified contributions with other amounts by maintaining a section 25F segregated account, which must contain only qualified contributions and the earnings therefrom, for each covered State on whose State SGO list the SGO appears, deposited all qualified contributions into that section 25F segregated account, and maintained a complete set of books and records for each of its section 25F segregated accounts; satisfied the operational requirements of section 25F(d)(1) and proposed § 1.25F–3(c); did not award a scholarship to any disqualified person; was located in each State on whose State SGO list the organization was listed; provided each donor a timely written acknowledgement; and commissioned a financial and programmatic audit as described in part IV.E. of this Explanation of Provisions by a qualified independent third party (or, for organizations with annual receipts of $500,000 or less, a committee of independent persons unrelated to the organization's management) and provided the audit report to each covered State on whose State SGO list the organization was listed.

Proposed § 1.25F–4(d)(2)(ii) would provide additional certifications relating to operational requirements. Proposed § 1.25F–4(d)(2)(ii)(A) would provide that a single-State SGO must certify that it provided scholarships to 10 or more students, not all of whom attended the same school; spent not less than 90 percent of the income of the organization on scholarships for eligible students; verified that scholarships were used solely for qualified elementary or secondary education expenses; verified that scholarships were awarded only to eligible students who were members of an eligible household and who were eligible to enroll at a public elementary or secondary school; verified that the recipient eligible students were solely within the State; awarded scholarships with a priority (as defined in the proposed regulations) for eligible students awarded a scholarship for the previous school year and, thereafter, for any eligible students who have a sibling who was awarded a scholarship from such SGO; did not earmark or set aside contributions for scholarships on behalf of any particular student; and, if the organization used the safe harbor found in proposed § 1.25F–3(c)(6)(iii)(C) for providing individual scholarships for individual academic tutoring or special needs services at schools in low-income areas, that it obtained a third-party audit and provided the audit report to the covered State in accordance with proposed § 1.25F–3(c)(6)(iii)(C)(*2*).

Proposed § 1.25F–4(d)(2)(ii)(B) and (C), respectively, would require an organization that was either a single State SGO using the safe harbor in § 1.25F–3(c)(2) or a multistate SGO for any part of a calendar year within its taxable year to annually certify that at least 85 percent of such organization's activities during the taxable year were scholarship granting activities and that each of the elements of proposed § 1.25F–4(d)(2)(ii)(A) was met separately with respect to the organization's section 25F segregated account for each covered State on whose State SGO list the SGO appeared.

Proposed § 1.25F–4(d)(3) would describe the information an organization that was a single-State SGO for any part of a calendar year within its taxable year is annually required to report to the IRS. The information described in proposed § 1.25F–4(d)(3) would assist States, the IRS, and taxpayers considering making a qualified contribution in determining the organization's compliance with the requirements of section 25F, its size, and its mission.

Proposed § 1.25F–4(d)(3)(i) would require an organization to report, with respect to its taxable year, or the period within its taxable year during which it was an SGO, the following information: (1) the number of students that applied for a scholarship; (2) the number of students selected for a scholarship in accordance with the safe harbor in proposed § 1.25F–3(c)(6)(iii)(C); (3) the number of scholarships awarded; (4) the highest, lowest, and average amount of the scholarships awarded; (5) the number of schools at which the scholarship recipients were enrolled; (6) aggregate data on each category of qualified elementary and secondary education expenses for which scholarship funds were used; (7) the amount of the organization's income; (8) with regard to the amounts spent on scholarships for eligible students solely within the State during the taxable year: the total amount spent during the year; and of the total amount spent during the year, the amount counted as satisfying the 90 percent of income spending requirement for the prior year, and the amount counted as satisfying that requirement for the current year; (9) the percentage of the prior year's income spent on scholarships for eligible students solely within the State, taking into account the amounts spent in both the prior and current years; (10) the percentage of the current year's income spent on scholarships for eligible students solely within the State; and (11) any other information required in accordance with guidance.

Proposed § 1.25F–4(d)(3)(ii) would require a single-State SGO using the safe harbor found in proposed § 1.25F–3(c)(2) to report the information described in proposed § 1.25F–4(d)(3)(i) with respect to its section 25F segregated account, rather than with respect to the organization as a whole.

Proposed § 1.25F–4(d)(3)(iii) would require a multistate SGO to report this information separately with regard to its section 25F segregated account for each covered State on whose State SGO list the SGO appears.

Proposed § 1.25F–4(d)(4) would provide the time and manner of reporting the annual certification and information. Except to the extent otherwise provided in guidance, the certification and information would need to be provided at such time and in such manner as the IRS may prescribe by publication, form, or instructions, and attached to the annual Form 990 for those SGOs required to file Form 990. This requirement would be consistent with feedback advocating for the use of the Form 990 as an efficient mechanism for reporting SGO activity due to its standardization, transparency, and consistency across jurisdictions.

For organizations required to file an annual information return under section 6033(a), the required form must be included as an attachment. An organization that is not required to file

an annual information return under section 6033(a) must provide this form separately to the IRS on or before the 15th day of the 5th calendar month following the close of the period for which the form reports the required certifications and information. Organizations must concurrently provide a copy of the form to each State on whose State SGO list the organization appears in accordance with guidance.

*E. Required Audits*

Some stakeholders suggested periodic SGO audit requirements, noting the need for lenience in an SGO's first year on a State SGO list. Another stakeholder suggested that new SGOs should receive ''heightened scrutiny'' compared to those with a proven track record of managing donations and administering student scholarships. Stakeholders suggested that, in years after the first year of operation, SGOs should be subject to periodic audits, mandatory reporting requirements, and immediate removal upon noncompliance.

In considering what regulations or other guidance would best carry out the purposes of section 25F, including for purposes of enforcing the SGO operational requirements in section 25F(d) and ensuring the integrity of the State lists of SGOs in section 25F(g), the Treasury Department and the IRS have attempted to balance the need for State oversight of SGOs with the burden that such requirement places on State governments. As a result, proposed § 1.25F–4(e) would require each organization that was an SGO during any part of the preceding taxable year to commission and undergo an annual financial and programmatic audit by a qualified independent third party and to provide the audit results to each covered State on whose State SGO list the SGO appeared.

Proposed § 1.25F–4(e)(2) would define ''qualified independent third party,'' for organizations whose total receipts (whether or not required to be deposited into its section 25F segregated account) for the most recent taxable year were more than $500,000 as an external, independent professional or accredited body that regularly assesses an organization's compliance, financial records, or processes (including internal controls) against specific standards to perform the audit required by proposed § 1.25F–4(e). To provide flexibility and reduce expenses for small entities, proposed § 1.25F–4(e)(2) would permit an organization whose total receipts for the taxable year did not exceed $500,000 to use a committee of independent persons unrelated to the organization's management to conduct the audit, with the report signed under penalties of perjury.

Proposed § 1.25F–4(e)(3) and (4) would describe the content and scope of the required audit, providing a list of the items to be reviewed and addressed.

**V. State Election, SGO List, and Certification of SGOs**

*A. Overview*

Proposed § 1.25F–5 would provide rules for a State election and a State's identification and certification of organizations located in the State that are SGOs. Proposed § 1.25F–5(b) describes rules that would apply for the State to register in the IRS State section 25F portal, which, except for the first year for which the State makes an election, may be used for the submission of the State election (including advance election), State SGO list, any changes to the State SGO list, annual certifications, and any other information required in accordance with guidance. Proposed § 1.25F–5(c) describes the requirements that would apply for a State election. Section 1.25F–5(d) provides rules that would apply regarding the State SGO list, including information and certifications a State is required to provide for each organization included on the State SGO list and procedures a State is required to use in determining whether an organization is an SGO. Proposed § 1.25F–5(e) addresses rules that would apply to State administrative requirements for SGOs.

*B. IRS State Section 25F Portal*

Notice 2025–70 stated that the Treasury Department and the IRS anticipated that the forthcoming proposed regulations would require the State to electronically submit the State election, the State SGO list, and certification to the IRS. Commenters supported an electronic process for States to submit State SGO lists, as they considered electronic submissions to be more efficient and timelier than paper submissions. Thus, proposed § 1.25F–5(b) would require a State that chooses to participate under section 25F to register for and use the IRS State section 25F portal in accordance with the instructions therein.

Proposed § 1.25F–5(b)(2)(i) would provide that the Governor of the State or such other individual, agency, or entity as is designated under State law to make elections with respect to Federal tax benefits on behalf of the State may authorize up to two designated officials to register for and use the IRS State section 25F portal. Proposed § 1.25F–5(b)(2)(ii) would require each designated official to be an elected official, the Director of Taxation, or an appointed official of the State.

Proposed § 1.25F–5(b)(3) would require States to obtain or be assigned a special-purpose EIN for purposes of registering. The IRS will inform States how to obtain this EIN and States will not be required to use a Form SS–4 for these purposes.

Proposed § 1.25F–5(b)(4) would require that the following information be provided to register: the special-purpose EIN; contact information, including the name, official title, telephone number, and email address of the State's designated officials; and any other information the IRS deems necessary for purposes of administering the requirements of section 25F as may be described in future guidance.

At the conclusion of the registration process, a State would be able to electronically transmit through the IRS State section 25F portal its State election (including advance election), State SGO list, any changes to the State SGO list, annual certifications, and any other information required in future guidance.

To mitigate the risk of any State's implementation issues for the first year for which the IRS State section 25F portal will be operational, the IRS is considering the creation of alternative temporary procedures that would be outlined in future guidance to help ensure that all States that wish to participate under section 25F are reasonably able to complete their registration for the IRS State section 25F portal or otherwise submit the State election and State SGO list for calendar year 2027.

*C. State Election*

1. In General

Proposed § 1.25F–5(c) would provide the procedure for making a State election. Proposed § 1.25F–5(c)(1) would provide that, except as provided in proposed § 1.25F–5(c)(3), the State election may be made either as an advance election that is perfected through the submission of the State SGO list or as an election made with such submission.

Several stakeholders recommended restricting a State's ability to ''opt out'' after having made an election. Many stakeholders believe that States should not be able to opt out on a year-to-year basis, as families and students will rely on these scholarships for multiple years. However, consistent with the requirement in section 25F(c)(5) that the list submitted for the applicable covered

State under section 25F(g) is ''for the applicable year,'' proposed § 1.25F–5(c)(1) would confirm that an election to participate under section 25F is made only for a single calendar year, and that all of the requirements in proposed § 1.25F–5(c) must be satisfied for each year for which an election is made. The advance election procedure in proposed § 1.25F–5(c)(3), discussed in part V.C.2. of this Explanation of Provisions, would enable a State to opt in for an upcoming calendar year by making an advance election and then later, in effect, opt out by failing to perfect the election in accordance with proposed § 1.25F–5(c)(3)(ii). The Treasury Department and the IRS do not interpret section 25F(g) and (c)(5) as allowing for any revocation once a State has completed its State election, including an advance election that has been perfected.

As described in section 25F(g)(1)(B), proposed § 1.25F–5(c)(2) would specify that an election must be made by the Governor of the State or by such other individual, agency, or entity as is designated under State law to make such elections on behalf of the State with respect to Federal tax benefits.

2. Advance Election Procedure

Notice 2025–70 stated that the Treasury Department and the IRS read section 25F(g) to provide that an election by a State to participate under section 25F may be made prior to or contemporaneously with the submission of the State's list of all organizations located in the State that satisfy the definition of an SGO. On December 12, 2025, the Treasury Department and the IRS issued Rev. Proc. 2026–6, *Advance Election to Participate Under Section 25F for 2027,* to allow States, including the District of Columbia, to make an Advance Election to participate in a new tax credit for calendar year 2027.

Proposed § 1.25F–5(c)(3) would provide guidance for States on how to submit an election in advance of the submission of the State SGO list, including guidance for States that have submitted an advance election for 2027 on Form 15714, *Advance Election to Participate Under Section 25F for 2027.* A State's failure to timely perfect its advance election by providing its State SGO list for a calendar year by the specified date in § 1.25F–5(c)(3)(ii) would result in a failure to meet the requirements of section 25F(g), effectively preventing any organization in the State from qualifying as an SGO for the calendar year for which the advance election was not perfected.

Proposed § 1.25F–5(c)(3)(iii) would provide that the IRS will maintain and publish on *https://www.irs.gov* a list of States that have made an advance election.

3. Timing of State Elections Under Proposed § 1.25F–5(c)(3)(i) and (c)(4)

Proposed § 1.25F–5(c)(3)(i) would identify the time period during which an advance election may be made and proposed § 1.25F–5(c)(4) would identify the time period during which a State election may be made with the submission of the State SGO list.

Notice 2025–70 stated that the Treasury Department and the IRS anticipated that the forthcoming proposed regulations under section 25F would require each State electing to participate under section 25F for the 2027 calendar year to submit to the IRS, by a specified date before January 1, 2027, the State's list of organizations located in that State meeting the requirements of section 25F(c)(5) for the 2027 calendar year along with the State's certification under section 25F(g)(2), and that those forthcoming proposed regulations would include a similar requirement for submission of an annual list and certification from each electing State for subsequent years.

Proposed § 1.25F–5(c)(3)(i)(A) would provide that, except as otherwise provided in the transition rule in proposed § 1.25F–5(c)(3)(i)(B), a State may submit an advance election through the IRS State section 25F portal on or after January 2 and on or before September 30 of the calendar year immediately preceding the calendar year for which the election is being made. The IRS will acknowledge or otherwise confirm receipt of a State's advance election.

Proposed § 1.25F–5(c)(3)(i)(B) would provide a transition rule for the first calendar year for which the State makes an election. Proposed § 1.25F–5(c)(3)(i)(B)(*1*) would provide that, for calendar year 2027, a State must submit an advance election on Form 15714 on or before January 1, 2027. Proposed § 1.25F–5(c)(3)(i)(B)(*2*) would provide that, for future years, a State making its first election to participate under section 25F must submit an advance election as provided in future guidance. Consistent with these transition rules, proposed § 1.25F–5(c)(4) would provide that, for the first year in which the State is electing to participate under section 25F, it cannot make its election with the submission of the State SGO list.

During the last three months of the immediately preceding calendar year or on January 1 of the year for which the election is being made, a State may make its election to participate under section 25F either as part of submitting its State SGO list for that year with the required information and certifications, or by perfecting its advance election made under proposed § 1.25F–5(c)(3)(i)(A) by providing its State SGO list for that year with the required information and certifications.

Several stakeholders requested clarification that the deadline for an election to participate for the 2027 calendar year should be after January 1, 2027, consistent with section 25F(g)(1)(A). For calendar year 2027 only, a State must submit its advance election on or before January 1, 2027, however, the State may perfect its advance election by submitting its State SGO list on or before February 15, 2027.

Some stakeholders recommended clarifying that the election deadline for calendar years after 2027 should be no later than 11:59 p.m. on January 1 of the calendar year, to accommodate an election made by a Governor who is newly inaugurated. The Treasury Department and the IRS agree and clarify that, for these purposes, ''on or before January 1 of that year'' means up to 11:59 p.m. on January 1.

4. Certifications and Other Required Information for State Elections

Proposed § 1.25F–5(c)(5) would require that the person with authority to make the State election, or a designated official, certify that the individual, agency, or entity making the State election has the authority to make the State election on behalf of the State, and the person authorizing any individuals as designated officials under proposed § 1.25F–5(b)(2) has the authority to do so.

In addition, proposed § 1.25F–5(c)(5) would require the person with authority to make the State election or a designated official to:

(1) Provide the enacted statutory or regulatory provisions that are binding on the State and establish the authority of an individual to make the State election on behalf of the State, if the individual making the election is not the Governor of the State (or the Mayor of the District of Columbia);

(2) Provide the required information and certifications for each SGO on the State SGO list;

(3) Certify that the State SGO list includes every organization located in the State that is seeking inclusion on the State SGO list, and that meets the definition of an SGO, and is operating in a manner that satisfies the operational requirements in section 25F(d) and proposed § 1.25F–3(c) and the applicable State requirements;

(4) Provide the certification of State policies and procedures required for its

State SGO list in proposed § 1.25F–5(d)(6);

(5) Describe any tax credit (including relevant State statutes, regulations, and other authoritative guidance) available under State law for contributions made to SGOs during the calendar year for which the State is electing to participate under section 25F; and

(6) Provide any other information and certifications described in future guidance.

*D. State SGO Lists*

1. Overview

Section 3.03 of Notice 2025–70 stated that the Treasury Department and the IRS interpret section 25F(g) as requiring each covered State to verify that each organization on the State's list satisfies all the requirements of section 25F(c)(5). Section 3.04 of Notice 2025–70 further stated that the Treasury Department and the IRS anticipate that States will be required to have implemented, and to comply with, various procedures to verify that the required information submitted by the covered State is accurate and complete. Section 3.04 of Notice 2025–70 requested comments on what types of uniform policies, procedures, recordkeeping, or other requirements would be reasonable to ensure States can reliably verify that each organization meets the requirements of section 25F(c)(5), and, for States with similar programs, how those States determine whether organizations are meeting applicable requirements.

Many stakeholders favored self-attestation by SGOs that they met the requirements of section 25F(c)(5) so as to avoid the need for any State-level review process, stating that requiring States to verify compliance is overly burdensome and could discourage participation. Several stakeholders expressed concern that providing States with significant discretion over organizations seeking certification as an SGO would permit State officials to discriminate against organizations based on factors other than compliance with the requirements of section 25F. Some stakeholders requested explicit limits on State authority to prevent intrusion into SGO operations, as well as an appeals process for any organizations excluded from a State's list based on the State's administration of SGO requirements.

Proposed § 1.25F–5(d) would provide guidance on State SGO lists. Proposed § 1.25F–5(d)(2) and (3) would describe the information and certifications required as part of the State's election or advance election for a calendar year. Proposed § 1.25F–5(d)(4) would provide a transition rule for an organization that has not yet been required to provide information and certifications. Proposed § 1.25F–5(d)(5) would provide a procedure that applies when an organization's application for recognition of tax-exempt status is pending with the IRS. Proposed § 1.25F–5(d)(6) would require a State to make a certification regarding its policies and procedures. Proposed § 1.25F–5(d)(7) would provide rules for changes to a State SGO list, and proposed § 1.25F–5(d)(8) would provide rules for the removal of an SGO from the IRS SGO list. Proposed § 1.25F–5(d)(9) would provide for the publication of the names of covered States and their State SGO lists on *https://www.irs.gov.*

2. Information the State Is Required To Provide About Each SGO on Its State SGO List

Proposed § 1.25F–5(d)(2) would set forth the information that a State is required to provide annually with respect to each organization named on the State SGO list, including the name, the EIN, address, and telephone number of the organization; whether the organization has received recognition as a section 501(c)(3) public charity, or has a pending application for such recognition; and any other information the IRS deems necessary for purposes of administering the requirements of section 25F as may be described in future guidance.

3. Certifications the State Is Required To Provide About Each SGO on Its State SGO List

Except as provided by the transition rule described in part V.D.4. of this Explanation of Provisions, proposed § 1.25F–5(d)(3) would require the State to certify that, with respect to each organization included on the State SGO list, the organization is located in the State and the organization prevents the co-mingling of qualified contributions with other amounts by maintaining a segregated section 25F account exclusively for qualified contributions, depositing all qualified contributions into its section 25F segregated account, and maintaining a complete set of books and records for its section 25F segregated account. The State also would be required to certify that the organization satisfies each of the operational requirements in section 25F(d) and proposed § 1.25F–3(c) and that the State has determined whether the SGO is a single-State or multistate SGO, reviewed the annual financial and programmatic audit report the organization is required to provide to the State, reviewed annual certifications and other information the organization is required to provide to the IRS and investigated any failure by the SGO to provide the required certifications and other information, and has become reasonably satisfied that the SGO has corrected the failure, if possible, or has put in place procedures to prevent future failures. Finally, a State would be required to certify that the organization satisfies any other requirements the IRS deems necessary for purposes of administering section 25F as may be described in future guidance.

The Treasury Department and the IRS request comments on the certifications States would be required to make in accordance with proposed § 1.25F–5(d)(3), including any other certifications that should be required for a multistate SGO. Comments are also requested on whether any certification is disproportionately burdensome compared to the benefits to tax administration.

4. Transition Rule for an Organization That Has Not Yet Been Required To Provide Information and Certifications to the IRS

In recognition of the fact that much of the required reporting is of data derived from operations in the prior fiscal year, proposed § 1.25F–5(d)(4) would provide a transition rule for recently formed entities and other organizations without such historical data that have not yet been required to report on their operations as an SGO. This transition rule allows the State to rely on the organization's governing documents or bylaws, written policies and procedures, and other documentation the organization provides to the State as part of its request to be included on its State SGO list, reducing the burden on the State for this type of SGO.

However, for each year for which such an organization is included on the State SGO list during this transition period, proposed § 1.25F–5(d)(4) would require the State to determine that the organization's provisions, policies, and procedures expressly require the organization to satisfy the operational requirements in section 25F(d) and proposed § 1.25F–3(c), and that the documentation and information available to the State evidences the organization's ability and intent to satisfy such operational requirements. Proposed § 1.25F–5(d)(4) also would require the organization to concurrently provide the State with a copy of any information and certifications required to be provided to the IRS before the end of the transition period.

5. Procedure That Would Apply When an Organization's Application for Recognition of Tax-Exempt Status Is Pending With the IRS

Proposed § 1.25F–5(d)(5) would allow a State to include on its State SGO list those organizations whose application for recognition of tax-exempt status is pending with the IRS, but only if the State includes on its State SGO list all organizations seeking inclusion on that list whose application for recognition of tax-exempt status is pending with the IRS, the State has complied with the requirements of proposed § 1.25F–5(d)(4) for each organization, and the State makes the required certifications regarding the organization's tax-exempt status. The required certifications include that the organization has applied for tax-exempt status as a section 501(c)(3) public charity, the organization's tax-exempt status, if granted, will be effective retroactively to a date that is on or before January 1 of the year for which the State SGO list applies, and the State SGO list indicates that such organization's tax-exempt status is pending IRS recognition. The determination of whether tax-exempt status will be effective retroactively to a date on or before that January 1 is determined by the date of the formation of the organization and the date of its application for recognition of tax-exempt status. *See* section 6.09 of Rev. Proc. 2026–5, 2026–1 I.R.B. 258 (updated annually).

As provided in proposed § 1.25F–5(d)(9)(ii), discussed in part V.D.9 of this Explanation of Provisions, the IRS will add each of these organizations to the IRS SGO list upon determining that the organization qualifies for tax-exempt status as a section 501(c)(3) public charity, if the organization consents to being included on the IRS SGO list.

6. Certification of State Policies and Procedures

Proposed § 1.25F–5(d)(6) would require a State to certify that its policies and procedures, including its procedures for assessing and responding to audit results, enable the State to make its own determination that each organization on the State SGO list is located in the State, is in compliance with section 25F(c)(5)(A) and (B) and § 1.25F–3(b)(1) through (4) and (6) and is operating in a manner that satisfies the operational requirements in section 25F(d) and proposed § 1.25F–3(c) and the applicable State requirements. Proposed § 1.25F–5(d)(6) also would require that a State certify that its policies and procedures provide for the prompt removal of an organization from the State SGO list, and notification to the IRS through the IRS State section 25F portal of such removal, upon a determination that an organization is not an SGO or does not meet the applicable State requirements. A State also would be required to certify that its policies and procedures require any publicly available lists of SGOs maintained by the State to be identical to the most recently submitted State SGO list, include the IRS SGO list's URL (Uniform Resource Locator), and state that a taxpayer may rely on an organization's inclusion on the IRS SGO list in accordance with proposed § 1.25F–2(b). Finally, proposed § 1.25F–5(d)(6) would require that the State certify that its policies and procedures ensure that the State's procedures before and after the removal of an organization from the State SGO list are fairly administered and afford due process in accordance with applicable Federal and State laws.

7. Changes to State SGO List

Proposed § 1.25F–5(d)(7)(i) and (ii) would provide guidance regarding the time period during which a State may replace or supplement its State SGO list for a calendar year. A State would be able to replace or supplement its State SGO list for a calendar year at any time before the deadline for perfecting or completing an election for that year by submitting the change in the IRS State section 25F portal in accordance with guidance published in the **Federal Register** or Internal Revenue Bulletin (see §§ 601.601(d)(2) and 601.602 of this chapter) or, as appropriate, in forms, instructions, and publications available on *https://www.irs.gov* and through the IRS SGO portal or IRS State section 25F portal, as applicable. A State would not be able to make any additions to the State SGO list for a calendar year after that deadline; instead, any additions a State seeks to make after such deadline may be included as part of the State's submission of its State SGO list for the following calendar year.

Proposed § 1.25F–5(d)(7)(iii) would provide that a State may remove an SGO from its State SGO list at any time during the calendar year to which that list applies. If an SGO requests to be removed from a State SGO list, the State would be required to comply.

Many stakeholders requested guidance regarding the State's discretion in removing an SGO from the State SGO list. Stakeholders expressed concern that States could remove SGOs arbitrarily or for political reasons and sought rules to ensure transparency and uniformity regarding the removal process. In response, proposed § 1.25F–5(d)(7)(iii) would provide that a State could remove an organization from its State SGO list if the State determines, through a procedure providing due process to the organization, that the organization is not located in the State, does not satisfy the requirements for an SGO in section 25F(c)(5)(A) or (B) and proposed § 1.25F–3(b), or is not operating in a manner that satisfies the operational requirements in section 25F(d) and proposed § 1.25F–3(c) and the applicable State requirements. In each event, the State would need to indicate the removal and its effective date on its State SGO list and promptly notify the IRS so the IRS can remove the SGO from the IRS SGO list for the current year. The organization would be removed from the relevant part of the IRS SGO list for the current year to ensure that any contributions to the organization after the date of its removal from the State or IRS SGO list are not treated as qualified contributions.

8. Removal of a Non-Compliant Organization From the IRS SGO List

Proposed § 1.25F–5(d)(8) would provide the list of circumstances under which an organization may be removed from the IRS SGO list. Under proposed § 1.25F–5(d)(8)(i), the IRS would remove an organization from the IRS SGO list following its determination that the organization is not a section 501(c)(3) public charity or automatic revocation of the organization's tax-exempt status by function of section 6033(j). Proposed § 1.25F–5(d)(8)(ii) would further provide that the IRS may remove an organization following its determination that the organization has failed to comply with a requirement of section 25F (other than the tax-exempt status requirement in section 25F(c)(5)(A)), or has failed to comply with the regulatory reporting, recordkeeping or audit requirements, including a failure to report qualified contributions in accordance with proposed § 1.25F–4(c). This IRS determination of non-compliance with the requirements of section 25F would be a Federal tax controversy under section 7803(e)(3) and § 301.7803–2, which provides the organization an opportunity to seek review by the IRS Independent Office of Appeals in the time and manner prescribed in applicable forms, instructions, or other administrative guidance. Under proposed § 1.25F–5(d)(8)(iii)(A), the IRS would remove an organization from the part of the IRS SGO list for a particular covered State upon notification that it has been removed from the State SGO list of that covered State.

Finally, proposed § 1.25F–5(d)(8)(iii)(B) would provide that, if a multistate SGO that is removed from a State SGO list under proposed § 1.25F–5(d)(8)(iii)(A) continues to satisfy the operational requirements in section 25F(d) and proposed § 1.25F–3(c) and one or more other covered States' applicable requirements as described in proposed § 1.25F–5(e)(1), the SGO will remain on the IRS SGO list with respect to such other covered States, subject to any further discretionary examination of the SGO by such other covered States or the IRS.

9. Publication of Covered States and State SGO Lists

Proposed § 1.25F–5(d)(9)(i) would provide that the IRS will maintain and publish the IRS SGO list on *https://www.irs.gov.* For those SGOs that have authorized the disclosure of their information on the IRS SGO list, the IRS SGO list will contain each SGO included on a State SGO list for each of the covered States for the calendar year and reflect each removal from a State SGO list and the date of the removal. If an SGO does not consent to the disclosure of its information on the IRS SGO list, a taxpayer would not be able to use the reliance offered by the IRS SGO list for purposes of establishing that the taxpayer's contribution to that organization is a qualified contribution. Instead, the taxpayer would need to rely on other evidence to establish that the organization is an SGO. If an SGO is removed from the IRS SGO list, its name and identifying information would be displayed in strike-through text, along with the date of the organization's removal from the list, to provide taxpayers with the information they may need in determining if their contribution is being made, or was made, to a valid SGO and thus is a qualified contribution eligible for the section 25F credit.

Proposed § 1.25F–5(d)(9)(ii) would provide for updating the IRS SGO list to include an organization whose tax-exempt status was pending when the State SGO list was submitted. Upon determining that the organization qualifies for tax-exempt status and that the effective date of such tax-exempt status is on or before January 1 of the calendar year for which the State SGO list applies, the IRS would add the organization to the IRS SGO list for that year as soon as the organization gives permission to be included on that list.

The publication of an IRS SGO list is consistent with feedback requesting that the IRS publish information to facilitate taxpayers' ability to determine which tax-exempt organizations are eligible to receive qualified contributions. *See* proposed § 1.25F–2(b)(1) (permitting reliance on the IRS SGO list to establish that a contribution is being made to an SGO).

*E. State Administrative Requirements*

Stakeholders submitted a broad range of comments regarding the level of discretion the State should have in reviewing and certifying SGOs. Concerns were raised that States might seek to prioritize particular types of schools or students or otherwise implement State education policies in a manner inconsistent with section 25F.

Proposed § 1.25F–5(e) would provide guidance on State administrative requirements. Proposed § 1.25F–5(e)(1) would provide that a State must require that SGOs meet all generally applicable State requirements for charitable organizations, including any State requirements that any organization must satisfy to be authorized to do business in the State and to solicit charitable contributions in the State. Additionally, States would be required to impose certain application, documentation and financial reporting requirements that are reasonably tailored to support the State's determination that the organization satisfies the operational requirements in section 25F(d) and proposed § 1.25F–3(c), and to facilitate the prevention and detection of fraud or abuse, including the misuse of scholarship funds such as through the duplication of scholarship awards to the same student for the same qualified elementary or secondary education expense.

Proposed § 1.25F–5(e)(2) would prohibit a State from requiring SGOs to operate in a manner that is more restrictive than the requirements set forth in section 25F(c)(5) and proposed § 1.25F–3(b) and (c), such as by limiting the type of school that scholarship recipients may attend or the types of qualified elementary or secondary education expenses for which scholarship funds may be used. This prohibition would be responsive to stakeholder feedback expressing concern that permitting States to impose additional requirements on SGOs or to exercise discretion to exclude an otherwise qualifying organization from the State SGO list could lead to arbitrary determinations and improper discrimination.

Proposed § 1.25F–5(e)(3) would provide that the procedures a State implements in accordance with proposed § 1.25F–5(e) are subject to Federal review. Upon discovering a pattern of irregularities or noncompliance, the IRS, in its discretion, may require a State to modify its procedures to ensure that its determinations regarding an organization's location in the State, and its satisfaction of proposed § 1.25F–3(b) and of the operational requirements in section 25F(d) and proposed § 1.25F–3(c) are being administered in accordance with the applicable statutory, regulatory, and appropriate State requirements.

Nothing in section 25F or these proposed regulations would alter States' obligations to comply with all other applicable Federal and State law, for example, the requirements under the Individuals with Disabilities Education Act, 20 U.S.C. 1400 *et seq.*

## VI. Proposed Applicability Date

Each of proposed §§ 1.25F–1 through 1.25F–5 is proposed to apply to taxable years ending on or after the date on which the Treasury decision adopting these regulations as final regulations is published in the **Federal Register**. Taxpayers, organizations, and States may rely on these proposed regulations for qualified contributions made on or after January 1, 2027, in taxable years ending before the date the Treasury decision adopting these regulations as final regulations is published in the **Federal Register**, provided that taxpayers, organizations, and States follow the portions of the proposed regulations applicable to each in their entirety and in a consistent manner.

## Special Analyses

### I. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

The proposed regulations have been designated by the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) as subject to review under Executive Order 12866 pursuant to the Memorandum of Agreement (MOA, July 4, 2025) between the Treasury Department and the Office of Management and Budget regarding review of tax regulations. OIRA has determined that the proposed rulemaking is economically significant

and subject to review under Executive Order 12866 and section 1(c) of the Memorandum of Agreement. Accordingly, the proposed regulations have been reviewed by OMB.

Executive Order 14192, titled ''Unleashing Prosperity Through Deregulation,'' was issued on January 31, 2025. Section 3(a) of E.O. 14192 requires an agency, unless prohibited by law, to identify at least 10 existing regulations to be repealed when the agency issues a new regulation. In furtherance of this requirement, section 3(c) of E.O. 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 E.O. 12866) that would impose total costs greater than zero is considered an E.O. 14192 regulatory action. This proposed rule, if finalized as proposed, is, therefore, expected to be an E.O. 14192 regulatory action.

*Need for Regulation*

Public Law 119–21, 139 Stat. 72 (July 4, 2025), commonly known as the OBBBA, added new section 25F (*Qualified elementary and secondary education scholarships*) to the Code. Section 25F creates a dollar-for-dollar nonrefundable Federal tax credit of up to $1,700 for contributions made by individuals to scholarship granting organizations (SGOs).

The proposed regulations provide clarity to taxpayers, States, and SGOs to make the section 25F credit operable, including defining certain terms found in the statute and establishing procedures that ensure that the qualified contributions that generate the Federal tax credits are implemented in accordance with the statute.

*The Statute and the Proposed Regulations*

Section 70411 of the OBBBA added section 25F to the Code. Section 25F creates a tax credit for qualified contributions made by individual taxpayers to SGOs. SGOs are a type of charitable tax-exempt organization subject to unique reporting rules and operational and spending restrictions. They are required to focus their spending almost exclusively on the provision of scholarships for students eligible to attend elementary or secondary school who reside in households where the household income falls below a certain threshold. These scholarships are restricted to being used for qualified elementary and secondary school expenses, and the SGO must provide scholarships to at least 10 students per year who do not all attend the same school.

The proposed regulations provide a number of definitions and clarifications to the statutory rules governing section 25F. In particular, the proposed regulations explain the calculation of the credit amount a taxpayer may claim and specify that qualified contributions must be made by individuals to receive the section 25F credit.

In addition, the proposed regulations address operational requirements of SGOs. The proposed regulations provide guidance for tax-exempt organizations that wish to operate as SGOs in multiple States, including what it means to be ''located in the State.'' Furthermore, the proposed regulations consider the statutory requirement that an SGO spend not less than 90 percent of the organization's income on scholarships. Recognizing the potential for organizations to incur legitimate administrative costs in excess of 10 percent of income, the proposed regulations provide a safe harbor for organizations whose scholarship granting activities are at least 85 percent of the organization's activities. Such organizations may satisfy the 90% of income spending requirement solely on the basis of a section 25F segregated account, rather than on the basis of all of the organization's income. The proposed regulations also provide that an SGO is responsible for verifying that the scholarships awarded from qualified contributions it collects are used only to fund qualified elementary or secondary school expenses for eligible students.

To clarify the definition of an eligible student, the proposed regulations provide guidance regarding the definition of household income and family size and clarify that the income limits specified in the statute will be adjusted for family size. The proposed regulations offer various methods SGOs may use to verify that a potential scholarship recipient meets the eligibility criteria set out in the statute, including safe harbors that do not require SGOs to conduct a full, direct verification of recipients' household income. Under these safe harbors, students qualify as eligible to benefit from section 25F scholarship funds if someone in their household already benefits from one of a few specified needs-based benefit programs, if the student attends a school serving students in certain qualified census tracts and receives a scholarship for academic tutoring or special needs services, or if a student has been placed in foster care.

The proposed regulations further clarify the definition of student eligibility by specifying that students are treated as ''solely within the State'' if the student is a resident of the State under State law, subject to two exceptions. The proposed regulations also provide rules defining a ''disqualified person.''

The proposed regulations provide reporting and recordkeeping requirements for SGOs, including an annual audit requirement. They also set forth procedures for donors to report and SGO to substantiate the amount of qualified contributions made by the donor during the taxable year.

The proposed regulations ensure that SGOs are able to conduct their scholarship-granting activities with the maximum flexibility permitted under the statute. The proposed regulations clarify that States cannot condition inclusion on the SGO list on any additional requirements more stringent than those specified in the statute and in the proposed regulations; nor can a State exercise discretion over which SGOs are included or excluded from the SGO list. The proposed regulations also prevent States from placing restrictions on the definition of qualified elementary or secondary school expenses.

*A. Baseline*

The Treasury Department and the IRS have assessed the benefits and costs of the proposed regulations relative to a no-action baseline reflecting anticipated Federal income tax-related behavior in the absence of these proposed regulations.

*B. Affected Entities and Taxpayers*

The proposed regulations would affect taxpayers who make qualified contributions to SGOs and seek to claim the section 25F credit and students who receive scholarships funded with such contributions. They would also affect the SGOs that solicit qualified contributions and award scholarships from these contributions, as well as the States that may choose to participate in the section 25F credit and, in doing so, assess the eligibility of SGOs and authorize SGOs to facilitate such scholarships.

As of August 2026, 30 States have elected to participate in the section 25F credit. The Treasury Department and the IRS estimate that 600 to 700 SGOs [4] will operate in these States by 2030. The Treasury Department and the IRS also

[4] This range is based on the average amount of SGOs operating at the State level, in States which have tax credit scholarships. The same amount of SGOs per State is assumed to obtain in each State which opts into the Federal credit.

estimate that more than 11 million taxpayers will make qualified contributions totaling $26 billion to these SGOs annually.[5] This is expected to allow the SGOs operating in these States to fund 2 million annual ($12,000)[6] full-time scholarships, or 5 million part-time ($4,500) scholarships, per year by 2030.

*C. Economic Effects of the Proposed Regulations*

In general, the proposed regulations would provide clarity to operationalize the section 25F credit. This clarity is expected to benefit the up to 2 million students who are expected to receive a scholarship annually. Research shows that educational choice can lead to increases in college enrollment and test scores, particularly for students from economically disadvantaged backgrounds.[7] The students who benefit from the proposed regulations are therefore expected to enjoy an increased probability of completing secondary school and attending college. Because the financial return from each additional year of schooling is approximately 10%,[8] the students who benefit from the proposed regulations are expected to experience a significant increase in lifetime earnings.

The following sections describe in detail the potential economic impacts of certain specific elements of the proposed regulations.

1. Calculation of Tax Credit

Under section 25F(b), the amount of the credit allowed for a taxpayer's qualified contributions is reduced by any State tax credit for such contributions and is limited to a maximum of $1,700. As noted in part II.F. of the Explanation of Provisions, the Treasury Department and the IRS interpret section 25F(b) as limiting the credit to $1,700 after applying the State credit reduction, notwithstanding that the $1,700 limitation in section 25F(b)(1) appears before the State credit reduction in section 25F(b)(2). This interpretation benefits taxpayers by maximizing their ability to claim the section 25F credit if they claim state credits for qualified contributions.

Section 25F(e) states that any qualified contribution for which a section 25F credit is allowed is not to be taken into account as a charitable contribution for purposes of section 170. Section 25F(f) further specifies that the section 25F credit may be carried forward for up to 5 years if the amount of the credit allowable exceeds the taxpayer's tax liability. The proposed regulations provide a stacking order to operationalize these limitations while maximizing the economic benefits for taxpayers relative to an alternative.

Proposed § 1.25F–2(c) provides a clear and taxpayer-favorable methodology consistent with the statutory limitations for calculating the amount of the section 25F credit, beginning with the aggregate amount of qualified contributions. Under the proposed rule, taxpayers must first determine the aggregate amount of qualified contributions for the tax year and then determine which State credits were claimed on the taxpayer's State tax return or otherwise allowed with respect to those qualified contributions. The amount allowable as a credit under section 25F(a) is then the lesser of the aggregate qualified contributions made during the tax year as reduced by any State tax credits allowed for such qualified contributions and $1,700.[9] The proposed rule clarifies that, if a State credit is allowed with respect to an individual's contributions of cash to an SGO that includes both a qualified contribution and an amount that is not a qualified contribution, then the State credit will be treated as first being allowed with respect to the amount of the donor's contribution that is not a qualified contribution and only thereafter treated as being allowed with respect to the donor's qualified contributions to an SGO.

This proposed rule benefits the taxpayer by adopting an ordering rule that preserves the maximum credit available under the statute. To illustrate this benefit, consider an example taxpayer who lives in a State that allows a 100% tax credit of up to $2,000 for contributions to SGOs. Suppose this taxpayer makes a cash contribution of $5,000 to an SGO and designates $1,700 of this contribution as a section 25F qualified contribution. For simplicity, further suppose that this taxpayer does not itemize the taxpayer's Federal deductions.

The proposed regulation allows the taxpayer to count the $3,300 that is not designated as a ''qualified contribution'' toward the State tax credit (if otherwise eligible). In this example, the taxpayer could then receive $2,000 in State tax credits and the remaining $1,700 of the qualified contribution would qualify for the section 25F credit, without violating the section 25F(e) denial of double benefit requirement. Under the proposed regulations, this contribution would reduce the taxpayer's Federal tax liability by $1,700, and reduce the State tax liability by $2,000, for a total tax benefit of $3,700.

An alternative interpretation of the statute could have instructed the taxpayer to use State credits to reduce the amount of qualified contributions before the amount of non-qualified contributions. Under this alternative, the taxpayer would have been required to reduce their $1,700 qualified contribution to zero, because the taxpayer claimed $2,000 as a credit against State tax liability. Under this alternative, the taxpayer's $5,000 contribution would not reduce the taxpayer's Federal tax liability, but would reduce the State tax liability by $2,000, for a total tax benefit of $2,000.

By adopting this interpretation of the statute, and providing a corresponding ordering rule, the proposed regulations provide the example taxpayer with a net benefit of $1,700 relative to the alternative interpretation referenced in the previous paragraph. Similar benefits would be conferred upon all taxpayers who avail themselves of both a State and a Federal credit for contributions to SGOs. The Treasury Department and the IRS estimate that approximately 46.5 million taxpayers[10] will be eligible to take both a State and a Federal tax credit for contributions to SGOs. At a take-up

[5] Estimates are produced using a 10% take-up rate. This projected take-up rate is based on data from the 2023 Panel Study of Income Dynamics, variable ER85243, and estimates of the increased propensity to contribute when directing the expenditure of one's tax dollars. *Li, Sherry Xin, et al.* ''*Directed giving enhances voluntary giving to government.*'' *Economics Letters 133 (2015): 51–54.*

[6] The annual amount of $12,000 is a rounded average of the cost to attend one year of private elementary or secondary school in the states which have opted in to the section 25F credit as of August 2026. ''Average Private School Tuition Cost'', Private School Review for 2026, *https://www.privateschoolreview.com/tuition-stats/private-school-cost-by-state,* last accessed May 1, 2026. Internal Revenue Service, Federal Scholarship Tax Credit (FSTC). *https://www.irs.gov/government-entities/federal-state-local-governments/federal-scholarship-tax-credit-fstc,* last accessed August 11, 2026.

[7] Deming, David J., Justine S. Hastings, Thomas J. Kane, and Douglas O. Stanger. ''School choice, school quality, and postsecondary attainment.'' *American Economic Review* 104.3 (2014): 991–1013; Angrist, Joshua D., Parag A. Pathak, and Christopher R. Walters. ''Explaining charter school effectiveness.'' *American Economic Journal: Applied Economics* 5.4 (2013): 1–27.

[8] Deming, David J. ''Four facts about human capital.'' *Journal of Economic Perspectives* 36.3 (2022): 75–102. Urquiola, Miguel. ''Competition among schools: Traditional public and private schools.'' *Handbook of the Economics of Education.* Vol. 5. Elsevier, 2016. 209–237.

[9] After taking the lesser of these two amounts, the amount allowable as a credit is then augmented by the value of any unused credit carried forward to the tax year from an earlier year.

[10] IRS, Statistics of Income Division, Historic Table 2. Last accessed in July 2026. *https://www.irs.gov/statistics/soi-tax-stats-historical-data-tables.*

rate of 10%, this proposed rule is expected to provide a net benefit of at most $1,700 per year to 3.1 million taxpayers, and at most $3,400 per year to an additional 1.55 million married taxpayers.

In addition to the financial benefits that the proposed rule would confer on the taxpayers who claim both Federal and State tax credits for contributions to SGOs, the proposed regulations will benefit all taxpayers by providing clarity regarding the calculation of the credit amount each taxpayer may claim under section 25F. These clarifications will help to preserve horizontal equity between taxpayers. In the absence of the proposed regulations, taxpayers may encounter difficulty in ascertaining which portions of their contribution are eligible for a given tax credit or deduction. Without further guidance, taxpayers in similar tax situations, who make similar gifts to SGOs, may come to different conclusions about how to maximize the economic benefits from their charitable contributions.

2. Definition of Terms Needed To Determine Student Eligibility for Scholarships

The proposed regulations define both income and a family-size adjustment for income. The income definition expands the number of students who would be eligible for a scholarship from an SGO that receives qualified contributions and minimizes compliance burdens relative to alternatives.

Section 25F(c)(2) defines an eligible student as an individual who is a member of a household with a calendar-year income not exceeding 300 percent of the area median gross income, and who is eligible to enroll in a public elementary or secondary school.

Section 25F(c)(2)(A) specifies an income limit for potential scholarship recipients. This income limit is set at ''300 percent of the area median gross income (as such term is used in section 42).'' Section 42(g)(4) provides that ''paragraph (2) (other than subparagraph (A) thereof) . . . of section 142(d) . . . shall apply for purposes of determining whether any project is a qualified low-income housing project and whether any unit is a low-income unit.'' Section 142(d)(2)(B)(i) provides a definition of area median gross income as follows:

''The income of individuals and area median gross income shall be determined by the Secretary in a manner consistent with determinations of lower income families and area median gross income under section 8 of the United States Housing Act of 1937 (or, if such program is terminated, under such program as in effect immediately before such termination). Determinations under the preceding sentence shall include adjustments for family size.''

i. Defining a Family Size Adjustment

The proposed regulations use family size adjustments as defined by the Department of Housing and Urban Development (HUD) to administer lower income housing assistance under section 8 of the United States Housing Act of 1937 (Pub. L. 75–896) (Section 8 housing); see Table 1 below. Section 25F(c)(2)(A) specifies the income limit used to determine eligibility as ''300 percent of the area median gross income (as such term is used in section 42).'' To ensure consistency with the income limits used in section 42, the income limit must be calculated as the product of 300 percent of the area median gross income and the HUD family-size multiplier. For example, if a household of three lived in a location where the area median gross income was $100,000, a child in this household could be eligible to receive a scholarship funded by section 25F if the household's income was less than, or equal to, $270,000 (3 * $100,000 * 0.90). For a household of four living in the same area, this income limit would be $300,000 (3 * $100,000 * 1.0).

TABLE 1—CURRENT HUD FAMILY SIZE MULTIPLIERS

| Family size | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|---|---|---|---|---|---|---|---|---|
| Multiplier | 0.70 | 0.80 | 0.90 | 1.00 | 1.08 | 1.16 | 1.24 | 1.32 |

**Notes:** For each member of the family in excess of 8, the family size multiplier increases by 0.08.
Sources: Methodology for Determining FY 2026 Section 8 Income Limits, last accessed June 11, 2026. *https://www.huduser.gov/portal/datasets/il/il26/IncomeLimitsMethodology-FY26.pdf.*

Alternative family size adjustments are widely used in a similar fashion to achieve horizontal equity. Other alternatives were not considered for purposes of section 25F, because the statute references the HUD definition of area median gross income, which uses the HUD family size multiplier. The HUD multiplier and potential alternatives all balance adjusting for the higher costs associated with larger family units with the higher returns to scale available to larger family units.

ii. Defining Family Size

The proposed regulations define family size as the number of persons who reside in the same household as the eligible student, including the eligible student. If the eligible student is part of multiple households over the course of the year, the relevant household is the one in which the student resided for the majority of the year. If the student splits time equally among multiple households, the proposed regulation states that the relevant household is the one with the highest household income. This definition is chosen for its consistency with other commonly used definitions of family size. Relative to the alternative of not defining family size, its simplicity is expected to increase administrability and thus alleviate some of the burdens on SGOs and families as they determine which students are eligible to receive a scholarship funded by the section 25F credit.

iii. Defining Household Income

Having defined the income limits as a function of area median gross income and family size, the proposed regulations also provide guidelines for determining whether a student's household income exceeds these limits. As the income limits used to determine eligibility for a section 25F scholarship are closely related to those used by HUD in administration of section 8 housing and section 42 relating to the low-income housing credit, a natural candidate for the definition of household income under section 25F would also follow the definition used by HUD for those purposes. The proposed regulations would adopt this definition of income with one modification: household income includes only cash sources of income, and excludes non-cash sources of income, such as imputed income on net assets. When a family holds net assets of $50,000 or more, and the actual returns of this asset cannot be calculated, the HUD definition of annual income imputes returns on this asset based on the current passbook savings rate.[11] This

[11] 24 CFR 5.609 (2000), last accessed June 11, 2026. *https://www.ecfr.gov/current/title-24/subtitle-*

Continued

condition will often prove irrelevant for families who benefit from section 8 housing vouchers or section 42 rent restrictions: the most recent available data indicates that the median renter has a net worth of only $10,400, far below the threshold for imputing returns on net assets. By contrast, the median homeowner has a net worth of $396,000.[12] If the section 25F definition of household income were to conform exactly to the definition used by HUD to provide support to renter households, then many students who reside in owner-occupied households would be rendered ineligible to receive section 25F scholarships due to imputed income on family assets.

By using a definition of income that focuses exclusively on cash income, as opposed to the HUD definition of income, the proposed regulations greatly expand the universe of children who would be eligible to receive a scholarship funded through section 25F. The Treasury Department and the IRS estimate that, under the strict HUD definition, 64 percent of elementary and secondary school age children would be expected to be eligible to receive a scholarship, compared to the 95 percent of children expected to be eligible as a result of the exclusion of non-cash income provided in the proposed regulations.

These proposed regulations also benefit taxpayers and SGOs by reducing the burden placed on SGOs to verify eligible students' incomes: they are able to count only cash sources of income, without being required to augment this value with an imputation of the non-cash income received by a student's family or household.

The Treasury Department and the IRS also considered defining household income as adjusted gross income (AGI) as calculated on Form 1040. This alternative was not chosen for several reasons. First, AGI must be calculated based on the income and marital status of a tax unit. The statute contains references to households and families, rather than tax units. In general, a tax unit may consist of a smaller set of individuals than a household or a family.[13] Second, between 3 and 12 percent of U.S. children are not claimed on Federal tax returns. These unclaimed children are disproportionately concentrated in lower-income households[14] and therefore would likely be eligible to receive a scholarship financed by section 25F contributions if they had been claimed on a tax return. If the proposed regulations were to adopt AGI as the definition of income under section 25F, the proposed regulations would introduce inequities between children who are claimed as dependents on a Federal tax return, and those who are not because of potential claimants having insufficient taxable income to require the filing of a return. The Treasury Department and the IRS estimate that using AGI as the definition of household income would have reduced the number of children eligible to receive scholarships by 17%.[15]

3. Safe Harbor Rules for Student Eligibility

Section 25F(d)(1)(F)(i) specifies that SGOs must verify students' annual household income and family size to ensure that these students meet these eligibility requirements. The proposed regulations further reduce the administrative burden placed on SGOs associated with income verification by specifying certain safe harbors under which a student may be considered eligible. The proposed regulations include three safe harbors: one for students who live with an individual who receives certain specified types of needs-based social assistance; one for students generally who attend school in certain low-income or high-poverty census tracts and receive a scholarship for academic tutoring or special needs services; and one for students in the foster care system.

First, the proposed regulations specify that, if an individual in a student's household currently benefits from specified needs-based benefit programs, then that student may be considered categorically eligible to receive a section 25F scholarship. The Treasury Department and the IRS estimate that 36% of all students are covered by this safe harbor rule. The Treasury Department and the IRS estimate that the creation of this safe harbor will not change the number of students who are eligible to receive scholarships under section 25F.[16] Rather, the primary economic impact of this safe harbor is to allow SGOs to reduce the burden of satisfying the income verification requirement. With fewer hours and dollars devoted to the income verification process, this safe harbor would benefit the taxpayer by allowing a greater share of dollars received by SGOs to be paid out as scholarships. The Treasury Department and the IRS estimate that the cost savings to SGOs enabled by the proposed safe harbor will allow SGOs to fund nearly 45,000 scholarships (estimated using an average annual scholarship amount of $12,000).[17]

*A/part-5/subpart-F/subject-group-ECFR174c6349abd095d/section-5.609.*

[12] Aladangady, Aditya, Jesse Bricker, Andrew C. Chang, Sarena Goodman, Jacob Krimmel, Kevin B. Moore, Sarah Reber, Alice Henriques Volz, and Richard A. Windle (2023). *Changes in U.S. Family Finances from 2019 to 2022: Evidence from the Survey of Consumer Finances.* Washington: Board of Governors of the Federal Reserve System, October, *https://doi.org/10.17016/8799.*

[13] Larrimore, Jeff, Jacob Mortenson, and David Splinter. ''Household incomes in tax data: Using addresses to move from tax-unit to household income distributions.'' *Journal of Human Resources* 56.2 (2021): 600–631.

[14] Gee, Geoffrey, Goldin, Jacob, Gray-Hancuch, Joseph, Lurie, Ithai, and Vedant Vohra. (2026). The Claiming of Children on US Tax Returns. *National Tax Journal, 79*(1), 51–71. *https://doi.org/10.1086/736708.*

[15] To arrive at this estimate, Treasury and the IRS analyzed data from the American Community Survey, using methodology adapted from the CPS ASEC Tax Model to assign children to eligible tax units. U.S. Census Bureau, 2024 American Community Survey 1-Year Public Use Microdata Sample. *https://www.census.gov/programs-surveys/acs/microdata/access.html,* last accessed May 11, 2026. Lin, Daniel. ''Methods and assumptions of the CPS ASEC Tax Model.'' US Census Bureau (2022). *https://www.census.gov/content/dam/Census/library/working-papers/2022/demo/sehsd-wp2022-18.pdf.*

[16] The Treasury Department and the IRS used Census data from the American Community Survey to measure total household income and household size. Total household income was compared to 300% of area median gross income, as published by HUD. Using these data sources, the Treasury Department and the IRS have estimated that substantially all households with children eligible to attend elementary or secondary school, located in states which have elected to participate in the FSTC, have incomes that fall below the 300% of AMGI limit. U.S. Department of Housing and Urban Development, Office of Policy Development and Research (PD&R). HUD Multifamily Tax Subsidy Project (MTSP) Income Limits. *https://www.huduser.gov/portal/datasets/mtsp.html#data_2026,* last accessed June 12, 2026. U.S. Census Bureau, 2024 American Community Survey 1-Year Public Use Microdata Sample. *https://www.census.gov/programs-surveys/acs/microdata/access.html,* last accessed May 11, 2026. Internal Revenue Service, Federal Scholarship Tax Credit (FSTC). *https://www.irs.gov/government-entities/federal-state-local-governments/federal-scholarship-tax-credit-fstc,* last accessed June 12, 2026. Annual Update of the HHS Poverty Guidelines, 91 FR 1797 (January 15, 2026). *https://www.govinfo.gov/content/pkg/FR-2026-01-15/pdf/2026-00755.pdf* Last accessed June 15, 2026.

[17] As of June 2026, The Work Number charges $46.95 to verify one employer record for the period of one calendar year. If each eligible student lives in a household where the adults collectively have two employer records per calendar year, verifying the sources of household income associated with the scholarship application will cost approximately $100. The proposed safe harbor will reduce these costs for scholarship applications from students who live in states which have elected to participate in the FSTC, and who live with at least one recipient of a means-tested assistance program. The Treasury Department and the IRS analyzed data from the American Community Survey and determined that approximately 6 million households, containing 10 million children between the ages of 5 and 17, meet these criteria. Per EdChoice, 52% of parents would prefer to educate their child at a private school, charter school, or homeschool. If 52% of the children who are eligible to receive section 25F scholarships

Second, the proposed regulations specify that, if an SGO provides scholarships to individual students at a school in a low-income area for individual academic tutoring or for special needs services of a special needs student, and the recipient students are selected by the school on the basis of the particular student's need, the SGO may consider those students as having satisfied the income eligibility requirement if either the school is located in, or at least 80% of students at the school reside in, a qualified census tract. A census tract is designated as ''qualified'' under section 42 if a sufficiently large number of resident households are low-income or if the poverty rate there is sufficiently high.[18] The Treasury Department and the IRS do not have readily available parameters and models to quantify the number or location of schools that work with SGOs to fund tutoring or other educational services for their students. The Treasury Department and the IRS estimate that the creation of this safe harbor will modestly increase the number of students who are eligible to receive scholarships under section 25F, and that it will facilitate the awarding of scholarships to students whose family may be unlikely to provide sufficient information to allow the SGO to verify the students' household income. This safe harbor would confer eligibility on approximately 170,000 students who would otherwise not be considered eligible. This represents only 0.6% of the estimated number of eligible students, inclusive of this safe harbor.[19] However, this safe harbor is expected to reduce the barriers to take-up faced by students who live in qualified census tracts, or who attend school in a qualified census tract, and thereby increase these students' access to educational resources provided through section 25F scholarships.[20]

Finally, the proposed regulations specify that a foster child is categorically eligible to receive a scholarship under section 25F. Nearly 350,000 school-age children were in the foster care system as of December 2024.[21] The median amount of time a foster child remains in foster care is 15 months,[22] during which time as many as one-third of foster children will experience at least three separate placements.[23] If a child is a transitory resident of several different households over the course of the year, most of which do not reflect the true set of resources available to that child,[24] then an SGO may be uncertain how to verify this child's household income or receive cooperation from all available households. Nevertheless, children in foster care disproportionately come from families with incomes well below 300% of area median gross income, which would make these children eligible to receive a section 25F scholarship.[25] This proposed rule would reduce the administrative burden associated with verifying household income for foster children by reducing any uncertainty the SGO may face in the income verification process. This would further benefit the taxpayer, eligible students, and SGOs by allowing the SGO to reduce expenses on income verification; the Treasury Department and the IRS estimate that the associated savings total nearly $20 million per year and could be redirected toward scholarships for at least an additional 1,500 children.[26]

As a result of the choice to define household income as cash income, and the inclusion of these three safe harbors, the Treasury Department and the IRS estimate that 96% of children located in States that have elected to designate SGOs under section 25F will be eligible to receive section 25F scholarship funds.

under this safe harbor apply to an SGO for a scholarship, the cost of conducting employment verifications for all of these applications will be $520 million. If the cost of an average scholarship is assumed to be $12,000 per child, these cost savings are sufficient to cover an average annual scholarship for nearly 45,000 eligible children. ''Social Service Verification,'' Equifax: The Work Number, *https://theworknumber.com/solutions/products/social-service-verification,* last accessed June 16, 2026; U.S. Census Bureau, *2024 American Community Survey 1-Year Public Use Microdata Sample. https://www.census.gov/programs-surveys/acs/microdata/access.html,* last accessed May 11, 2026; ''Monthly Public Opinion Tracker,'' EdChoice, *https://edchoice.mcdatahub.com/edchoice/,* last accessed June 16, 2026.

[18] See § 42(5)(B)(ii).

[19] To arrive at this estimate, the Treasury Department and the IRS analyzed Census data from the American Community Survey, together with the 2026 list of qualified census tracts published by the Department of Housing and Urban Development. U.S. Department of Housing and Urban Development, Office of Policy Development and Research (PD&R). HUD Multifamily Tax Subsidy Project (MTSP) Income Limits. *https://www.huduser.gov/portal/datasets/mtsp.html#data_2026,* last accessed June 12, 2026. U.S. Census Bureau, 2024 American Community Survey 1-Year Public Use Microdata Sample. *https://www.census.gov/programs-surveys/acs/microdata/access.html,* last accessed May 11, 2026. Internal Revenue Service, Federal Scholarship Tax Credit (FSTC). *https://www.irs.gov/government-entities/federal-state-local-governments/federal-scholarship-tax-credit-fstc,* last accessed June 12, 2026.

[20] These barriers may include, for example, the effort costs associated with learning about the availability of section 25F credit-funded scholarships, finding out about one's own eligibility, and completing the application. Currie, Janet. 2006. ''The Take-up of Social Benefits.'' In *Public Policy and the Distribution of Income* (pp. 80–148). Russell Sage Foundation. *https://collaborate.princeton.edu/en/publications/the-take-up-of-social-benefits/;* Finkelstein, Amy, and Notowidigdo, Matthew J. 2019. ''Take-up and Targeting: Experimental Evidence from SNAP.'' *The Quarterly Journal of Economics, 134*(3), 1505–1556. *https://doi.org/10.1093/qje/qjz013.*

[21] Annie E. Casey Foundation, ''Children in Foster Care by Age Group in United States,'' *https://datacenter.aecf.org/data/tables/6244-children-in-foster-care-by-age-group.* Last accessed June 16, 2026.

[22] Bald, Anthony, Joseph J. Doyle Jr., Max Gross, & Brian Jacob. (2022). ''Economics of Foster Care.'' *Journal of Economic Perspectives, 36*(2), 223–246. *https://pubs.aeaweb.org/doi/pdf/10.1257/jep.36.2.223.*

[23] Annie E. Casey Foundation. 2023. ''What impacts placement stability?'' *https://www.casey.org/media/23.07-QFF-SF-Placement-Stability-Impacts.pdf.* Last accessed June 16, 2026.

[24] As of 2019, only 31.94% of children in the foster care system were placed in kinship care. Bald, Anthony, Joseph J. Doyle Jr., Max Gross, & Brian Jacob. (2022). ''Economics of Foster Care.'' *Journal of Economic Perspectives, 36*(2), 223–246. *https://pubs.aeaweb.org/doi/pdf/10.1257/jep.36.2.223.*

[25] Berger et al. (2017) reports that the mean income of families who experience a Child Protective Services investigation is $19,142, measured in constant 2009 dollars; the standard deviation of this mean was $12,247. An unusually high-income investigated family, with an income of two standard deviations above the mean, would then have an income of $43,636. This value was less than 300% of the 2009 area median gross income for all 50 states and the District of Columbia. Berger, L. M., Font, S. A., Slack, K. S., & Waldfogel, J. (2017). Income and child maltreatment in unmarried families: Evidence from the earned income tax credit. *Review of Economics of the Household, 15*(4), 1345–1372. *https://link.springer.com/article/10.1007/s11150-016-9346-9.* U.S. Department of Housing and Urban Development, Office of Policy Development and Research (PD&R). *HUD Multifamily Tax Subsidy Project (MTSP) Income Limits. https://www.huduser.gov/portal/datasets/mtsp.html#data_2009,* last accessed June 18, 2026.

[26] This estimate again assumes $100 per income verification and a take-up rate of 52%. These values are multiplied by the approximately 350,000 children in foster care and then divided by the $12,000 assumed average cost of a scholarship to arrive at the estimated number of additional scholarships that could be provided with the savings enabled by the proposed regulations.

TABLE 2—SHARE OF CHILDREN IN STATES ELIGIBLE TO RECEIVE 25F SCHOLARSHIPS, BY INCOME DEFINITION

| Family size multiplier | Family definition | Income definition | Safe harbors | Share eligible (%) |
|---|---|---|---|---|
| No multiplier | Tax unit | Adjusted Gross Income | None | 79 |
| No multiplier | Family | All | None | 64 |
| HUD family size multipliers | Family | All | None | 65 |
| HUD family size multipliers | Household | All | None | 64 |
| HUD family size multipliers | Household | Cash only | None | 95 |
| HUD family size multipliers | Household | Cash only | Categorical eligibility, qualified census tracts, foster care | 96 |

**Notes:** Denominator includes all children ages 5 to 17 who reside in States that have made advance elections to participate in the section 25F credit as of July 2026.

Sources: U.S. Department of Housing and Urban Development, Office of Policy Development and Research (PD&R). HUD Multifamily Tax Subsidy Project (MTSP) Income Limits. *https://www.huduser.gov/portal/datasets/mtsp.html#data_2026,* last accessed June 12, 2026. U.S. Department of Housing and Urban Development, Office of Policy Development and Research (PD&R). Qualified Census Tracts (QCT) Data. *https://www.huduser.gov/portal/datasets/qct.html,* last accessed June 12, 2026. U.S. Census Bureau, 2024 American Community Survey 1-Year Public Use Microdata Sample. *https://www.census.gov/programs-surveys/acs/microdata/access.html,* last accessed May 11, 2026. Internal Revenue Service, Federal Scholarship Tax Credit (FSTC). *https://www.irs.gov/government-entities/federal-state-local-governments/federal-scholarship-tax-credit-fstc,* last accessed June 12, 2026. Feenberg, Daniel, and Elisabeth Coutts, (1993). ''An introduction to the TAXSIM model.'' Journal of Policy Analysis and Management, 12(1), 189–194. *https://taxsim.nber.org/taxsim35/,* last accessed June 29, 2026. Steven Ruggles, Sarah Flood, Matthew Sobek, Daniel Backman, Grace Cooper, Julia A. Rivera Drew, Stephanie Richards, Renae Rodgers, Jonathan Schroeder, and Kari C.W. Williams. IPUMS USA: Version 16.0 [dataset]. Minneapolis, MN: IPUMS, 2025. *https://doi.org/10.18128/D010.V16.0.* Lin, Daniel, (2022). ''Methods and assumptions of the CPS ASEC tax model.'' US Census Bureau. *https://www.census.gov/content/dam/Census/library/working-papers/2022/demo/sehsd-wp2022-18.pdf,* last accessed June 29, 2026.

4. Safe Harbor Rules for Income and Spending Requirements Faced by SGOs

Under section 25F(d)(1)(B), SGOs are required to spend no less than 90% of the income of the organization on scholarships for eligible students. This would be a binding constraint for most SGOs. The proposed regulations would clarify the definition of ''income of the organization'' and provide several safe harbor rules which would allow for greater participation by SGOs and more scholarships for eligible students. In particular, the proposed regulations would allow the income spending requirement to be satisfied at the level of the section 25F segregated account provided that at least 85 percent of the SGO's activities are scholarship granting activities. This proposed regulation would allow SGOs to spend more than 10% of their income on overhead or other expenses if such income is not part of the section 25F segregated account.

The Treasury Department and the IRS estimate that, among the SGOs currently authorized to administer State-level scholarship programs, program-related expenditures represented 78% of total revenues, on average, in fiscal year 2024. Analysis of Form 990-series data reveals that 72% of existing SGOs spend less than 90% of revenue on program-related expenditures. These program-related expenditures include, but are not limited to, scholarship disbursements. Therefore, nearly three-quarters of SGOs—approximately 450 SGOs in participating States—are expected to benefit from this provision.

The Treasury Department and the IRS expect that the downstream effect of this proposed rule will be a function of its impact on the aggregate flow of donations to SGOs. The proposed rule would have two types of economic effects: the first would increase the number of SGOs, while the second would reduce the contributions made to each individual SGO.

First, the proposed regulation is expected to increase the number of SGOs able to operate under section 25F. In the absence of the regulation, nearly 75% of SGOs would need to make substantial changes to their operations, and many might choose not to be certified as an SGO at all.[27] The Treasury Department and the IRS do not have readily available parameters and models to assess precisely the number of public charities that would decline to operate as SGOs in the absence of the regulation; however, a conservative estimate suggests that as many as 450 public charities would find the 90% of income rule too burdensome and difficult to satisfy to justify seeking SGO status.[28] As charitable donations tend to rise with the number of public charities,[29] this first effect of the regulation should tend to increase the volume of scholarship dollars available to students. Given the conservative estimate of the effect of this regulation on the number of public charities applying to operate as SGOs, the Treasury Department and the IRS estimate that, in the absence of this proposed regulation, SGOs would receive 18% fewer qualified contributions. The proposed regulation is estimated to benefit SGOs and eligible students by increasing qualified contributions by $4 billion per year.[30]

A second effect of the proposed regulation follows from donors' documented sensitivity to overhead costs.[31] For the minority of organizations expected to operate as SGOs in the absence of the proposed regulation, the Treasury Department and the IRS estimate that this proposed regulation will increase the overhead ratio by 125%.[32] This should translate

[27] The Treasury Department and the IRS assume that, in the absence of a requirement to spend no more than 10% of income on scholarship disbursements, SGOs would choose the allocation of their expenditures to best serve their intended beneficiaries: the children and families who apply for, or receive, scholarships. This unconstrained allocation may result in a greater share of expenses spent on the costs of administering scholarship funds. This assumption follows the Weak Axiom of Revealed Preference: Samuelson, Paul A. ''A Note on the Pure Theory of Consumer's Behaviour.'' *Economica* 5.17 (1938): 61–71.

[28] This figure approximates 75% of the 600–700 SGOs ultimately anticipated to operate.

[29] Gayle, Philip G., Teresa D. Harrison, and Jeremy Thornton. ''Entry, donor market size, and competitive conduct among nonprofit firms.'' *International Journal of Industrial Organization* 50 (2017): 294–318.; Schmitz, Jan. ''Is charitable giving a zero-sum game? The effect of competition between charities on giving behavior.'' *Management Science* 67.10 (2021): 6333–6349.

[30] Per Table 2 of Schmitz (2021), when the number of charities in the market increases by 1%, total giving rises by 0.245%. In the absence of the proposed regulations, the set of SGOs is expected to contract by nearly 75%. The Treasury Department and the IRS therefore estimate that total giving to SGOs would fall by 18% in the absence of the proposed regulation.

[31] Gneezy, Uri, Elizabeth A. Keenan, and Ayelet Gneezy. ''Avoiding overhead aversion in charity.'' *Science* 346.6209 (2014): 632–635; Meer, Jonathan. ''Are overhead costs a good guide for charitable giving?.'' *The Fundraising Reader.* Routledge, 2023. 314–318.

[32] Note that the overhead ratio is here defined as the share of income devoted to non-program-related spending: for the set of SGOs operating as of fiscal year 2024, analysis of Form 990 series data places the overhead ratio at 22.45%.

into a 29% reduction in flows of donations to the estimated 28% of public charities that would operate as SGOs regardless of the proposed regulation.[33] However, the Treasury Department and the IRS anticipate that the reduction in giving to this subset of SGOs would be a reallocation of qualified contributions across the full set of SGOs.

On net, the proposed regulations would therefore benefit students by increasing the flow of qualified contributions available to fund scholarships by up to an estimated $3 billion per year, thus expanding the set of scholarship recipients by approximately 250,000 each year.[34] The proposed regulations would also benefit the donor by expanding the number and variety of organizations available to them as appropriate recipients of their qualified contributions.

5. Rules Concerning State Elections

Sections 25F(c) and 25F(g) describe the role that States play in facilitating the provision of scholarship funds through SGOs. In particular, States may elect to participate in section 25F and thus become a ''covered State.'' Covered States must submit a list of SGOs to the IRS. This list must consist of all SGOs in that State that meet the requirements outlined in section 25F(c)(5). The statute defines an SGO as a public charity which also must satisfy additional requirements.

The proposed regulations would further detail the responsibilities incurred by covered States with respect to the State SGO list. They require that the State certify that each SGO meets the requirements outlined in section 25F(c)(5) and specify that this certification process includes State review of the SGO's financial information and program activities. The proposed regulations would require State officials to have policies enabling them to detect and respond to misuse of scholarship funds, including duplication of scholarship awards. If this process were to reveal that an SGO currently included on the State SGO list has failed to meet the requirements set forth in section 25F(c)(5), the proposed regulations would allow the State to remove an organization from its SGO list for the current year. Contributions made after the date of removal from the State SGO list would not be treated as qualified contributions under section 25F, except to the extent a taxpayer may rely on the IRS SGO list. Alternatives to these proposed rules would be to disallow contributions made at any time during the year of removal (thus depriving taxpayers otherwise entitled to the credit for a qualified contribution) or allowing contributions made during the entire year, even after the SGO became disqualified.

These proposed regulations would benefit the taxpayer by assigning responsibility to the States for ensuring that SGOs comply with the requirements of section 25F. The State is responsible for the State SGO list and for ensuring that the SGOs on its list comply with the requirements of section 25F, including that the SGO be located in the State. States regulate entities that are located in their State and, as the statute requires that States administer the State SGO lists, States are best positioned to determine that the SGO is located in the State, and scholarship funds must be disbursed to students located in the State. By explicitly adding enforcement of section 25F(c)(5) requirements to the set of responsibilities held by States, the proposed regulations ensure that SGO compliance will be monitored by entities that already have the infrastructure in place to ensure charitable organizations comply with applicable State charitable law. This represents an efficiency gain to the taxpayer.[35] As the proposed regulations direct State officials to examine SGO financial records for the SGO's compliance with the section 25F requirements and for SGO-specific forms of fraud, these proposed rules are expected to benefit the taxpayer by reducing opportunities for waste, fraud, and abuse in the provision of section 25F scholarships. The Treasury Department and the IRS do not have readily available parameters or models to estimate the extent of these benefits.

As SGOs are section 501(c)(3) public charities, many SGOs will be required to file a Form 990-series return. The proposed regulations would add a new form on which an SGO must report information on its activities including the number of scholarship applicants, the number of scholarship recipients, the number of schools at which the SGO's scholarship recipients were enrolled, the dollar amount of the scholarships, and the categories of qualified elementary and secondary expenses for which scholarship funds were used. These metrics, which are detailed in § 1.25F–4(d)(3) of the proposed regulations, can be used by States to verify that a particular SGO meets the requirements of section 25F(c)(5) and (d)(1). The Treasury Department and the IRS estimate the reporting requirements will cost nearly $45,000, in the aggregate, each year.[36]

This proposed regulation would benefit the taxpayer by reducing uncertainty about whether the taxpayer's contributions qualify for the section 25F credit. The proposed regulations state that, in general, a taxpayer may rely on the fact that an organization is listed on the IRS SGO list at the time a contribution is made to establish that the taxpayer's contribution is being made to an SGO.[37] By empowering States with the ability to remove noncompliant SGOs in the middle of the year and providing guidelines for whether contributions made to SGOs which fall into non-compliance qualify for the section 25F credit, the proposed regulations reduce one major source of uncertainty taxpayers might have faced as they select which SGOs to support.

In the absence of the proposed regulations on SGO accountability, the resulting uncertainty would be expected to reduce the flow of contributions to SGOs.[38] The Treasury Department and the IRS do not have a precise estimate of the extent of the counterfactual reduction in qualified contributions to SGOs.

[33] The Treasury Department and the IRS arrive at this figure by applying an elasticity of charitable giving with respect to its efficiency price, and noting that the efficiency price of giving can be stated as a function of the overhead ratio. Meer, Jonathan. ''Effects of the price of charitable giving: Evidence from an online crowdfunding platform.'' *Journal of Economic Behavior & Organization* 103 (2014): 113–124.

[34] This figure assumes each recipient receives an average assumed scholarship amount of $12,000 per year.

[35] An alternative would have been to create a new oversight body to monitor SGO compliance, or to assign oversight to an existing Federal entity. If these alternative organizations do not already have the infrastructure in place to conduct oversight activities, then they would need to incur fixed costs associated with creating this infrastructure. These startup costs are avoided by assigning oversight duties to entities which already handle compliance for tax-exempt organizations.

[36] This figure encompasses costs expected to be incurred by all SGOs as a group, each year.

[37] The proposed rules also lay out specific exceptions to this general rule. If, at the time of the contribution, the taxpayer had knowledge that the recipient organization did not satisfy the requirements of being an SGO or was at least in part responsible for, or was aware of, the act, the failure to act, or the substantial and material change on the part of the organization that gave rise to the removal of the organization from the IRS SGO list, then taxpayer cannot rely on the fact that the SGO is on the IRS SGO list to establish that the organization is an SGO.

[38] A straightforward extension of Alm (1988) shows that an increase in the uncertainty of a tax credit rate can result in reduced expenditure on the creditable good. The extent of this reduction depends on the nature of taxpayers' preferences. Alm, James. 1988. ''Uncertain tax policies, individual behavior, and welfare.'' *The American Economic Review, 78*(1), 237–245. *https://www.jstor.org/stable/pdf/1814712.pdf.*

6. Rules Concerning SGO Certification

Section 25F(g)(1)(A) requires that a State's SGO list must include all SGOs located in the State that meet the requirements described in section 25F(c)(5). The proposed regulations guarantee the freedom of individual SGOs to offer funding for any type of qualified elementary or secondary school expense. That is, an SGO may choose to specialize in providing one type of qualified expense—*e.g.,* academic tutoring for qualified students in public schools—but the State cannot condition inclusion on the SGO list on the State's approval of such a choice. In the absence of this proposed regulation, the scope of the benefits a qualified student could derive from scholarships awarded from contributions eligible for the section 25F credit would depend on the student's State of residence. This follows from the requirement that SGOs must provide scholarships only to eligible students within the State where the SGO is located. The proposed regulation therefore benefits students by ensuring that States cannot limit the types of benefits that can be made available to eligible students. In particular, the inclusivity requirement is anticipated to broaden school choice, enabling students to attend schools that best match their needs, thus maximizing the lifetime benefits that will accrue to the students as a consequence of receiving a section 25F scholarship.[39] The Treasury Department and the IRS do not have the models or data to estimate the effects of this inclusivity requirement but expect that it will have broad benefits for many students, taxpayers, and SGOs.

The proposed regulations also provide States with a procedure for when an organization's application for recognition of tax-exempt status is pending with the IRS, as well as a roadmap for evaluating whether an SGO meets the criteria for inclusion on the State SGO list when the organization has not yet been required to provide information and certifications to the IRS. Furthermore, the proposed regulations provide a transition rule, specifying a deadline for States to submit their SGO lists for calendar year 2027, the first year of the section 25F credit. These rules benefit the taxpayer by removing barriers to entry for SGOs.

7. Defining Location of an SGO Within the State

Section 25F(c)(5)(D) requires that, for a tax-exempt charitable organization to be an SGO for purposes of section 25F, the organization must be included on the list of SGOs submitted to the IRS by a covered State for the applicable year. Section 25F(g)(1) requires that this SGO list be limited to organizations that are ''located in the State.'' However, the statute does not offer any definitions or guidelines that would help States or SGOs determine whether a particular organization is located in the State. The proposed regulations provide that an organization is located in the State if it is authorized to do business in the State and complies with the laws and requirements for charitable organizations in the State. The proposed regulations also provide a framework for SGOs to operate in multiple States at once. These SGOs are referred to as ''multistate SGOs'' and must maintain a separate section 25F segregated account for each State that includes the organization on its State SGO list.

The proposed regulations would enable SGOs that currently operate in multiple States to facilitate the provision of scholarships using qualified contributions without establishing a separate legal structure for each State in which they operate. By allowing an organization to operate as a multistate SGO, the proposed regulations effectively increase the size of the market that each SGO is able to serve. Instead of limiting each organization to competing to serve the aggregate demand for scholarship funds in a single State, all organizations are free to compete to serve the aggregate demand for scholarship funds in all States that have elected to participate in the section 25F credit. Because charitable organizations may respond to private incentives when deciding whether to enter a market, and such organizations have been shown to value the ability to take credit for providing social benefits, the absence of a multistate rule could produce an inefficiently large number of providers in each State, and all providers will end up inefficiently small.[40] By expanding each SGO's market size, the proposed regulations would induce a less-than-proportional increase in the number of SGOs. This will benefit taxpayer contributors by reducing inefficient over-entry among SGOs. The Treasury Department and the IRS do not have readily available models or parameters to assess the extent of the increase, generated by the proposed regulation, in market efficiency among SGOs; however, the increase in efficiency is expected to be significant. As of 2026, 11 SGOs operate in multiple States.

8. Defining a Student Solely Within the State

Section 25F(c)(3) defines a qualified contribution as a contribution to an SGO using that contribution to fund scholarships for eligible students solely within the State. The statute does not provide a definition of ''solely within the State.'' The proposed regulations would define this term, benefiting eligible students and the SGO by providing clarity with regard to its meaning. Section 1.25F–3(c)(7) of the proposed regulations would clarify that ''solely within the State'' refers to the residency of the student, rather than the location where the student attends school or otherwise procures the items or services paid for with scholarship funds. A student's residency must be determined in accordance with State law. If a student is a resident of a State that is not a covered State but attends school in a covered State, these proposed regulations would prevent that student from receiving a section 25F scholarship from an SGO located in either State.[41] The Treasury Department and the IRS are not aware of any data that would identify the number of students who have this fact pattern. However, it is expected that the choice to use residency, rather than school attendance or location of item or service provision, to determine location within the State will result in a reallocation of section 25F scholarships among eligible students, leaving the overall number of scholarship recipients unchanged. This aspect of the proposed regulations will therefore have a minimal effect on elementary and secondary student outcomes, or economic growth in general.

The proposed regulation provides two exceptions to this residency rule. First, students who are dependents of a member of the Armed Forces may be treated for this purpose as a resident of both the State in which the student is domiciled and the location where the member of the Armed Forces resides. As of 2024, military families included approximately 821,500 school-age children, roughly 480,000 of whom are

[39] Deming, David J., Justine S. Hastings, Thomas J. Kane, and Douglas O. Stanger. ''School choice, school quality, and postsecondary attainment.'' *American Economic Review* 104.3 (2014): 991–1013; Angrist, Joshua D., Parag A. Pathak, and Christopher R. Walters. ''Explaining charter school effectiveness.'' *American Economic Journal: Applied Economics* 5.4 (2013): 1–27.

[40] Lapointe, Simon, Carlo Perroni, Kimberley Scharf, & Janne Tukiainen. 2018. ''Does market size matter for charities?'' *Journal of Public Economics, 168,* 127–145. *https://doi.org/10.1016/j.jpubeco.2018.10.003.*

[41] Conversely, if an otherwise eligible student is a resident of a covered State but attends a school in a state that is not a covered State, these proposed regulations would not restrict that student's ability to receive a section 25F scholarship.

in families with at least one active-duty service member.[42] In the same year, 7% of active-duty spouses reported living apart from their Armed Forces member spouse for reasons not related to deployment.[43] The Treasury Department and the IRS are not aware of any data that would help to determine how many of these families have at least one member located in a covered State. The Treasury Department and the IRS estimate that, using the above figures, this proposed exception to the residency rule will benefit as many as 33,600 students per year.[44]

The second exception to this proposed residency rule concerns students who are dependents of an individual residing on Indian Lands. This proposed exception to the residency rule would treat such students as residents of both the State of the student's residence and the State in which the student attends school. The Treasury Department and the IRS estimate that this proposed exception to the residency rule will benefit as many as 6,200 students per year.[45]

9. Disqualified Person Rules

Section 25F(d)(2) includes a prohibition on self-dealing by SGOs and requires that a ''disqualified person shall be determined pursuant to rules similar to the rules of section 4946.'' The proposed regulations articulate the application of ''rules similar to the rules of section 4946.''

As in section 4946, the proposed regulations state that substantial contributors and members of their families are considered disqualified persons, and that a substantial contributor is any person who contributed an aggregate amount of more than $5,000 to the SGO during the taxable year, if such amount is more than 2 percent of the total contributions received by the SGO during the taxable year. In addition, the proposed regulations provide that any person who contributed an aggregate amount of more than $5,000 to a section 25F segregated account during the taxable year, if such amount is more than 2 percent of the total contributions received by the section 25F segregated account during the taxable year, is also a substantial contributor. An individual is treated as making all contributions made by his or her spouse, and substantial contributor status is determined as of the close of each taxable year of the SGO.

To prevent inadvertent violations in which an SGO awards a scholarship to a student who later becomes a disqualified person, the proposed regulations provide that a scholarship awarded by an SGO to a substantial contributor or a substantial contributor's family member will not be treated as an award to a disqualified person if, at the time the scholarship was awarded, the recipient would not have been a disqualified person had the substantial contributor determination been made as of the date of the award, based on contributions received by the SGO through that date; and the SGO did not know and did not reasonably expect that the recipient would be a disqualified person, based on the substantial contributor determination made as of the close of the taxable year.

Consistent with section 4946, the proposed regulations state that officers, directors, trustees, and individuals with similar powers and responsibilities are disqualified persons, along with members of their families.

The proposed regulations also provide that any individual participating in, including as a member of a committee, the selection of scholarship recipients or the determination of scholarship awards, and members of their families, are considered disqualified persons.

These proposed regulations would benefit SGOs by providing clarity regarding the rules prohibiting self-dealing. The Treasury Department and the IRS estimate that these proposed rules will affect between 70,000 and 80,000 disqualified persons per year.[46] These proposed rules are anticipated to have minimal direct economic effects but will help to preserve the integrity of the section 25F scholarships and ensure that scholarships are granted and funds are spent in a manner consistent with the statute.

10. Audit Requirements

Section 25F(d) sets forth a set of operational requirements for SGOs. Section 1.25F–4(e) of the proposed regulations would specify that each SGO must undergo an annual third-party financial and programmatic audit. The results of this audit would then be furnished to the State or States in which the SGO is located. This requirement will benefit States by improving the consistency and quality of the information available to them as they consider whether the organization meets the requirements for SGOs outlined in section 25F(d). For SGOs whose total receipts exceed $500,000, the audits must be conducted by an external, independent professional or accredited body; for SGOs whose total receipts do not exceed $500,000, the audit may be conducted by a committee of independent persons unrelated to the SGO's management.

The Treasury Department and the IRS estimate that audit costs faced by an SGO may range between $10,000 and $30,000 annually. Approximately 53% of SGOs are estimated to exceed the $500,000 receipts threshold; these organizations will consequently pay higher audit costs of approximately $30,000 per year. The remaining 47% of SGOs are estimated to fall below the receipts threshold and therefore pay audit costs closer to $10,000 per year.[47] The total amount of SGO receipts used to satisfy these audit costs is therefore expected to fall between $12 million and $15 million per year. Assuming an average scholarship amount of $12,000 per year, these funds could alternatively have financed scholarships for between 1,000 and 1,250 eligible students per year, assuming that all SGOs comply with their spending requirements in the absence of the audit requirement. The Treasury Department and the IRS expect

[42] U.S. Department of Defense, Office of the Deputy Assistant Secretary of Defense for Military Community and Family Policy. 2024. ''2024 Demographics Profile of the Military Community.'' *https://www.militaryonesource.mil/data-research-and-statistics/military-community-demographics/2024-demographics-profile/.*

[43] U.S. Department of Defense, Office of People Analytics. 2024. ''2024 Active Duty Spouse Survey.'' *https://download.militaryonesource.mil/12038/MOS/Presentations/2024-active-duty-spouse-survey-full-briefing.pdf.*

[44] This estimate multiplies the 7% of active-duty spouses living separately from their servicemember spouse by the number of children in military families which include at least one active-duty service member. It represents an upper bound on the possible number of beneficiaries of this policy, assuming that within each of the active-duty military families where spouses live apart, all spouses live in separate states; and furthermore, that the active-duty service member lives in a non-covered state while the spouse lives in a covered state.

[45] The Bureau of Indian Education operates some off-reservation boarding schools and dormitories. As of fiscal year 2027, these schools and dormitories are expected to serve nearly 6,200 students per year. The Treasury Department and the IRS are not aware of any data which would provide insight into how many of these students attend school in a different state from their state of residency; nor are they aware of another data source which would better reflect the number of students who live on Indian Lands but attend elementary or secondary school elsewhere. U.S. Department of the Interior, Bureau of Indian Education. ''Tribally Controlled Schools.'' *https://www.bie.edu/topic-page/tribally-controlled-schools,* last accessed June 18, 2026. U.S. Department of the Interior, Bureau of Indian Education. 2026. ''Budget Justifications and Performance Information, Fiscal Year 2027.'' *https://www.doi.gov/sites/default/files/documents/2026-04/fy2027greenbookbie_0.pdf.*

[46] To arrive at this figure, the Treasury Department and the IRS analyzed Form 990 information returns filed by organizations that provided scholarships as of tax year 2023.

[47] To arrive at these figures, the Treasury Department and the IRS analyzed the distribution of total receipts among currently operating organizations that provided scholarships, as reported on the Form 990.

that the audit requirement will protect the integrity of section 25F against waste, fraud, abuse, and improper use of funds.

As audit costs are likely to be higher for SGOs with total receipts over $500,000, the Treasury Department and the IRS anticipate that some SGOs with receipts near this threshold may refer potential donors to another SGO for a given year, so that the SGO can avoid incurring the higher audit cost.[48] The Treasury Department and the IRS estimate that the amount of contributions redirected to another SGO to avoid incurring excess audit costs would range from approximately $1.9 million to $2.2 million per year. However, the Treasury Department and the IRS do not anticipate that these donations would be lost; they are instead expected to accrue to organizations whose receipts far exceed, or fall far short of, the audit threshold. This economic effect of the tiered structure of the audit requirement may affect the distribution of eligible students who ultimately receive scholarship funds under section 25F, but is not anticipated to affect the number of eligible students receiving scholarships or the amount of the scholarship.

11. Pass-Through Entities Rule

Section 25F specifies that individual taxpayers who are citizens or residents of the United States may claim credits for qualified contributions to SGOs. The proposed regulations address the question of whether an individual can claim a section 25F credit for qualified contributions made by a pass-through entity in which the individual has an interest. The Treasury Department and the IRS interpret the statute as applying to individual taxpayers. Consequently, the proposed regulations provide that section 25F credits are allowed for qualified contributions made directly by individual taxpayers but are not allowed for qualified contributions made indirectly through pass-through entities. This proposed rule is expected to reduce aggregate contributions made to SGOs, relative to a no-action baseline. The Treasury Department and the IRS do not have readily available models or parameters to assess precisely the amount of foregone contributions associated with this proposed rule. However, because pass-through entities have the alternative of distributing cash to their partners or shareholders, who in turn could contribute directly to SGOs, these effects may be small.

12. Reporting and Substantiation of Qualified Contributions

Section 25F(h) states that ''[t]he Secretary shall issue regulations or guidance . . . with respect to recordkeeping or information reporting for purposes of administering the requirements of this section.'' To facilitate administration of the section 25F credit, the proposed regulations would require SGOs to issue donors a timely written acknowledgement, no later than January 31 of the calendar year following the calendar year in which a donor made a qualified contribution to the organization. The acknowledgement would need to contain information including the total amount of contributions made by the donor to the organization during the calendar year that the donor designated as qualified contributions and the unique donor number the organization created for the donor. The proposed rules would further require SGOs to report to the IRS through the SGO portal information with respect to each unique donor number assigned by the organization and information about the donor to whom that number was issued, including the donor's name, address, and the amount of the qualified contributions provided by the donor during the calendar year. A taxpayer who claims the section 25F credit on the taxpayer's Federal income tax return would need to substantiate the credit on Form 8525, *Federal Scholarship Tax Credit* (or successor form), by reporting such information as may be required in the form instructions, including, for each SGO to which the taxpayer has made a qualified contribution during the taxable year, the unique donor number that the SGO was required to provide as part of a timely written acknowledgement. This reporting by SGOs and taxpayers facilitates the administration of section 25F credits by assisting the IRS in identifying potentially improper credit claims. The use of the donor number avoids the need to have SGOs collect and report each donor's taxpayer identification number, such as a social security number.

As SGOs are section 501(c)(3) charitable organizations, these organizations are already required to provide a contemporaneous written acknowledgment for contributions of $250 or more and may be required to report information concerning certain substantial contributors to the IRS.[49] The proposed reporting requirement represents a relatively minor extension of these organizations' existing reporting responsibilities. As such, the proposed rule is expected to impose only minimal additional costs on SGOs.

This proposed reporting requirement will benefit the taxpayer by reducing a major source of waste, fraud, and abuse in credit claiming, while avoiding any unnecessary exposure of taxpayers' Federal tax information that could arise if the SGO were to require some other form of donor identification, such as a taxpayer identification number. The Treasury Department and the IRS do not have readily available models or parameters to precisely assess the extent of the waste, fraud, and abuse that would be prevented by this proposed regulation. However, the Treasury Department and the IRS anticipate that the benefits to the integrity of section 25F will outweigh the minimal additional costs imposed by the reporting requirements.

SUMMARY OF COSTS AND BENEFITS

| Aspects of the proposed regulation | Benefits | | Costs | |
|---|---|---|---|---|
| | Counts | Amounts | Counts | Amounts |
| a. Calculation of tax credit .. | 4.7 million donors will derive a financial benefit, annually; all taxpayers benefit from clarity. | Affected donors will enjoy a reduced tax burden of up to $11 billion annually, in the aggregate. | (*) ..... | (*) |
| b. Definition of terms needed to determine student eligibility for scholarships. | Approximately 9 million students rendered eligible to receive a 25F scholarship, annually. | The proposed regulation will not change the dollar value of scholarships granted, only the volume of applicants. | (*) ..... | (*) |

[48] St. Clair, Travis. ''How do nonprofits respond to regulatory thresholds: Evidence from New York's audit requirements.'' *Journal of Policy Analysis and Management* 35.4 (2016): 772–790.

[49] IRS Publication 526, *https://www.irs.gov/pub/irs-pdf/p526.pdf.*

SUMMARY OF COSTS AND BENEFITS—Continued

| Aspects of the proposed regulation | Benefits | | Costs | |
|---|---|---|---|---|
| | Counts | Amounts | Counts | Amounts |
| c. Safe harbor rules for student eligibility. | Approximately 170,000 students rendered newly eligible to receive a 25F scholarship, annually; 45,000 students whose scholarships can be funded using saved funds, annually. | $540 million in saved eligibility verification costs, annually. | (*) | (*) |
| d. Safe harbor rules for income and spending requirements faced by SGOs. | 450 additional SGOs relative to the alternative, annually; 250,000 additional scholarship recipients relative to the alternative, annually. | $4 billion additional funds donated to SGOs each year. | (*) | (*) |
| e. Rules concerning State elections. | All donors | Moderate increases in contributions. | (*) | (*) |
| f. Rules concerning SGO certification. | All donors | Moderate increases in contributions. | (*) | (*) |
| g. Defining location of an SGO in the State. | All SGOs and scholarship recipients. | Significant increases in market efficiency. | (*) | (*) |
| h. Defining a student within the State. | 40,000 students rendered eligible to receive a 25F scholarship annually. | The proposed regulation will not change the dollar value of scholarships granted, only the volume of applicants. | (*) | (*) |
| i. Disqualified person rules | All scholarship recipients | Minimal impact | 70,000–80,000 disqualified persons. | Minimal impact. |
| j. Audit requirements | All scholarship recipients | The proposed regulation will facilitate section 25F credit integrity and proper use of funds. | Funds equivalent to approximately 1,000 to 1,250 annual scholarships. | Between $12 million and $15 million per year. |
| k. Partnerships rule | (*) | (*) | All pass-through entities and their partners or shareholders. | Modest impact. |
| l. Reporting and substantiation of qualified contributions. | 600–700 SGOs and 11 million donors per year. | The proposed regulation will facilitate section 25F credit integrity and proper use of funds. | 600–700 SGOs per year | Minimal impact. |

*The Treasury Department and the IRS do not have the data or models to precisely determine the indicated effects.

## II. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA) generally requires that a Federal agency obtain the approval of the OMB before collecting information from the public, whether that collection of information is mandatory, voluntary, or required to obtain or retain a benefit. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by section 6103.

The collections of information in these proposed regulations contain reporting, third-party disclosure, and recordkeeping requirements for States, SGOs, taxpayers, and students. Therefore, the likely respondents are State governments, tax-exempt organizations, and individuals. The collection requirements are necessary to administer the section 25F credit for contributions to SGOs. The collections of information generally would be used by the States to be able to identify and certify SGOs in the State; by SGOs to provide information to donors to enable them to qualify for the credit; by SGOs to report on their compliance with the rules of the statute to the IRS; by donors to allow them to report and take the credit on their Federal income tax return; and by the IRS to administer the credit to ensure that only qualified contributions give rise to the tax credit.

### *A. Collection Requirements Applicable to States*

The collections of information applicable to States can be grouped into three categories: (1) registering through the IRS State section 25F portal; (2) electing to participate under section 25F, and (3) submitting the State SGO list and required certifications about the SGOs and the State's policies for certifying SGOs.

#### 1. State Registration

Proposed § 1.25F–5 would provide rules under section 25F(g) for a State's election to participate under section 25F and the State's identification and certification of organizations located in the State that are SGOs. Proposed § 1.25F–5(b) describes the IRS State section 25F portal used for the submission of State elections and State SGO lists.

Proposed § 1.25F–5(b)(1) would require a State that chooses to make an election to participate under section 25F to obtain a special-purpose EIN under the procedures in proposed § 1.25F–5(b)(3) and complete a registration process under the procedures in proposed § 1.25F–5(b)(4) on *https://www.irs.gov* to electronically transmit information through the IRS State section 25F portal.

A State will use the IRS State section 25F portal to submit the State election and State SGO list and required certifications and information. To complete its registration, proposed § 1.25F–5(b)(4) would require a State to provide the special-purpose EIN, contact information for the State, and any other information the IRS deems necessary for purposes of administering the requirements of section 25F. The burden associated with State registration and obtaining a special-purpose EIN was approved by the OMB under 1545–2335 under the PRA procedures in 5 CFR 1320.13 and will be renewed under the PRA procedures in 5 CFR 1320.10.

#### 2. State Election To Participate

Proposed § 1.25F–5(c) would provide rules for State elections. As part of providing an election and the State SGO list, the State would need to provide certain certifications and other required information as described in proposed

§ 1.25F–5(c)(5), which includes the information and certifications required by proposed § 1.25F–5(d)(2) through (5) for each organization on the State SGO list and a certification that the State SGO list includes every organization located in the State that is described in section 25F(c)(5)(A) and (B), is seeking inclusion on the State SGO list and is operating in a manner that satisfies the operational requirements in section 25F(d) and proposed § 1.25F–3(c) and the applicable State requirements described in proposed § 1.25F–5(e)(1). The State election and its associated burden were approved by the OMB under 1545–2335 under the PRA procedures in 5 CFR 1320.13 and will be renewed under the PRA procedures in 5 CFR 1320.10.

3. State Submission of State SGO List and Required Certification

The collection of information in proposed § 1.25F–5 includes recordkeeping requirements related to the section 25F credit. A State will use these records to submit its State SGO list and the required certifications and other information. These recordkeeping requirements are considered general tax records under § 1.6001–1(e). For PRA purposes, general tax records and their associated burdens are already approved by OMB under control number 1545–0047 for tax-exempt organizations and governmental entities.

Proposed § 1.25F–5(d)(1) would require a State to provide its State SGO list and include the information and certifications required under proposed § 1.25F–5(d)(2) through (5) as part of its State election. Proposed § 1.25F–5(d)(6) would require a State to provide a certification regarding its policies and procedures for determining whether an organization is an SGO. Proposed § 1.25F–5(d)(7)(iii)(B) would provide rules for a State's removal of an SGO from the State SGO list. Proposed § 1.25F–5(e) would provide general guidance regarding the policies and procedures States adopt for SGOs and Federal review of such policies and procedures. The submission of the State SGO list and required certification, and its associated burden, was approved by the OMB under 1545–2335 under the PRA procedures in 5 CFR 1320.13 and will be renewed under the PRA procedures in 5 CFR 1320.10.

*B. Collection Requirements Applicable to SGOs*

The collections of information applicable to SGOs can be grouped into three categories: (1) registering through the IRS SGO portal; (2) providing the donor with a written acknowledgement of the qualified contribution(s) as well as reporting information related to those contributions to the IRS; and (3) recordkeeping and reporting information to the IRS on the SGO's compliance with the requirements of section 25F.

1. SGO Registration

SGOs will need to report information related to contributions and scholarships and information related to the SGO's compliance with the requirements of section 25F(c)(5) through the IRS SGO portal, described in proposed § 1.25F–1(a)(8), in accordance with the instructions provided therein. As such, SGOs will need to register through the IRS SGO portal and provide the information required to complete the registration process.

Proposed § 1.25F–4(b) would provide rules regarding the mandatory registration through the IRS SGO portal that an organization must complete. An organization would need to complete the registration process electronically through the IRS SGO portal and in accordance with the instructions provided therein, providing the information in proposed § 1.25F–4(b)(3). This includes the organization's general information, a point of contact, the organization's tax year, and any other information required in guidance. As part of the registration process, SGOs may authorize the IRS to disclose their information for inclusion on the IRS SGO list, as described in proposed § 1.25F–4(b)(1). The SGO registration, and its associated burden, was approved by the OMB under 1545–2335 under the PRA procedures in 5 CFR 1320.13 and will be renewed under the PRA procedures in 5 CFR 1320.10.

2. Collections of Information by SGOs Related to Contributions and Scholarships

Proposed § 1.25F–4(c) would provide rules on the reporting, recordkeeping, and third-party disclosure requirements of qualified contributions received by SGOs.

The collections of information in proposed § 1.25F–4(c) include recordkeeping requirements related to the section 25F credit. An SGO will use these records to enable it to provide the donor with a timely written acknowledgement of a contribution and to report to the IRS the necessary information about qualified contributions that the SGO received. These recordkeeping requirements are considered general tax records under § 1.6001–1(e). For PRA purposes, general tax records and their associated burdens are already approved by OMB under control number 1545–0047 for tax-exempt organizations.

Proposed § 1.25F–4(c)(1)(i) would provide that an SGO must provide a timely written acknowledgement to each donor with respect to qualified contributions made by the donor to the SGO during the calendar year. The timely written acknowledgement would need to include the total amount of contributions made by the donor, the unique donor number the SGO created for the donor (pursuant to proposed § 1.25F–4(b)(4)), and a statement as to whether or not the SGO provided any goods or services in consideration, in whole or in part, for any qualified contributions made by the donor and if so, a description and good faith estimate of the value of any goods or services. The SGO can provide timely written acknowledgement in writing or in any other form acceptable to the donor, including by electronic delivery. The timely written acknowledgement must be provided no later than January 31 of the calendar year following the calendar year in which a donor made a qualified contribution to the SGO. The timely written acknowledgement, and its associated burden, was approved by the OMB under 1545–2335 under the PRA procedures in 5 CFR 1320.13 and will be renewed under the PRA procedures in 5 CFR 1320.10.

Proposed § 1.25F–4(c)(2) would require an SGO to annually report to the IRS, no later than February 28 of the year following the year in which qualified contributions were made, information with respect to each unique donor number assigned by the SGO, including the donor's name and address, and the aggregate amount of qualified contributions made by the donor to the SGO during the calendar year. The SGO would need to report the information to the IRS through the IRS SGO portal in accordance with the instructions provided therein. This information is necessary to allow the IRS to validate donor information collected by SGOs against filed tax returns claiming the section 25F credit. Availability of this information through the portal may facilitate earlier identification and resolution of discrepancies between filed returns and SGO data, allowing for timelier resolution of any disparities and limiting duplication, fraud, or abuse in the operation of the credit. This annual reporting, and its associated burden, was approved by the OMB under 1545–2335 under the PRA procedures in 5 CFR 1320.13 and will be renewed under the PRA procedures in 5 CFR 1320.10.

3. Collections of Information Related to Compliance With the Requirements of Section 25F(c)(5)

SGOs would need to keep records related to their scholarship granting activities to be able to provide the annual certification and information required by proposed § 1.25F–4(d). This includes records to ensure that an SGO spends not less than 90 percent of the income of the organization on scholarships for eligible students solely within the State in accordance with proposed § 1.25F–3(c)(4) and records to allow an SGO to verify whether the amount that any person, who contributed an aggregate amount of more than $5,000 to the organization during the taxable year, contributed more than 2 percent of the total contributions received by the organization through the end of the taxable year. This recordkeeping is necessary to allow the SGO to determine whether the person is a substantial contributor to the SGO, making the person a disqualified person for purposes of section 25F(d)(2).

In addition, proposed § 1.25F–3(c)(5) would require an SGO to verify that scholarship funds are used exclusively for qualified elementary or secondary education expenses; proposed § 1.25F–3(c)(6) would require an SGO to verify the annual household income and family size of students who apply for scholarships using one or more of the methods described in proposed § 1.25F–3(c)(6) to ensure the scholarship applicants meet the definition of an eligible student; and proposed § 1.25F–3(c)(7) would require an SGO to ensure that qualified contributions are used to fund scholarships that are awarded to eligible students solely within the State on whose State SGO list the SGO appears.

The general recordkeeping requirements for SGOs necessitated by these proposed regulations are considered general tax records under § 1.6001–1(e). For PRA purposes, general tax records are already approved by OMB under 1545–0047 for tax-exempt organizations and governmental entities.

Proposed § 1.25F–4(d) would detail an SGO's annual reporting requirements. SGOs would need to annually provide a certification and certain information to the IRS. Proposed § 1.25F–4(d)(2) would provide rules relating to the annual certification. Proposed § 1.25F–4(d)(3) would provide rules relating to information that would need to be reported annually. Proposed § 1.25F–4(d)(4) would provide that an SGO would need to provide the certifications and information required by proposed § 1.25F–4(d)(2) and (3) on an attachment to the annual Form 990 for those SGOs required to file Form 990, *Return of Organization Exempt from Income Tax.* An SGO that is not required to file a Form 990 will be required to file this form separately with the IRS. SGOs will need to provide a copy of this form to each State on whose State SGO the SGO appears. This annual reporting, and its associated burden, was approved by the OMB under 1545–0047 under the PRA procedures in 5 CFR 1320.13 and will be renewed under the PRA procedures in 5 CFR 1320.10.

Proposed § 1.25F–4(e) would provide a third-party reporting and disclosure requirement that each SGO must engage a qualified independent third party to conduct an annual financial and programmatic audit and must provide the results of this audit to each covered State on whose State SGO list the SGO appears. This third-party disclosure requirement, and its associated burden, was approved by the OMB under 1545–0047 under the PRA procedures in 5 CFR 1320.13 and will be renewed under the PRA procedures in 5 CFR 1320.10.

*C. Individual Taxpayers' Collection Requirements*

Proposed § 1.25F–2 would require the taxpayer to keep records of any information needed to calculate the amount of any section 25F credit from the taxpayer's qualified contributions (including any State credit the taxpayer will take on the taxpayer's State tax return with regard to the taxpayer's qualified contributions), as well as any limitations on the amount of the credit based on the taxpayer's tax liability to calculate the amount of credit able to be claimed and to determine any carryforward of unused credits. The recordkeeping requirements are considered general tax records under § 1.6001–1(e). A taxpayer would use these records to establish the taxpayer'seligibility for the section 25F credit and the amount of the credit claimed. For PRA purposes, general tax records are already approved by OMB under 1545–0074 for individuals.

Proposed § 1.25F–2(g) would require a taxpayer who claims the section 25F credit on the taxpayer's Federal income tax return to substantiate the credit on Form 8525 (or successor form) by reporting such information as may be required in the form instructions, including, for each SGO to which the taxpayer has made a qualified contribution during the taxable year, the unique donor number that the SGO was required to provide as part of a timely written acknowledgement in accordance with proposed § 1.25F–4(c).

A taxpayer that does not provide the required donor number(s) on the taxpayer's Form 8525, *Federal Scholarship Tax Credit* (or successor form), will be presumed not to have made a qualified contribution to that SGO. To rebut this presumption, the taxpayer will need to submit the timely written acknowledgement from the SGO that includes the unique donor number or otherwise provide evidence satisfactory to the Commissioner of the amount of the taxpayer's qualified contribution(s).

These collections will be made by individual taxpayers as part of filing a Form 1040, including completing new Form 8525, *Federal Scholarship Tax Credit* (or successor form), and attaching the form to the taxpayer's Form 1040 when the taxpayer files the return. The forms and their associated burdens will be accounted for and approved by OMB under 1545–0074 in accordance with the PRA procedures under 5 CFR 1320.10.

To make a qualified contribution as defined in proposed § 1.25F–1(a)(12), a taxpayer would be required to identify, to the recipient SGO at the time of making the contribution, that the contribution is intended to be a qualified contribution and should be deposited in the SGO's section 25F segregated account (or, if the SGO is a multistate SGO, that the qualified contribution should be allocated to the SGO's section 25F segregated account for one or more of the covered States on whose State SGO list the SGO appears). This third-party disclosure requirement will be listed within the instructions for Form 8525, *Federal Scholarship Tax Credit* (or successor).

These collections will be made by individual taxpayers as part of filing Form 1040 and will be included within OMB control number 1545–0074. The Form 8525 and its Instructions, and their associated burdens, will be accounted for and approved by OMB under 1545–0074 in accordance with the PRA procedures under 5 CFR 1320.10.

*D. Student Collection Requirements*

Proposed § 1.25F–3(c)(6) would require SGOs to verify students' annual household income and family size, which generally would necessitate students providing certain information for verification. Additionally, proposed § 1.25F–3(c)(7) would require students to provide the SGO with proof of their State residency. The IRS anticipates that students customarily provide this or similar information when applying for

scholarships. This information is disclosed by students and maintained by SGOs in the normal course of scholarship administration. Information collection and maintenance in the normal course of business is considered part of usual and customary business activity and is excluded from the definition of burden under 5 CFR 1320.3(b)(2).

**III. Regulatory Flexibility Act**

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Unless an agency determines that a proposal will not have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires the agency to present an initial regulatory flexibility analysis (IRFA) of the proposed regulations. The Treasury Department and the IRS have not determined whether the proposed regulations, when finalized, will have a significant economic impact on a substantial number of small entities.

This determination requires further study. However, because there is a possibility of a significant economic impact on a substantial number of small entities, these proposed regulations include an IRFA. The Treasury Department and the IRS invite comments on both the number of entities affected by these proposed regulations and the economic impact of these proposed regulations on small entities.

Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking has been submitted to the Chief Counsel of the Office of Advocacy of the Small Business Administration for comment on its impact on small business.

*A. Need for and Objectives of the Rule*

Section 25F allows an income tax credit to an individual for qualified contributions to a public charity that meets certain statutory requirements and is included on a covered State's list of SGOs. Section 25F(c)(3) defines a ''qualified contribution'' as a contribution to an SGO that uses the contribution to fund scholarships for eligible students solely within the State in which the organization is listed pursuant to section 25F(g). For a contribution to be a qualified contribution eligible for a section 25F credit, the State would need to complete an election to participate under section 25F (or perfect an advance election) by including the organization on its State SGO list. An organization is an SGO only if it satisfies each criterion set forth in section 25F(c)(5).

The proposed regulations would provide rules and definitions for determining the amount of the credit, rules on how a State would elect to participate under section 25F by submitting its State SGO list, and rules on how an organization would satisfy each criterion of section 25F(c)(5) so that the organization could appear on a State SGO list. The proposed rules are expected to clarify and implement section 25F, which Congress intended to help meet the stated policy of Executive Order 14191, Expanding Educational Freedom and Opportunity for Families, issued January 29, 2025, to support parents in choosing and directing the upbringing and education of their children. Thus, the Treasury Department and the IRS intend and expect that the proposed rules will provide clear rules to facilitate and support charitable contributions to SGOs, which in turn will make additional scholarships available to allow more parents to make the decisions that best support their goals and objectives for providing high-quality educational opportunities to their children.

*B. Affected Small Entities*

The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity.''

The SBA estimated in its 2023 Small Business Profile that 99.9 percent of United States businesses meet its definition of a small business. The applicability of these proposed regulations does not depend on the size of the business, as defined by the SBA. As described more fully in the preamble to these proposed regulations and in this IRFA, the small entities that these rules will primarily affect will be SGOs, some of which may be part of larger charitable endeavors. SGOs may be classified under the North American Industry Classification System (NAICS) code 813211 (Grantmaking Foundations). According to SBA size standards (effective January 1, 2022), entities with average annual receipts of $40 million or less are considered small entities for this NAICS code.

The Treasury Department and the IRS currently estimate that 600 to 700 organizations may be impacted by these proposed regulations because they will accept contributions and use those contributions to fund scholarships for elementary and secondary educational expenses of eligible students for purposes of the credit under section 25F. As SGOs organized to meet the requirements of section 25F do not currently exist, this estimate is based on the current number of organizations providing similar services in States that provide a State tax credit. The Treasury Department and the IRS have determined that currently there are approximately 450 such organizations, spread over 20 different States. It is anticipated that many of these organizations also will apply to be SGOs for purposes of the section 25F credit. As 30 States have submitted an Advance Election to participate under section 25F as of the date of publication of these proposed regulations, and more States may elect to participate prior to 2027, the first year in which the section 25F credit is applicable, the Treasury Department and the IRS believe the number of organizations wanting to be SGOs will be larger than the number of organizations currently engaging in similar activities.

Of the estimated 600 to 700 organizations that may be impacted by these proposed regulations, the Treasury Department and the IRS expect that at least 95 percent of these organizations will likely be considered a small entity. To prepare these estimates, the Treasury Department and the IRS reviewed Tax-Exempt return (Form 990 series) filings for the 2023 taxable year for organizations providing scholarship granting activities.

1. Impact of the Rules

The recordkeeping, reporting, and third-party disclosure requirements under these proposed regulations would apply to SGOs. SGOs would have administrative costs related to reading and understanding the rules as well as recordkeeping, reporting, and third-party disclosure requirements. SGO recordkeeping and reporting arise from the need to register on the IRS SGO portal, verify the eligibility of students applying for a scholarship, file a form with the IRS to report on the SGOs' compliance with the rules of section 25F, and provide the IRS with information on the contributions received. SGO third-party disclosure requirements arise from the need to provide to donors a timely written

acknowledgement of a donor's qualified contributions and to provide a copy of the form reporting the SGOs' compliance with the rules of section 25F to each State on whose State SGO list the SGO appears. Although the Treasury Department and the IRS do not have sufficient data to precisely determine the likely extent of the costs of compliance, the estimated burden of complying with the recordkeeping and reporting requirements is described in the Paperwork Reduction Act section of the preamble.

2. Alternatives Considered

The Treasury Department and the IRS considered alternatives to the proposed regulations. However, they are of the view that there are no significant alternatives that would both achieve the policy objectives and goals of these proposed rules and be less burdensome to small entities. For example, some comments in response to Notice 2025–70 favored a self-attestation approach for SGO compliance and enforcement, while others insisted that an SGO's mere self-attestation should not be sufficient. While a self-attestation approach would have been less burdensome, it could lead to SGOs not meeting the requirements of the statute by (i) providing scholarships for non-eligible students or for non-eligible expenses or (ii) not satisfying the 90 percent of income requirement. Accordingly, the proposed regulations require organizations appearing on a State SGO list to certify and provide information demonstrating that the organization fulfilled the criteria and requirements of being an SGO as required by section 25F.

Many of the compliance burdens in the proposed regulations are statutory requirements, but to reduce these burdens the Treasury Department and the IRS considered and included safe harbors in the proposed regulations, such as permitting SGOs to test their separate accounts maintained exclusively for qualified contributions for purposes of satisfying the operational requirements found in proposed § 1.25F–3(c)(1) and for providing individual scholarships for individual academic tutoring or special needs services at schools in low-income areas found in proposed § 1.25F–3(c)(6)(iii)(C). Comments are requested on the requirements in the proposed regulations, including specifically whether there are less burdensome alternatives that adequately mitigate the risk of fraud or improper payment of scholarships under section 25F.

3. Duplicative, Overlapping, or Conflicting Federal Rules

The proposed regulations would not duplicate, overlap, or conflict with any relevant Federal rules. As discussed in the Explanation of Provisions, the proposed regulations would merely provide requirements, procedures, and definitions related to the section 25F credit for qualified contributions to SGOs. The Treasury Department and the IRS invite input from interested members of the public about identifying and avoiding overlapping, duplicative, or conflicting requirements.

**IV. Unfunded Mandates Reform Act**

Section 202 (2 U.S.C. 1532(a)) of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. The Treasury Department and the IRS have concluded that these proposed regulations, and the cross-referenced temporary regulations (TD 10057) published elsewhere in this issue of the **Federal Register**, do not include any Federal mandate that may result in expenditures by State, local, or Tribal governments, or by the private sector, in excess of that threshold.

A ''Federal intergovernmental mandate'' is defined in 2 U.S.C. 658(5)(A), in part, as any provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or Tribal governments, except for a duty arising from participation in a voluntary Federal program. Among other things, ''federal tax policies that preempt specific state and local tax policies, and administrative rules issued by federal agencies cannot be avoided, [therefore] they are enforceable duties and are covered under UMRA.'' Adam G. Levin, *Unfunded Mandates Reform Act: History, Impact, and Issues* (CRS Report No: R40957) (2021) *https://www.congress.gov/crs-product/R40957.*

Proposed § 1.25F–5 would provide rules for the State's submission of its election to participate under section 25F and the State SGO list; rules regarding the information and certifications a State is required to provide for each organization included on the State SGO list; requirements that States would need to use in determining whether organizations meet the requirements of section 25F(c)(5) and proposed § 1.25F–3; procedures for notifying the IRS of any determination by the State that an organization on the State SGO list is being removed from such list for not satisfying an applicable requirement.

These rules do not create a Federal intergovernmental mandate as defined in title 2 of the United States Code. First, the rules do not impose an ''enforceable duty'' on the States. For States that provide a State tax credit for donations to scholarship granting entities, these rules do not replace State laws in this area. Second, even if these rules imposed an ''enforceable duty,'' that duty arises from a State's voluntary participation in a Federal tax credit. Section 25F(g)(1)(A) provides that a State voluntarily elects to participate under section 25F. If a State does not want to participate, it is not required to do so.

A ''Federal private sector mandate'' is defined in 2 U.S.C. 658(7)(A), in part, as any provision in legislation, statute, or regulation that would impose an enforceable duty upon the private sector, except for a duty arising from participation in a voluntary Federal program. For this purpose, 2 U.S.C. 658(9) provides that the term ''private sector'' means ''all persons or entities in the United States, including individuals, partnerships, associations, corporations, and educational and nonprofit institutions, but shall not include State, local, or Tribal governments.''

Proposed § 1.25F–4(b) would provide rules for the mandatory registration process through the IRS SGO portal that each SGO would need to complete. Proposed § 1.25F–4(c) would provide the requirements for acknowledgement, recordkeeping, and reporting of qualified contributions received by the SGO.

Proposed § 1.25F–3 would provide rules for scholarship granting organizations under section 25F(c)(5) and (d), including a definition of SGOs and the operational requirements for SGOs. Proposed § 1.25F–4(c) and (d) detail an SGO's annual reporting requirements and proposed § 1.25F–4(e) describes the annual financial and programmatic audit requirements for SGOs. Proposed § 1.25F–2 would provide rules for determining the credit and any credit carryforward under section 25F for qualified contributions made by individuals.

These rules do not create a Federal private sector mandate as defined in title 2 of the United States Code. First, the rules do not impose an ''enforceable duty'' on any member of the private sector. These rules do not include direct statutory orders, a total or partial

preemption, or administrative rules issued by Federal agencies that cannot be avoided. Instead, they fall squarely in the exception for a duty arising from voluntary participation in a Federal tax credit. Tax-exempt organizations are not required to be SGOs, but to the extent that an organization wants to be an SGO, the organization would then be subject to the rules in these regulations. Likewise, an individual taxpayer is not required to claim a credit under section 25F, but to the extent that a taxpayer wants to claim a credit, the taxpayer would need to follow the rules provided in the proposed regulations.

**V. Executive Order 13132: Federalism**

Executive Order 13132 (Federalism) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on State and local governments, and is not required by statute, or preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. The Treasury Department and the IRS conclude that these proposed regulations do not have federalism implications, do not impose substantial direct compliance costs on State and local governments, and do not preempt State law within the meaning of the Executive order.

Section 1(a) of Executive Order 13132 provides that, for purposes of the order, ''Policies that have federalism implications'' refers to regulations, legislative comments or proposed legislation, and other policy statements or actions that 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.'' As such, Executive Order 13132 prohibits an agency from publishing a rule if the rule either imposes substantial, direct compliance costs on State and local governments, and is not required by statute, or preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. The Tenth Amendment to the United States Constitution provides that ''[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.'' Proposed § 1.25F–5 would make States responsible for ensuring SGOs on their SGO list have complied with the requirements of section 25F, but only if a State ''voluntarily elects to participate under'' section 25F. These proposed regulations do not violate the Executive order or the Tenth Amendment because States will only need to comply with the guidance if they voluntarily elect to participate under section 25F.

The proposed regulations would not coerce State governments into administering Federal law in violation of the Executive order or the Tenth Amendment because States do not lose any funding or face any other negative consequences if they decline to participate under section 25F. A State that does not want to ensure that organizations have complied with reporting requirements can decline to submit an annual list of SGOs under section 25F(g)(1)(A). If a State does not submit a list of SGOs, it does not need to comply with any guidance related to section 25F.

In addition, section 25F and these proposed regulations would not insulate the Federal or State governments from political accountability, which indicates that the section and guidance would be permissible under the Tenth Amendment. If residents want their State to submit a list of SGOs (and to take on the resulting administrative responsibilities), they can lobby their State government to do so. The same is true for residents who do not want their State to participate under the section. Thus, rather than invading the domain of State authority, section 25F enables States to determine whether to implement a Federal policy. Any State that does not want to participate in section 25F can decline to submit a list of SGOs, which would prevent taxpayers from claiming credits based on contributions to organizations within the State that would otherwise be SGOs.

Further, these proposed regulations do not impose substantial direct compliance costs on State and local governments. While States will incur some costs in complying with the requirements of these proposed regulations, those costs will not be substantial. See the discussion of the RFA and Executive Order 12866 elsewhere in this Special Analyses section.

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

Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments) prohibits an agency from publishing any rule that has Tribal implications if the rule either imposes substantial, direct compliance costs on Indian Tribal governments and is not required by statute, or preempts Tribal law, unless the agency meets the consultation and funding requirements of section 5 of the Executive order. These proposed regulations do not have a substantial direct effect on one or more federally recognized Indian Tribes and do not impose substantial direct compliance costs on Indian Tribal governments within the meaning of the Executive order. These proposed regulations do not impose substantial, direct compliance costs on Indian Tribal governments, but they have been coordinated with the director, Office of Tribal and Native Affairs, Office of the Treasurer.

**Comments and Public Hearing**

Pursuant to the Administrative Procedure Act at 5 U.S.C. 553(b)(4), a plain language summary of the rule is available on the rulemaking docket at *https://www.regulations.gov.*

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments regarding the notice of proposed rulemaking that are submitted timely to the IRS, as prescribed in this preamble under the **ADDRESSES** section. The Treasury Department and the IRS request comments on all aspects of the proposed regulations. All comments will be made available at *https://www.regulations.gov.* Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn.

A public hearing has been scheduled for Tuesday, December 15, 2026, beginning at 10 a.m. ET, in the Auditorium at the Internal Revenue Building, 1111 Constitution Avenue NW, Washington, DC. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. Participants may alternatively attend the public hearing by telephone.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit an outline of the topics to be discussed and the time to be devoted to each topic by December 1, 2026. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing. If no outline of the topics to be discussed at the hearing is received by December 1, 2026, the public hearing will be cancelled. If the public hearing is cancelled, a notice of cancellation of

the public hearing will be published in the **Federal Register**.

Individuals who want to testify in person at the public hearing must send an email to *publichearings@irs.gov* to have their names added to the building access list. The subject line of the email must contain the regulation number REG–117199–25 and the language TESTIFY in Person. For example, the subject line may say: Request to TESTIFY in Person at Hearing for REG–117199–25.

Individuals who want to testify by telephone at the public hearing must send an email to *publichearings@irs.gov* to receive the telephone number and access code for the hearing. The subject line of the email must contain the regulation number REG–117199–25 and the language TESTIFY Telephonically. For example, the subject line may say: Request to TESTIFY Telephonically at Hearing for REG–117199–25.

Individuals who want to attend the public hearing in person without testifying must also send an email to *publichearings@irs.gov* to have their names added to the building access list. The subject line of the email must contain the regulation number REG–117199–25 and the language ATTEND In Person. For example, the subject line may say: Request to ATTEND Hearing in Person for REG–117199–25. Requests to attend the public hearing must be received by 5 p.m. ET on Thursday, December 10, 2026.

Individuals who want to attend the public hearing by telephone without testifying must also send an email to *publichearings@irs.gov* to receive the telephone number and access code for the hearing. The subject line of the email must contain the regulation number REG–117199–25 and the language ATTEND Hearing Telephonically. For example, the subject line may say: Request to ATTEND Hearing Telephonically for REG–117199–25. Requests to attend the public hearing must be received by 5 p.m. ET on Thursday, December 10, 2026.

Hearings will be made accessible to people with disabilities. To request special assistance during a hearing, please contact the Publications and Regulations Branch of the Office of Associate Chief Counsel (Procedure and Administration) by sending an email to *publichearings@irs.gov* (preferred) or by telephone at (202) 317–6901 (not a toll-free number) no later than Wednesday, December 9, 2026.

### Drafting Information

The principal authors of these regulations are Nicole Cammarota of the Office of Division Counsel (Litigation & Advisory), Constance Chien of the Office of Associate Chief Counsel (Income Tax & Accounting), and Andrew Fahmy of the Office of Associate Chief Counsel (Corporate). However, other personnel from the Treasury Department and the IRS participated in their development.

### List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

### Proposed Amendments to the Regulations

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

## PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding entries for §§ 1.25F–1 through 1.25F–5 in numerical order to read, in part, as follows:

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

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Section 1.25F–1 also issued under 26 U.S.C. 25F(h).

Section 1.25F–2 also issued under 26 U.S.C. 25F(h).

Section 1.25F–3 also issued under 26 U.S.C. 25F(h).

Section 1.25F–4 also issued under 26 U.S.C. 25F(h).

Section 1.25F–5 also issued under 26 U.S.C. 25F(h).

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■ **Par. 2.** Sections 1.25F–0 through 1.25F–5 are added to read as follows:

#### § 1.25F–0 Table of contents.

This section lists the table of contents for §§ 1.25F–1 through 1.25F–5.

§ 1.25F–1 Definitions.
(a) In general.
(1) Advance election.
(2) Covered State.
(3) Disqualified person.
(4) Eligible student.
(i) In general.
(ii) Area median gross income.
(iii) Household.
(5) Foster child.
(i) In general.
(ii) Authorized placement agency.
(6) Guidance.
(7) IRS scholarship granting organization (SGO) list.
(8) IRS SGO portal.
(9) IRS State section 25F portal.
(10) Located in a State.
(11) Multistate SGO.
(12) Qualified contribution.
(i) In general.
(ii) Goods or services received as consideration for the contribution.
(iii) Cash.
(13) Qualified digital wallet.
(14) Qualified elementary or secondary education expense.
(15) Resident of the United States.
(16) Scholarship granting organization (SGO).
(17) School.
(18) Section 25F segregated account.
(19) Sibling.
(20) Single-State SGO.
(21) State.
(22) State credit.
(23) State election.
(24) State SGO list.
(25) Timely written acknowledgement.
(26) Unused credit.
(b) Applicability date.

§ 1.25F–2 Federal scholarship tax credit for qualified contributions.
(a) Allowance of credit.
(1) In general.
(2) Treatment of married taxpayers filing jointly.
(3) Treatment of contributions from partnerships and S corporations.
(b) Donor reliance on SGO status.
(1) In general.
(2) Exception.
(c) Calculation of the section 25F credit.
(1) In general.
(2) Ordering rule for State credit reduction.
(d) Tax liability limitation.
(e) Carryforward of unused credit amounts.
(1) In general.
(2) Five-year carryforward limitation.
(3) First-in first-out.
(f) Denial of double benefit.
(g) Reporting and substantiation of qualified contributions.
(1) In general.
(2) Presumption.
(h) Examples.
(1) Example 1. Annual limitation and no double benefit.
(i) Facts.
(ii) Analysis.
(2) Example 2. Married taxpayers filing jointly.
(i) Facts.
(ii) Analysis.
(3) Example 3. State credit reduces credit under section 25F.
(i) Facts.
(ii) Analysis.
(4) Example 4. Taxpayer designates less than the entire contribution as a qualified contribution.
(i) Facts.
(ii) Analysis
(5) Example 5. Credit carryforward.
(i) Facts.
(ii) Analysis for 2033.
(i) Applicability date.

§ 1.25F–3 Scholarship granting organizations.
(a) Overview.
(b) Scholarship granting organization.
(c) Operational requirements for SGOs.
(1) In general.
(2) Safe harbor for a single-State SGO whose activities are at least 85 percent scholarship granting activities.
(i) In general.
(ii) Application of paragraph (b)(4) of this section to a single-State SGO that qualifies for the safe harbor.

(3) Multistate SGOs.
(4) 90 percent of income spending requirement.
(i) In general.
(ii) Income of the organization.
(A) In general.
(B) Meaning of income for purposes of the safe harbor and multistate SGOs.
(iii) Timing of 90 percent of income spending requirement.
(A) In general.
(B) Amounts treated as spent when paid.
(C) Ordering rule.
(D) Treatment of return of excess payment.
(E) No double counting.
(5) Verification that scholarships are used solely for qualified elementary or secondary education expenses.
(i) In general.
(ii) No funds may be paid directly to the family of the eligible student unless it is a qualified reimbursement.
(iii) Direct payments to the school.
(iv) Paying other vendors directly.
(v) Qualified digital wallet.
(6) Methods of verifying that a student's household income is not greater than 300 percent of the area median gross income.
(i) In general.
(ii) Household income requirement.
(A) Area median gross income.
(B) Family size.
(C) Household income.
(iii) Permissible verification methods.
(A) Direct income verification method.
(B) Categorical eligibility verification method.
(C) Safe harbor for an SGO providing individual scholarships for individual academic tutoring or special needs services at schools in low-income areas.
(1) In general.
(2) Requirements for safe harbor.
(D) Safe harbor for foster children.
(7) Students solely within the State.
(i) In general.
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(A) Example 1.
(B) Example 2.
(8) Priority in awarding scholarships.
(d) Disqualified person.
(1) In general.
(2) Substantial contributor.
(i) In general.
(ii) Excepted scholarships.
(3) Member of the family.
(i) In general.
(ii) Descendant.
(4) Duration of disqualified person status.
(i) Substantial contributor to the SGO.
(ii) Officers, directors, trustees, individuals having similar powers and responsibilities, and individuals involved in selecting scholarship recipients.
(iii) Members of the family.
(5) Examples.
(i) Example 1. Determination of substantial contributor status.
(A) Facts.
(B) Analysis.
(ii) Example 2. Duration of disqualified person status.
(A) Facts.
(B) Analysis.
(iii) Example 3. Excepted scholarship.
(A) Facts.
(B) Analysis.
(e) Applicability date.

§ 1.25F–4 Reporting and recordkeeping requirements for SGOs.

(a) Overview.
(b) Mandatory registration through IRS SGO portal.
(1) In general.
(2) Time for registration through IRS SGO portal.
(3) Information required to complete registration.
(4) Donor number.
(c) Acknowledgement and reporting of qualified contributions received by SGOs.
(1) Reporting to donor.
(i) In general.
(ii) Time and manner of providing timely written acknowledgement.
(2) Reporting qualified contributions to the IRS.
(i) In general.
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(d) Reporting operational information to the IRS.
(1) In general.
(2) Annual certification.
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(ii) Additional certifications relating to operational requirements.
(A) Single-State SGO.
(B) Single-State SGO using the safe harbor found in § 1.25F–3(c)(2).
(C) Multistate SGO.
(3) Required annual information.
(i) In general.
(ii) Single-State SGO using the safe harbor found in § 1.25F–3(c)(2).
(iii) Multistate SGO. (4) Time and manner of reporting.
(e) Required audits.
(1) In general.
(2) Qualified independent third party.
(i) Organizations with annual receipts exceeding $500,000.
(ii) Organizations with annual receipts of $500,000 or less.
(3) Content of audit.
(4) Scope of audit.
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§ 1.25F–5 State election, State SGO list, and certification of SGOs.

(a) Overview.
(b) IRS State section 25F portal.
(1) In general.
(2) Delegation.
(i) In general.
(ii) Designated officials.
(3) Special-purpose EIN.
(4) Information required to complete registration.
(c) State election.
(1) In general.
(2) Authority to make a State's election.
(3) Advance election.
(i) Submission of advance election.
(A) In general.
(B) Transition rule for the first calendar year for which section 25F applies.
(1) Calendar year 2027.
(2) Future years.
(ii) Perfection of advance election.
(A) In general.
(B) Transition rule for the first calendar year for which section 25F applies.
(C) Failure to perfect.
(iii) IRS advance election list.
(4) Election with submission of the State SGO list.
(5) Certifications and other required information.
(d) State SGO lists.
(1) In general.
(2) Required SGO information.
(3) Required SGO certifications.
(4) Transition rule for an organization that has not yet been required to provide information and certifications to the IRS.
(5) Procedure that applies when an organization's application for recognition of tax-exempt status is pending with the IRS.
(6) Certification of State policies and procedures.
(7) Changes to State SGO list.
(i) Changes before the deadline for the elected calendar year.
(ii) Additions to State SGO list after the deadline for the elected calendar year.
(iii) Removal from State SGO list.
(A) Removal request from SGO.
(B) State removal procedures.
(8) Removal of a non-compliant organization from the IRS SGO list.
(i) Removal following change in tax-exempt status.
(ii) IRS determination of non-compliance with applicable requirements.
(iii) Removal following State SGO status determination.
(A) In general.
(B) Multistate SGO.
(9) Publication of covered States and State SGO lists.
(i) In general.
(ii) Addition of organizations with pending tax-exempt status to IRS SGO list.
(e) State administrative requirements.
(1) In general.
(2) Prohibition on additional State requirements or discretionary exclusions.
(3) Federal review.
(f) Applicability date.

**§ 1.25F–1 Definitions.**

(a) *In general.* The definitions of terms in this paragraph (a) apply for purposes of section 25F of the Internal Revenue Code (Code) and the section 25F regulations (that is, this section and §§ 1.25F–2 through 1.25F–5).

(1) *Advance election.* The term *advance election* means a State's submission described in § 1.25F–5(c)(3).

(2) *Covered State.* The term *covered State* means a State that makes a State election, in accordance with § 1.25F–5(c), to participate under section 25F for a particular calendar year.

(3) *Disqualified person.* The term *disqualified person* is defined in § 1.25F–3(d).

(4) *Eligible student*—(i) *In general.* The term *eligible student* means an individual who:

(A) Is a member of a household with an income that, for the calendar year prior to the date of the application for a scholarship, is not greater than 300

percent of the area median gross income; and

(B) Is eligible to enroll in a public elementary or secondary school.

(ii) *Area median gross income.* The term *area median gross income* means area median gross income calculated in a manner consistent with determinations of area median gross income under section 8 of the United States Housing Act of 1937 (or, if such program is terminated, under such program as in effect immediately before such termination), including adjustments for family size, meaning the number of persons who are part of a household for purposes of section 25F. Area median gross income will be published in the Internal Revenue Bulletin annually by the Internal Revenue Service.

(iii) *Household.* The term *household* includes the individual whose status as an eligible student is being determined, and the group of persons residing with that individual. *See* § 1.25F–3(c)(6)(ii)(B) if an individual resides in multiple households during the year.

(5) *Foster child*—(i) *In general.* The term *foster child* means a child who has been removed from the custody of a parent or legal guardian and placed under the care or placement authority of, or has become the legal responsibility of, a child welfare agency, regardless of whether the child has been or will be placed with a person by an authorized placement agency or by judgment, decree, custody order, or any other order of any court of competent jurisdiction (other than an order appointing a legal guardian of the child).

(ii) *Authorized placement agency.* The term *authorized placement agency* means a State, the District of Columbia, a possession of the United States, a foreign country, an Indian Tribal government (as defined in section 7701(a)(40)), or an agency or organization that is authorized by a State (including a non-federally recognized Tribe that otherwise is authorized to act on such matters under applicable State law), or a political subdivision of any of the foregoing, to place children for legal adoption or in foster care.

(6) *Guidance.* The term *guidance* means guidance published in the **Federal Register** or Internal Revenue Bulletin (*see* §§ 601.601(d)(2) and 601.602 of this chapter) or, as appropriate, in forms, instructions, and publications available on *https://www.irs.gov* and through the IRS SGO portal or IRS State section 25F portal, as applicable.

(7) *IRS scholarship granting organization (SGO) list.* The term *IRS SGO list* means the aggregated list of SGOs included on one or more State SGO lists that the IRS maintains and publishes on *https://www.irs.gov* in accordance with § 1.25F–5(d)(9).

(8) *IRS SGO portal.* The term *IRS SGO portal* consists of the module(s) on *https://www.irs.gov* that an SGO is required by § 1.25F–4(b) to use, in accordance with the instructions provided therein, to electronically obtain instructions for creating a unique donor number in a uniform format to be used by all SGOs, authorize disclosure of its name and identifying information on the IRS SGO list, and report specified information.

(9) *IRS State section 25F portal.* The term *IRS State section 25F portal* consists of the module(s) on *https://www.irs.gov* that a State is required by § 1.25F–5(b) to use, in accordance with guidance, to electronically transmit its State election (or advance election), State SGO list, any changes to the State SGO list, annual certifications, and any other information required in guidance.

(10) *Located in a State.* An organization is *located in a State* if the organization is authorized to do business in the State and is in compliance with the generally applicable State laws and requirements for charitable organizations in the State, including provisions for transparency, accountability, and fraud prevention. *But see* § 1.25F–5(e)(2) (prohibiting covered States from imposing requirements on SGOs that are more restrictive than the requirements in section 25F(c)(5)).

(11) *Multistate SGO.* The term *multistate SGO* means an SGO that is included on the State SGO list of more than one covered State.

(12) *Qualified contribution*—(i) *In general.* The term *qualified contribution* means a charitable contribution of cash made by an individual to an SGO to the extent that the donor designates to the recipient SGO, at the time of making the contribution, that the contribution is intended to be a qualified contribution for purposes of section 25F. Such designation, once made, is irrevocable.

(ii) *Goods or services received as consideration for the contribution.* If the SGO provides any goods or services as consideration for any part of the contribution, then the value of those goods and services must be subtracted from the amount of the charitable contribution to arrive at the amount of the qualified contribution.

(iii) *Cash.* For purposes of paragraph (a)(12)(i) of this section, the term *cash*—

(A) Means physical currency, check, money order, electronic transfer, after-tax payroll deduction, or other similar method, in each case all in U.S. dollars, and

(B) Does not mean any digital asset.

(13) *Qualified digital wallet.* The term qualified digital wallet means an electronic payment platform in which a third-party provider provides a streamlined interface for managing the administration of section 25F scholarships by having eligible students and their families submit purchase requests, tracking approved expenses, and maintaining controls to ensure that all payments are made for qualified elementary or secondary education expenses by pre-approving vendors and paying vendors directly or requiring timely submission of receipts.

(14) *Qualified elementary or secondary education expense.* The term *qualified elementary or secondary education expense* means any expense of an eligible student that is described in section 530(b)(3)(A) and any guidance thereunder.

(15) *Resident of the United States.* The term *resident of the United States* means an individual who is a resident of the United States under section 7701(b) or in accordance with an election under section 6013(g) or (h). For this purpose, the term *United States* means only the 50 States and the District of Columbia. *See* section 7701(a)(9).

(16) *Scholarship granting organization (SGO).* The term *SGO* is defined in section 25F(c)(5) and § 1.25F–3(b).

(17) *School.* The term *school* has the definition set forth in section 530(b)(3)(B) and any guidance issued thereunder.

(18) *Section 25F segregated account.* The term *section 25F segregated account* means the separate account exclusively for qualified contributions and the earnings therefrom that the SGO must maintain pursuant to section 25F(c)(5)(B) and § 1.25F–3(b)(2) (in the case of a single-State SGO) or § 1.25F–3(c)(3) (in the case of a multistate SGO).

(19) *Sibling.* The term *sibling* means an individual's brothers and sisters, adopted siblings, foster siblings, half-siblings, and step-siblings.

(20) *Single-State SGO.* The term *single-State SGO* means an organization included on the State SGO list of only one covered State.

(21) *State.* References to *State* include each of the 50 States and the District of Columbia.

(22) *State credit.* The term *State credit* means any tax credit offered by a State for making a contribution to an SGO

that is allowed on a State tax return of the taxpayer (whether or not such return is filed jointly with a spouse) for the taxable year. For this purpose, any State tax credit carryforward or carryback amount attributable to a contribution to an SGO will be treated as allowed for the taxable year of the contribution. *See* § 1.25F–2(c)(2) for an ordering rule that applies in the case of a State credit that is allowed for contributions that are not qualified contributions.

(23) *State election.* The term *State election* means a State election to participate under section 25F for a particular calendar year that is made in accordance with the procedures set forth in § 1.25F–5(b) and (c).

(24) *State SGO list.* The term *State SGO list* means the list of all SGOs located in the State that the covered State submits to the IRS for a particular calendar year in accordance with § 1.25F–5(d) (and that may be changed during such calendar year in accordance with § 1.25F–5(d)(7)).

(25) *Timely written acknowledgement.* The term *timely written acknowledgement* means the written acknowledgement an SGO must provide to donors with respect to qualified contributions made during the calendar year in accordance with § 1.25F–4(c)(1).

(26) *Unused credit.* The term *unused credit* means the amount of the credit determined under § 1.25F–2(c) for a taxable year that is not used by reason of the tax liability limitation in section 26(a).

(b) *Applicability date.* This section applies to taxable years ending on or after [date of publication of the final regulations in the **Federal Register**].

**§ 1.25F–2 Federal scholarship tax credit for qualified contributions.**

(a) *Allowance of credit*—(1) *In general.* Under section 25F(a) of the Internal Revenue Code (Code), an individual taxpayer who is a U.S. citizen or a resident of the United States for all or any portion of a taxable year is allowed a nonrefundable credit determined in accordance with paragraph (c) of this section for qualified contributions made by the taxpayer in the portion of that taxable year during which the taxpayer is a U.S. citizen or a resident of the United States (section 25F credit). A section 25F credit is allowed against the tax imposed for the taxable year by sections 1 and 55(a). In making a contribution to an organization to obtain a section 25F credit, a taxpayer may rely, in accordance with paragraph (b) of this section, on the donee organization's presence on the IRS scholarship granting organization (SGO) list at the time of the contribution to establish that the organization is an SGO. A taxpayer may make a qualified contribution to any SGO on any State SGO list, regardless of the taxpayer's State of residence. The amount of the section 25F credit allowed for a taxable year generally is equal to the aggregate amount of qualified contributions made by the taxpayer during the taxable year, reduced by the amount of any State credits claimed for such qualified contributions, and subject to a cap of $1,700. However, because the section 25F credit used in a particular year cannot exceed the tax liability of the individual taxpayer for that year, the section 25F credit is limited to the amount of the taxpayer's tax liability, as determined under paragraph (d) of this section. Any unused section 25F credit may be carried forward for up to five years, as provided in paragraph (e) of this section. Rules relating to the denial of a double benefit are provided in paragraph (f) of this section. Rules relating to the reporting and substantiation of qualified contributions are provided in paragraph (g) of this section. Paragraph (h) of this section contains examples illustrating the application of the rules of this section.

(2) *Treatment of married taxpayers filing jointly.* For purposes of section 25F(b)(1), married taxpayers who elect to file a joint return under section 6013(a) and § 1.6013–1(a) are treated as separate taxpayers.

(3) *Treatment of contributions from partnerships and S corporations.* A partner may not take into account such partner's distributive share of the partnership's charitable contributions to an SGO in determining the amount of the partner's qualified contributions under section 25F and paragraph (a) of this section. Similarly, a shareholder of an S corporation may not take into account such shareholder's pro rata share of the S corporation's charitable contributions to an SGO in determining the amount of the shareholder's qualified contributions under section 25F and paragraph (a) of this section. This paragraph (a)(3) applies whether or not a partner or an S corporation shareholder may treat the partner's or shareholder's share of such contributions as deductible under section 170.

(b) *Donor reliance on SGO status*—(1) *In general.* Except as provided in paragraph (b)(2) of this section, a taxpayer may rely on the fact that an organization is listed on the IRS SGO list (and not listed as removed from that list) at the time a contribution is made to establish that the taxpayer's contribution is being made to an SGO. *See* § 1.25F–5(d)(9) for additional guidance on the publication and maintenance of the IRS SGO list, including for the IRS's addition of SGOs whose tax-exempt status is recognized after the State's submission of the State SGO list.

(2) *Exception.* A taxpayer may not rely on the fact that an organization is listed on the IRS SGO list (and not listed as removed from that list) at the time a contribution is made to establish that the organization is an SGO if the taxpayer:

(i) Had knowledge that the recipient organization did not satisfy the requirements of section 25F(c)(5) and § 1.25F–3(b) at the time the contribution was made; or

(ii) Was at least in part responsible for, or was aware of, the act, the failure to act, or the substantial and material change on the part of the organization that gave rise to the removal of the organization from the IRS SGO list in accordance with § 1.25F–5(d)(8) after the date of the taxpayer's contribution.

(c) *Calculation of the section 25F credit*—(1) *In general.* A taxpayer's section 25F credit is the lesser of:

(i) The aggregate amount of qualified contributions made during the taxable year while the taxpayer was a United States citizen or a resident of the United States reduced (but not to below zero) by the sum of any State credits with regard to those qualified contributions; or

(ii) $1,700.

(2) *Ordering rule for State credit reduction.* For purposes of this section, if a State credit is allowed with respect to an individual's contributions of cash to an SGO that includes both a qualified contribution and an amount that is not a qualified contribution, then the State credit will be treated as first being allowed with respect to the amount of the donor's contribution that is not a qualified contribution and only thereafter treated as being allowed with respect to the donor's qualified contributions to an SGO.

(d) *Tax liability limitation.* The section 25F credit allowed for a taxable year may not exceed the taxpayer's tax liability as defined in section 26(a), based on the tax imposed for such taxable year as reduced by the sum of the nonrefundable personal credits allowable under sections 21, 22, 24, 25, 25A, 25B, 25C and 25E. *See* paragraph (e) of this section for rules regarding the carryforward of unused credit amounts.

(e) *Carryforward of unused credit amounts*—(1) *In general.* Under section 25F(f), a taxpayer may carry forward any unused credit to one or more succeeding taxable years and add it to the section

25F credit allowable for such taxable year(s), in accordance with this paragraph (e).

(2) *Five-year carryforward limitation.* No unused credit may be carried forward to any taxable year following the fifth taxable year after the taxable year in which the section 25F credit arose.

(3) *First-in first-out.* Section 25F credits carried forward to a taxable year pursuant to this paragraph (e) are used on a first-in first-out basis. Thus, a section 25F credit carried forward must be used prior to using any section 25F credit that arose for such taxable year.

(f) *Denial of double benefit.* Any qualified contribution for which a credit is allowed under section 25F may not be taken into account as a charitable contribution for purposes of section 170. For this purpose, an amount is treated as allowed if it may be carried forward pursuant to paragraph (e) of this section. Any portion of a qualified contribution for which a credit under section 25F is not allowed may be deductible as a charitable contribution if it meets the requirements of section 170 and the regulations thereunder.

(g) *Reporting and substantiation of qualified contributions*—(1) *In general.* A taxpayer who claims the section 25F credit on the taxpayer's Federal income tax return must substantiate the credit on Form 8525, *Federal Scholarship Tax Credit* (or successor form), by reporting such information as may be required in the form and instructions, including, for each SGO to which the taxpayer has made a qualified contribution during the taxable year, the unique donor number that the SGO was required to provide as part of a timely written acknowledgement in accordance with § 1.25F–4(c).

(2) *Presumption.* A taxpayer that does not provide the required donor number(s) on the taxpayer's Form 8525, *Federal Scholarship Tax Credit* (or successor form), will be presumed not to have made a qualified contribution to that SGO. However, this presumption may be rebutted by the taxpayer's submission of the timely written acknowledgement from the SGO that includes such unique donor number or other evidence satisfactory to the Commissioner of the amount of the contribution(s) from the taxpayer and the fact that the contributions were designated as qualified contributions, all within the response time prescribed in a written request from the IRS.

(h) *Examples.* The following examples illustrate the application of the rules of this section. For purposes of these examples, Org X and Org Y are listed on the IRS SGO list at the time of the contribution. In each case, the taxpayer provides the unique donor number for each SGO on the taxpayer's Form 8525, *Federal Scholarship Tax Credit* (or any successor form).

(1) *Example 1: Annual limitation and no double benefit*—(i) *Facts.* In January 2027, Taxpayer A contributes $2,000 to Org X, designates the entire amount of the contribution as a qualified contribution, and receives a timely written acknowledgement in accordance with § 1.25F–4(c). A's qualified contribution does not satisfy the requirements for any State credit.

(ii) *Analysis.* A's $2,000 qualified contribution results in a $1,700 allowed section 25F credit that may be claimed on A's return for 2027, subject to the tax liability limitation under section 26(a). *See* paragraph (c) of this section. This $1,700 portion of the qualified contribution cannot be taken into account as a charitable contribution for purposes of section 170. The remaining $300 from the $2,000 qualified contribution may be deductible as a charitable contribution if it meets the requirements of section 170 and the regulations thereunder.

(2) *Example 2: Married taxpayers filing jointly*—(i) *Facts.* In January 2027, Taxpayer B and Taxpayer C are a married couple. B and C each contribute $2,000 to Org X. Each designates the entire amount of their contribution as a qualified contribution and each receives a timely written acknowledgement in accordance with § 1.25F–4(c). Neither B's nor C's contribution satisfies the requirements for any state credits.

(ii) *Analysis.* Each of B and C's contributions result in a $1,700 allowed section 25F credit, resulting in a total of $3,400 that may be claimed on B and C's joint return. The credit will be subject to their combined tax liability limitation under section 26(a). *See* paragraph (c) of this section. The $3,400 of qualified contributions cannot be taken into account as a charitable contribution for purposes of section 170. The remaining $600 from the combined $4,000 qualified contributions may be deductible as a charitable contribution if it meets the requirements of section 170 and the regulations thereunder.

(3) *Example 3: State credit reduces credit under section 25F*—(i) *Facts.* In January 2027, Taxpayer D contributes $1,500 to Org X and $500 to Org Y. D designates the entire amount of each contribution as a qualified contribution and receives a timely written acknowledgement for each in accordance with § 1.25F–4(c). In addition, Org X qualifies as a State tuition granting organization under the laws of State Q. State Q offers a State credit equal to 40 percent of an individual's contributions up to $1,000 to a State tuition granting organization, and D's $1,500 contribution to Org X also satisfies the requirements for the State credit. In February 2028, D files a 2027 Form 1040 and the appropriate State Q income tax return. D claims a State credit of $400 on the State Q income tax return.

(ii) *Analysis.* D's $2,000 of qualified contributions are reduced by $400, the amount of State credits claimed on the taxpayer's State tax return with regard to those qualified contributions. The remaining $1,600 of qualified contributions is less than $1,700, so D is allowed a $1,600 section 25F credit that may be claimed on D's return for 2027, subject to the tax liability limitation under section 26(a) and paragraph (d) of this section. *See* paragraph (c) of this section.

(4) *Example 4: Taxpayer designates less than the entire contribution as a qualified contribution*—(i) *Facts.* In January 2027, Taxpayer E contributes $4,000 to Org X. E designates $1,700 as a qualified contribution and receives a timely written acknowledgement in accordance with § 1.25F–4(c). In addition, Org X qualifies as a State tuition granting organization under the laws of State Z. State Z offers a $400 State credit equal to 10 percent of an individual's contributions of up to $4,000 to a State tuition granting organization, and E's entire contribution (both the qualified contribution and non-qualified contribution portions) also satisfies the requirements for the State credit. In February 2028, E files a 2027 Form 1040 and the appropriate State Z income tax return. E claims a State tax credit of $400 on the State Z income tax return.

(ii) *Analysis.* Based on the ordering provision in paragraph (c)(2) of this section, E's $400 State credit is treated as being allowed first from the $2,300 non-qualified contribution to the SGO, so the $1,700 qualified contribution is not reduced by the $400 State credit. E's $1,700 qualified contribution to the SGO results in $1,700 of allowed section 25F credit that may be claimed on E's return for 2027, subject to the tax liability limitation under section 26(a) and paragraph (d) of this section. *See* paragraph (c) of this section.

(5) *Example 5: Credit carryforward*—(i) Facts. Taxpayer F has credit carryforwards under section 25F(f) for the last five years, as shown in Table 1 in this paragraph (h)(4)(i). F made qualified contributions of $2,000 in 2033 and has a limitation under section 26(a) of $4,500 for that year. F has no other nonrefundable credits. The

difference between the qualified contribution in the year the carryforward was generated and the credit used in such year is based on F's section 26(a) limitation for each year.

TABLE 1 TO PARAGRAPH (h)(5)(i)

| Year | Cumulative carryforward from *prior* years | Qualified contributions | Section 25F credit used after application of section 26(a) | Carryforward from that year to future years under section 25F(f) and paragraph (e) of this section |
|---|---|---|---|---|
| 2027 | 0 | $1,000 | $900 | $100 |
| 2028 | $100 | 1,000 | 0 | 1,000 |
| 2029 | 1,100 | 1,000 | 0 | 1,000 |
| 2030 | 2,100 | 1,500 | 0 | 1,500 |
| 2031 | 3,600 | 1,500 | 0 | 1,500 |
| 2032 | 5,100 | 2,000 | 0 | 1,700 |

(ii) *Analysis for 2033.* In taxable year 2033, F may use the section 25F(f) credit carryforwards from taxable years 2028 through 2032, but the carryforward from taxable year 2027 has expired as it was from more than five taxable years preceding the current taxable year. *See* paragraph (e)(2) of this section. As a result, the cumulative carryforward to 2033 is the sum of the amount carried forward to 2032 ($5,100) less the amount from 2027 ($100), plus the carryforward from 2032 ($1,700), for a total carryforward available in 2033 of $6,700. F's section 26(a) limitation of $4,500 will determine the amount of carryforwards F may use against F's income tax for taxable year 2033. Pursuant to paragraph (e)(3) of this section, F uses the credits in the following order: $1,000 from 2028, $1,000 from 2029, $1,500 from 2030, and $1,000 from 2031 for a total of $4,500. The remaining $500 from 2031, $1,700 from 2032, and the $1,700 from 2033 will be carried forward to a future year because they are limited by the section 26(a) limitation. *See* paragraphs (d) and (e) of this section.

TABLE 2 TO PARAGRAPH (h)(5)(ii)

| Year | Carryforward to future years | Carryforward used in 2033 | Carryforwards to 2034 |
|---|---|---|---|
| 2027 | $100 | $0—(expired) | $0 |
| 2028 | 1,000 | $1,000 | 0 |
| 2029 | 1,000 | $1,000 | 0 |
| 2030 | 1,500 | $1,500 | 0 |
| 2031 | 1,500 | $1,000 (partially used) | 500 |
| 2032 | 1,700 | $0 | 2,200 |
| 2033 (current year) | 1,700 | $0 | 3,900 |

(i) *Applicability date.* This section applies to taxable years ending on or after [date of publication of the final regulations in the **Federal Register**].

**§ 1.25F–3 Scholarship granting organizations.**

(a) *Overview.* This section provides rules for SGOs under section 25F(c)(5) and (d) of the Internal Revenue Code (Code). Paragraph (b) of this section lists the requirements to qualify as an SGO. Paragraph (c) of this section provides operational requirements for SGOs. Paragraph (d) of this section defines disqualified persons with respect to an SGO.

(b) *Scholarship granting organization.* The term *scholarship granting organization* (SGO) means an organization that:

(1) Is described in section 501(c)(3), exempt from tax under section 501(a), and not a private foundation, as defined in section 509(a);

(2) Prevents the co-mingling of qualified contributions with other amounts by maintaining a section 25F segregated account, which must contain only qualified contributions and the earnings therefrom, depositing all qualified contributions into its section 25F segregated account, and maintaining a complete set of books and records for its section 25F segregated account;

(3) Satisfies the operational requirements of section 25F(d)(1) and paragraph (c) of this section;

(4) Does not award scholarships to any disqualified person as defined in paragraph (d) of this section;

(5) Is included on the State SGO list of one or more covered States in which the organization is located; and

(6) Satisfies the reporting and recordkeeping requirements in § 1.25F–4.

(c) *Operational requirements for SGOs*—(1) *In general.* An SGO meets the requirements of this paragraph (c)(1) if the organization:

(i) Provides scholarships to 10 or more students who do not all attend the same school;

(ii) Spends not less than 90 percent of the income of the organization on scholarships for eligible students consistent with paragraph (c)(4) of this section;

(iii) Verifies, in accordance with paragraph (c)(5) of this section, that scholarships are used solely for qualified elementary or secondary education expenses;

(iv) Verifies that scholarships are awarded only to eligible students who are members of a household described in paragraph (c)(6) of this section and who are eligible to enroll at a public elementary or secondary school;

(v) Verifies that the recipient eligible students are solely within the State in accordance with paragraph (c)(7) of this section;

(vi) Awards scholarships with a priority, in accordance with paragraph (c)(8) of this section, for eligible students awarded a scholarship for the previous school year and, thereafter, for any eligible students who have a sibling who was awarded a scholarship from such SGO; and

(vii) Does not earmark or set aside contributions for scholarships on behalf of any particular student.

(2) *Safe harbor for a single-State SGO whose activities are at least 85 percent scholarship granting activities*—(i) *In general.* If at least 85 percent of a single-State SGO's activities consist of scholarship granting activities (whether pursuant to section 25F, in accordance with State tax credit scholarship rules, or any other scholarship granting activities), then the SGO may apply the operational requirements of paragraph (c)(1) of this section to the organization's section 25F segregated account, rather than to the organization as a whole. For purposes of this paragraph, administrative, fundraising, governance, investment, compliance, outreach, and other activities are treated as scholarship granting activities to the extent each such activity is conducted in support of scholarship granting activities. This activity test is separate from the 90 percent of income spending requirement, for which only expenditures on scholarships for eligible students are taken into account.

(ii) *Application of paragraph (b)(4) of this section to a single-State SGO that qualifies for the safe harbor.* In addition to satisfying the requirement in paragraph (b)(4) of this section at the level of the organization as a whole, such organization also must test and satisfy that requirement at the level of its section 25F segregated account.

(3) *Multistate SGOs.* At least 85 percent of a multistate SGO's activities must consist of scholarship granting activities (whether pursuant to section 25F, in accordance with State tax credit scholarship rules, or any other scholarship granting activities). In addition, a multistate SGO must maintain a separate section 25F segregated account for each covered State on whose State SGO list the SGO appears. The SGO must allow donors to designate how their qualified contribution should be allocated among one or more of those covered States, and all qualified contributions must be deposited into the SGO's section 25F segregated account for one or more of those covered States in accordance with donor designations. The SGO must maintain a complete set of books and records for its section 25F segregated account for each covered State on whose State SGO list the SGO appears. The SGO must meet the requirements of paragraph (c)(1) of this section separately for its section 25F segregated account for each such covered State. Finally, in addition to satisfying the requirement in paragraph (b)(4) of this section at the level of the organization as a whole, such organization also must test and satisfy that requirement at the level of its section 25F segregated account for each covered State on whose State SGO list the SGO appears, provided however that being a disqualified person at the section 25F segregated account level applies only with regard to that section 25F segregated account.

(4) *90 percent of income spending requirement*—(i) *In general.* An SGO must spend not less than 90 percent of the income of the organization, as provided in paragraph (c)(4)(ii) of this section, on scholarships for eligible students solely within the State within the time, and pursuant to the requirements, provided in paragraph (c)(4)(iii) of this section.

(ii) *Income of the organization*—(A) *In general.* Except as provided in paragraph (c)(4)(ii)(B) of this section, income of the organization means the total gross receipts of the organization from all sources computed using the cash receipts and disbursements method of accounting under section 446(c)(1) and § 1.446–1(c)(1)(i) during its annual accounting period, unreduced by any expenses, regardless of the overall method used by the organization in its books and records.

(B) *Meaning of income for purposes of the safe harbor and multistate SGOs.* For a single-State SGO using the safe harbor in paragraph (c)(2) of this section, income of the organization, for purposes of the spending requirement under this paragraph (c)(4)(ii), means the total amount of qualified contributions received by, and earnings credited to, the section 25F segregated account during the taxable year. For a multistate SGO, income of the organization, for purposes of the spending requirement under this paragraph (c)(4)(ii), means the total amount of qualified contributions received by, and earnings credited to, the section 25F segregated account during the taxable year, determined separately for the section 25F segregated account in each covered State.

(iii) *Timing of 90 percent of income spending requirement*—(A) *In general.* An organization must meet the 90 percent of income spending requirement as of the last day of the taxable year following the taxable year in which such income is received, including an organization's short period as set forth in section 443. Thus, satisfaction of the 90 percent of income spending requirement for the SGO's first year of operation does not need to be met until the end of its second year of operation.

(B) *Amounts treated as spent when paid.* For purposes of the 90 percent of income spending requirement, amounts are treated as spent when the amounts are paid under the cash method of accounting described in section 446(c)(1) and § 1.446–1(c)(1)(i).

(C) *Ordering rule.* Amounts are treated as paid from contributions and other income received in the earliest year first, and then from subsequent years in chronological order.

(D) *Treatment of return of excess payment.* An SGO that receives a return of any payments made to a school or vendor that are in excess of the student's costs, or that were disbursed in error, as set forth in paragraphs (c)(5)(iii) and (iv) of this section, respectively, must treat the return as income received in the year of the return and will have until the end of the taxable year following the year of the return to satisfy the 90 percent of income spending requirement with respect to such funds.

(E) *No double counting.* In no event may any amount spent by the SGO be treated as spent in more than one taxable year.

(5) *Verification that scholarships are used solely for qualified elementary or secondary education expenses*—(i) *In general.* An SGO must implement reasonable procedures for the prevention and detection of fraud and abuse, including systems to prevent and detect the duplication of scholarship awards to the same student for the same qualified elementary or secondary education expense that collectively exceed the cost of the expense. In addition, an SGO is required to verify that scholarship funds are used exclusively for qualified elementary or secondary education expenses in accordance with the allowable methods of payment described in paragraphs (c)(5)(ii) through (v).

(ii) *No funds may be paid directly to the family of the eligible student unless it is a qualified reimbursement.* An SGO will not be treated as satisfying this paragraph (c)(5)(ii) if money is paid to the family of the eligible student, unless the payment is a qualified reimbursement, meaning a reimbursement of expenses for which the family of the eligible student provides a receipt that verifies both that the payment was made and that the expense is a qualified elementary or secondary education expense and,

before making the reimbursement, the SGO satisfies its procedures to prevent a single expense from being reimbursed for more than the total cost by more than one source.

(iii) *Direct payments to the school.* Scholarship funds used for payments for tuition, fees, room and board, and other similar expenses described in section 530(b)(3)(A) that are charged by the school must be paid directly to the school. The school must return any payments from the SGO that are in excess of the student's costs or that are disbursed by the SGO in error.

(iv) *Paying other vendors directly.* An SGO will be considered to meet the requirements of this section if it pays a vendor directly for expenses described in section 530(b)(3)(A) and the vendor:

(A) Has been verified as an appropriate provider of such services or items;

(B) Is not related, directly or indirectly, to the scholarship recipient; and

(C) Is required to reimburse the SGO for any payments from the SGO that are in excess of the student's costs or that were disbursed by the SGO in error.

(v) *Qualified digital wallet.* An SGO will be considered to meet the requirements of this section if it uses a qualified digital wallet to pay qualified elementary or secondary education expenses.

(6) *Methods of verifying that a student's household income is not greater than 300 percent of the area median gross income*—(i) *In general.* A scholarship recipient must be an eligible student who satisfies the household income requirement described in section 25F(c)(2)(A), § 1.25F–1(a)(4), and paragraph (c)(6)(ii) of this section. An SGO must use one or more of the methods described in paragraph (c)(6)(iii) of this section to verify that a scholarship recipient is an eligible student who satisfies this household income requirement.

(ii) *Household income requirement*—(A) *Area median gross income.* For purposes of computing the household income limit under section 25F(c)(2)(A) of 300 percent of area median gross income, area median gross income means the income limit determined based on area median gross income and family size in accordance with section 8 of the United States Housing Act of 1937 (Section 8).

(B) *Family size.* Family size is equal to the number of persons who are part of a household. A student's household includes the individual whose status as an eligible student is being determined, as well as each other person residing with that individual. For purposes of determining the number of members of the student's household in situations in which the student resides in more than one household during the calendar year (for example, in cases of shared custody), the relevant household is the one in which the student resides for the longest period of time during the year or, if the time spent by the student in each household is equal, then the household of the taxpayer with the highest household income.

(C) *Household income.* For purposes of determining the household income of a particular eligible student to be measured against the limit established in section 25F(c)(2)(A) and § 1.25F–1(a)(4)(i)(A), the term *household income* means annual income, as defined in 24 CFR 5.609; however, for this purpose, household income must be determined by disregarding the imputed return on net assets (for example, unrealized appreciation in a home or stock). This definition includes receipts by a member of the household in the form of child support and alimony not included in taxable income but excludes non-cash receipts.

(iii) *Permissible verification methods*—(A) *Direct income verification method.* Under the direct income verification method, income may be verified through review of written documentation including pay stubs, prior-year Federal or State tax returns, IRS transcripts, Forms W–2, evidence of other income not reflected on such documents (such as evidence of child support and alimony not reported as income) or a certification that there is none, or may be verified through other relevant data sources.

(B) *Categorical eligibility verification method.* Under the categorical eligibility verification method, income may be verified through written documentation, such as an award letter, dated within the last 12 months, confirming that an individual in the student's household currently is approved for assistance from or participation in Supplemental Nutrition Assistance Program (SNAP), Temporary Assistance for Needy Families (TANF), the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), Section 8 housing, or Supplemental Security Income (SSI)).

(C) *Safe harbor for an SGO providing individual scholarships for individual academic tutoring or special needs services at schools in low-income areas*—(*1*) *In general.* If an SGO provides scholarships to individual students at schools in a low-income area for individual academic tutoring, or for special needs services in the case of a special needs student, and the individual students receiving those services are selected by the school on the basis of the particular student's academic or other need, the recipient students will be treated as satisfying the requirements in section 25F(c)(2)(A) and § 1.25F–1(a)(4), whether or not the student's household income is verified, if either:

(*i*) The school is located in a qualified census tract as identified at *https://www.huduser.gov/portal/sadda/sadda_qct.html* (or a tract identified in future guidance); or

(*ii*) The school certifies that at least 80 percent of its students reside in such a qualified census tract, regardless of the location of the school.

(*2*) *Requirements for safe harbor.* An SGO using the safe harbor described in paragraph (c)(6)(iii)(C) of this section must annually obtain, and provide to the covered State, a third-party audit to certify that:

(*i*) The school meets the eligibility requirement in paragraph (c)(6)(iii)(C)(*1*)(*i*) or (*ii*) of this section;

(*ii*) The scholarship recipients were selected by the school based on academic or special need;

(*iii*) Tutors or other providers were qualified to render the services;

(*iv*) The student's need for the services, including the nature and extent of the services needed, is independently diagnosed by a professional not associated with the provider or vendor of the services; and

(*v*) The services met appropriate quality standards, were provided with a duration and frequency commonly required to produce benefit, and their impact on each individual scholarship recipient was assessed.

(D) *Safe harbor for foster children.* An eligible student who is a foster child will be treated as satisfying the requirements in section 25F(c)(2)(A) and § 1.25F–1(a)(4)(i)(A), whether or not the student's household income is verified.

(7) *Students solely within the State*—(i) *In general.* An SGO must ensure that qualified contributions are used to fund scholarships that are awarded to eligible students solely within the State on whose State SGO list the SGO appears. Except as provided in paragraph (c)(7)(ii) of this section, an eligible student is considered solely within a State only if the eligible student resides in that State in accordance with State law. Attending school in a State or purchasing goods or services in a State is not sufficient to treat the student as being solely within a State.

(ii) *Exceptions.* A student who is a dependent (as defined in section 152) of a member of the Armed Forces of the United States will be treated as solely

within both the State of the domicile of the student and the State in which that member of the Armed Forces is residing. In addition, a student who is a dependent (as defined in section 152) of an individual residing on Indian Lands (as defined in 25 U.S.C. 3501(2)) will be treated as solely within both the State of the student's residence and the State in which the student attends school.

(iii) *Examples.* The application of this paragraph (c)(7) is illustrated by the following examples.

(A) *Example 1.* Organization EF is an SGO that operates only in State X and is on the IRS SGO list under State X for 2027. Student A resides in State X and attends school in State Y. Student B both resides and attends school in State Y. Neither student is in a military or Tribal family as described in paragraph (c)(7)(ii) of this section. Student A, but not Student B, is an eligible student solely within the State in which EF is listed as an SGO for purposes of section 25F. Thus, EF can award a scholarship from its section 25F segregated account to Student A, but not to Student B.

(B) *Example 2.* Organization GH is an SGO that operates in State X and State Y and is on the IRS SGO list under both State X and State Y for 2027. GH is not on the State SGO list of any other covered State. Student A resides in State X and attends school in State Y. Student B both resides and attends school in State Y. Student C resides in State Z and attends school in State Y. None of these students is in a military or Tribal family as described in paragraph (c)(7)(ii) of this section. Student A and Student B, but not Student C, are eligible students solely within the States in which GH qualifies as an SGO. Thus, GH can award a scholarship from its State X section 25F segregated account to Student A, and can award a scholarship from its State Y section 25F segregated account to Student B. However, GH cannot award a scholarship to Student C.

(8) *Priority in awarding scholarships.* In complying with section 25F(d)(1)(D), which requires that scholarships be awarded with priority consideration being given to eligible students awarded a scholarship for the previous school year and, thereafter, to any eligible students solely within the State who have a sibling who was awarded a scholarship from that SGO, an SGO has flexibility to consider the particular needs of potential scholarship recipients and the type of expenses for which the scholarship is being awarded. For example, a prior scholarship recipient should be given priority with regard to an award for tuition, fees, and room and board to ensure that the eligible student is able to continue attending the same school. Similarly, the siblings of such an award recipient should be given priority so that siblings are able to attend the same school. However, if a scholarship is awarded based on need for individual academic tutoring or special needs services, the fact that a student was a previous scholarship recipient, or that a student has a sibling who was a previous scholarship recipient, may not be relevant and priority instead can be based on need for the services.

(d) *Disqualified person*—(1) *In general.* The term disqualified person means, with respect to an SGO, a person who is:

(i) A substantial contributor to the SGO or to the section 25F segregated account, as defined in paragraph (d)(2) of this section;

(ii) An officer, director, or trustee of the SGO, as well as an individual having powers and responsibilities similar to those of such persons;

(iii) Any individual participating in, including as a member of a committee, the selection of scholarship recipients or the determination of scholarship awards; and

(iv) A member of the family, as defined in paragraph (d)(3) of this section, of any individual described in paragraph (d)(1)(i), (ii), or (iii) of this section.

(2) *Substantial contributor*—(i) *In general.* The term substantial contributor means any person who contributed an aggregate amount of more than $5,000 to the SGO during the taxable year, if such amount is more than 2 percent of the total contributions received by the SGO during the taxable year. For this purpose, an individual will be treated as making all contributions made by his or her spouse. In addition, the term substantial contributor means any person who contributed an aggregate amount of more than $5,000 to a section 25F segregated account during the taxable year, if such amount is more than 2 percent of the total contributions received by the section 25F segregated account during the taxable year. A person's status as a substantial contributor is determined as of the close of each taxable year of the SGO.

(ii) *Excepted scholarships.* A scholarship awarded by an SGO to a substantial contributor or a substantial contributor's family member will not be treated as an award to a disqualified person if, at the time the scholarship was awarded:

(A) The recipient would not have been a disqualified person had the substantial contributor determination been made as of the date of the award, based on contributions received by the SGO through that date; and

(B) The SGO did not know and did not reasonably expect that the recipient would be a disqualified person based on the substantial contributor determination made as of the close of the taxable year.

(3) *Member of the family*—(i) *In general.* The family of any individual includes only:

(A) The individual's spouse;

(B) The ancestors and descendants of the individual or the individual's spouse;

(C) The siblings of the individual or the individual's spouse;

(D) The descendants of siblings described in paragraph (d)(3)(i)(C) of this section; and

(E) The spouse of any individual described in paragraph (d)(3)(i)(B), (C), or (D) of this section.

(ii) *Descendant.* For purposes of this paragraph (d)(3)(ii), an individual's legally adopted child and an individual's step-child are each treated as a descendant of that individual.

(4) *Duration of disqualified person status*—(i) *Substantial contributor to the SGO.* An individual described in paragraph (d)(1)(i) of this section will be treated as a substantial contributor for any taxable year of the SGO in which the individual is so described and for the immediately succeeding taxable year of the SGO.

(ii) *Officers, directors, trustees, individuals having similar powers and responsibilities, and individuals involved in selecting scholarship recipients.* An individual described in paragraph (d)(1)(ii) or (iii) of this section will be treated as a disqualified person for so long as the individual is so described. An individual who ceases to be described in paragraph (d)(1)(ii) or (iii) of this section will continue to be treated as a disqualified person through the end of the taxable year of the SGO in which such cessation occurs and through the end of the immediately succeeding taxable year of the SGO.

(iii) *Members of the family.* An individual described in paragraph (d)(1)(iv) of this section is a disqualified person by virtue of that paragraph only while any family member is treated as a disqualified person under paragraph (d)(1)(i), (ii), or (iii) of this section.

(5) *Examples.* The following examples illustrate the application of this paragraph (d):

(i) *Example 1: Determination of substantial contributor status*—(A) *Facts.* On May 2, 2027, Taxpayer A, an individual, gave $6,000 to O, an SGO operating on a calendar year basis. As of May 2, 2027, O had received $250,000

from all sources as total contributions and bequests, including A's contribution, during the calendar year 2027. Between May 3, 2027, and December 31, 2027, O received $200,000 in contributions and bequests from others. Therefore, as of December 31, 2027, O had received $450,000 from all sources as total contributions and bequests during the year, and A's $6,000 contribution represented 1.33 percent of the total contributions and bequests received by O during 2027. Neither A nor any other family member of A is a disqualified person for any reason other than possible status as a substantial contributor.

(B) *Analysis.* A is not a substantial contributor to O for the tax year ending December 31, 2027, since A's contributions to O were not more than 2 percent of the total contributions and bequests received by O during its taxable year that ended on December 31, 2027.

(ii) *Example 2: Duration of disqualified person status*—(A) *Facts.* On July 1, 2027, Taxpayer B, an individual, gave $6,000 to P, an SGO operating on a calendar year basis. As of July 1, 2027, P had received $250,000 from all sources as total contributions and bequests, including B's contribution, during the calendar year 2027. Between July 2, 2027, and December 31, 2027, P received $30,000 in contributions and bequests. Therefore, as of December 31, 2027, P had received $280,000 from all sources as total contributions and bequests during the year, and B's $6,000 contribution represented 2.14 percent of P's total contributions and bequests during 2027. Neither B nor any other family member of B is a disqualified person for any reason other than possible status as a substantial contributor.

(B) *Analysis.* B will be treated as a substantial contributor for the tax year ending December 31, 2027, and for the following tax year ending December 31, 2028. Generally, any scholarships awarded to B's family members during the tax years ending December 31, 2027, or December 31, 2028, will be treated as scholarships awarded to a disqualified person. However, any scholarship awards made to B's family members prior to July 1, 2027, may qualify as an excepted scholarship if the requirements of paragraph (d)(2)(ii) of this section are met.

(iii) *Example 3: Excepted scholarship*—(A) *Facts.* On February 10, 2027, Taxpayer C, an individual, gave $7,000 to Q, an SGO operating on a calendar year basis. As of August 15, 2027, Q had received $400,000 from all sources as total contributions and bequests, including C's contribution, during the calendar year 2027. Q awarded a scholarship to C's daughter on August 15, 2027. Neither C nor any other family member of C is a disqualified person for any reason other than possible status as a substantial contributor. C did not make a pledge or otherwise inform Q of any intent to make additional contributions during 2027, and Q had no reason to anticipate any additional contribution from C during 2027. Nevertheless, on November 16, 2027, C gave an additional $7,000 to Q. As of December 31, 2027, Q had received $650,000 from all sources as total contributions and bequests during the year, and C's total contributions of $14,000 represented 2.15 percent of Q's total contributions and bequests during 2027.

(B) *Analysis.* Because C's contributions exceeded $5,000 and 2 percent of Q's total contributions and bequests for the tax year ending December 31, 2027, C is a substantial contributor for that tax year and for the succeeding tax year. However, had the substantial contributor determination been made as of the date of the award (August 15, 2027) based on contributions received by the organization through that date ($400,000), C would not have been considered a substantial contributor because C's contributions were not more than 2 percent of the total contributions received by Q by the date of the award. Further, as of August 15, 2027, Q did not know or have reason to expect that C would make an additional contribution to Q during 2027, resulting in C becoming a substantial contributor by the end of 2027. Based on these circumstances, the scholarship awarded to C's daughter on August 15, 2027, will not be treated as a scholarship awarded to a disqualified person by reason of paragraph (d)(2)(ii) of this section. However, C is otherwise considered a disqualified person for the tax years ending December 31, 2027, and December 31, 2028, and any scholarships awarded to C's family members in 2028 will be treated as scholarships awarded to a disqualified person.

(e) *Applicability date.* This section applies to taxable years ending on or after [date of publication of the final regulations in the **Federal Register**].

**§ 1.25F–4 Reporting and recordkeeping requirements for SGOs.**

(a) *Overview.* This section provides reporting and recordkeeping requirements for organizations relating to the credit determined under section 25F of the Internal Revenue Code (Code). Paragraph (b) of this section provides that each organization that receives an amount designated as a qualified contribution must complete a mandatory registration process through the IRS SGO portal. Paragraph (c) of this section provides the requirements for an organization's acknowledgement, recordkeeping and reporting for the receipt of amounts designated as qualified contributions. Paragraph (d) of this section details annual reporting requirements for organizations included on a State SGO list for any part of a calendar year within the organization's taxable year. Paragraph (e) of this section describes the annual financial and programmatic audit requirement.

(b) *Mandatory registration through IRS SGO portal*—(1) *In general.* Except to the extent otherwise provided in guidance, an organization that plans to solicit qualified contributions must electronically register through the IRS scholarship granting organization (SGO) portal in accordance with the instructions provided therein. Registration through the IRS SGO portal will allow the organization to obtain instructions for creating a unique donor number in the uniform format to be used by all SGOs, authorize disclosure of its name and identifying information on the IRS SGO list, and report qualified contribution information. An organization must authorize disclosure in accordance with section 6103(c) of its name and identifying information on the IRS SGO list for a calendar year if the organization wants the IRS to publish such information on the IRS SGO list for that year.

(2) *Time for registration through IRS SGO portal.* An organization must register with the IRS as soon as possible and preferably before the organization appears on any State SGO list. Until the organization has registered in the IRS SGO portal, the organization will not be able to comply with the acknowledgement and reporting requirements in paragraph (c) of this section, which is a necessary part of substantiating that a donor's qualified contribution is eligible for the credit allowed under section 25F.

(3) *Information required to complete registration.* An organization must provide the following information to the IRS to register in the IRS SGO portal:

(i) The organization's name, IRS employer identification number (EIN), address, telephone number, and year of formation;

(ii) The name of a person whom the IRS may contact if there is an issue with the registration, and who either possesses legal authority to bind the

organization or provides a properly executed power of attorney on Form 2848, *Power of Attorney and Declaration of Representative;*

(iii) The organization's taxable year; and

(iv) Any other information the IRS deems necessary for purposes of administering the requirements of section 25F as provided in guidance.

(4) *Donor number.* The IRS will review the registration submission to verify that all the required information has been submitted and will provide the organization with instructions for creating a unique donor number for each donor who has designated at least one payment to the organization as a qualified contribution to the SGO during the calendar year.

(c) *Acknowledgement and reporting of qualified contributions received by SGOs*—(1) *Reporting to donor*—(i) *In general.* An organization must provide a timely written acknowledgement to each donor that includes the following information:

(A) The organization's EIN;

(B) The total amount of contributions made by the donor to the organization during the calendar year that the donor designated as qualified contributions;

(C) The unique donor number the organization created for the donor in accordance with paragraph (b)(4) of this section;

(D) A statement as to whether or not the organization provided any goods or services in consideration, in whole or in part, for any qualified contributions made by the donor to the SGO during the calendar year; and

(E) A description and good faith estimate of the value of any goods or services described in paragraph (c)(1)(i)(D) of this section, if any.

(ii) *Time and manner of providing timely written acknowledgement.* An organization must provide the timely written acknowledgement no later than January 31 of the calendar year following the calendar year in which a donor made a qualified contribution to the organization. The timely written acknowledgement can be provided in writing or in any other form acceptable to the donor, including by electronic delivery if the donor consents to receive the statement electronically and does not withdraw the consent before the statement is furnished.

(2) *Reporting qualified contributions to the IRS*—(i) *In general.* An organization must annually report to the IRS the following information with respect to each unique donor number assigned by the organization as set forth in paragraph (b)(4) of this section:

(A) The donor's name;

(B) The donor's address;

(C) The aggregate amount of qualified contributions made by the donor to the organization during the calendar year; and

(D) Any other information the IRS deems necessary for purposes of administering the requirements of section 25F as may be described in future guidance.

(ii) *Time and manner of reporting.* An organization must report the information described in paragraph (c)(2)(i) of this section no later than February 28 of the year following the year in which such qualified contributions were made. Unless otherwise provided in guidance, the reporting must be done through the IRS SGO portal in accordance with the instructions provided therein.

(d) *Reporting operational information to the IRS*—(1) *In general.* An organization that has been included on a State SGO list for any part of a calendar year within its taxable year must annually provide a certification and certain information to the IRS. Paragraph (d)(2) of this section provides rules relating to the annual certification. Paragraph (d)(3) of this section provides rules relating to information that must be reported. Paragraph (d)(4) of this section provides the time and manner of reporting.

(2) *Annual certification*—(i) *In general.* An organization that was an SGO for any part of a calendar year within its taxable year must certify that, with respect to its taxable year (or the period during which it was an SGO, if not the entire year), such organization:

(A) Was described in section 501(c)(3), exempt from tax pursuant to section 501(a), and not a private foundation, as defined in section 509(a);

(B) Prevented the co-mingling of qualified contributions with other amounts by maintaining a section 25F segregated account, which must contain only qualified contributions and the earnings therefrom, for each covered State on whose State SGO list the SGO appears, deposited all qualified contributions into that section 25F segregated account, and maintained a complete set of books and records for that section 25F segregated account;

(C) Satisfied the operational requirements of section 25F(d)(1) and § 1.25F–3(c);

(D) Did not award a scholarship to any disqualified person, as tested at the organizational level and as tested at the section 25F segregated account level solely for that section 25F segregated account by each single-State SGO using the safe harbor in § 1.25F–3(c)(2) and by each multistate SGO;

(E) Was located in each State on whose State SGO list the organization was listed;

(F) Provided each donor a timely written acknowledgement; and

(G) Commissioned a financial and programmatic audit described in paragraph (e) of this section by a qualified independent third party and provided the audit report to each covered State on whose State SGO list the organization was listed.

(ii) *Additional certifications relating to operational requirements—(A) Single-State SGO.* A single-State SGO must certify that it—

(*1*) Provided scholarships to 10 or more students, not all of whom attended the same school;

(*2*) Spent not less than 90 percent of the income of the organization on scholarships for eligible students;

(*3*) Verified that scholarships were used solely for qualified elementary or secondary education expenses;

(*4*) Verified that scholarships were awarded only to eligible students who were members of an eligible household and who were eligible to enroll at a public elementary or secondary school;

(*5*) Verified that the recipient eligible students were solely within the State;

(*6*) Awarded scholarships with a priority (as provided in § 1.25F–3(c)(8)) for eligible students awarded a scholarship for the previous school year and, thereafter, for any eligible students who have a sibling who was awarded a scholarship from such SGO;

(*7*) Did not earmark or set aside contributions for scholarships on behalf of any particular student; and

(*8*) If the organization used the safe harbor found in § 1.25F–3(c)(6)(iii)(C) for providing individual scholarships for individual academic tutoring or special needs services at schools in low-income areas, that it obtained a third-party audit and provided the audit report to the covered State in accordance with § 1.25F–3(c)(6)(iii)(C)(*2*).

(B) *Single-State SGO using the safe harbor found in § 1.25F–3(c)(2).* If a single-State SGO used the safe harbor found in § 1.25F–3(c)(2), then it must certify that—

(*1*) At least 85 percent of the organization's activities during the taxable year were scholarship granting activities and

(*2*) Each of the elements of paragraph (d)(2)(ii)(A) was met with respect to the organization's section 25F segregated account.

(C) *Multistate SGO.* If an organization was a multistate SGO for any part of a calendar year within its taxable year, then it must certify that, with respect to

its taxable year (or the period during which it was an SGO, if not the entire taxable year):

(*1*) At least 85 percent of the organization's activities during the taxable year were scholarship granting activities, and

(*2*) Each of the elements of paragraph (d)(2)(ii)(A) of this section was met separately with respect to the organization's section 25F segregated account for each covered State on whose State SGO list the SGO appeared.

(3) *Required annual information*—(i) *In general.* An organization that was a single-State SGO for any part of a calendar year within its taxable year must report, with respect to its taxable year (or the period during which it was an SGO, if not the entire taxable year), the following information:

(A) The number of students that applied for a scholarship;

(B) The number of students selected for a scholarship in accordance with the safe harbor in § 1.25F–3(c)(6)(iii)(C);

(C) The number of scholarships awarded;

(D) The highest, lowest, and average amount of the scholarships awarded;

(E) The number of schools at which the scholarship recipients were enrolled;

(F) Aggregate data on each category of qualified elementary and secondary education expenses for which scholarship funds were used;

(G) The amount of the organization's income;

(H) With regard to the amounts spent on scholarships for eligible students solely within the State during the taxable year:

(*1*) The total amount spent during the year; and

(*2*) Of the total amount spent during the year, the amount counted as satisfying the 90 percent of income spending requirement for the prior year, and the amount counted as satisfying that requirement for the current year;

(I) The percentage of the prior year's income spent on scholarships for eligible students solely within the State, taking into account the amounts spent in both the prior and current years;

(J) The percentage of the current year's income spent on scholarships for eligible students solely within the State; and

(K) Any other information required in accordance with guidance.

(ii) *Single-State SGO using the safe harbor found in § 1.25F–3(c)(2).* A single-State SGO using the safe harbor found in § 1.25F–3(c)(2) must report the information described in paragraph (d)(3)(i) of this section with respect to its section 25F segregated account, rather than with respect to the organization as a whole.

(iii) *Multistate SGO.* An organization that was a multistate SGO for any part of a calendar year within its taxable year must provide the information described in paragraph (d)(3)(i) of this section separately with regard to its section 25F segregated account for each covered State on whose State SGO list the organization appears.

(4) *Time and manner of reporting.* Except to the extent otherwise provided in guidance, the certification and information required by paragraphs (d)(2) and (3) of this section must be provided at such time and in such manner as the IRS may prescribe by publication, form, or instructions. For organizations required to file an annual information return under section 6033(a), the required form must be included as an attachment. An organization that is not required to file an annual information return under section 6033(a) must provide this form separately to the IRS on or before the 15th day of the 5th calendar month following the close of the period for which the form reports the required certifications and information. Organizations must concurrently provide a copy of the form to each State on whose State SGO list the organization appears in accordance with guidance.

(e) *Required audits*—(1) *In general.* Each organization that was an SGO during any part of the preceding taxable year must undergo an annual financial and programmatic audit by a qualified independent third party and provide the audit results to each covered State on whose State SGO list the SGO appeared (or, if a multistate SGO, to each covered State on whose State SGO list the SGO appeared).

(2) *Qualified independent third party*—(i) *Organizations with annual receipts exceeding $500,000.* An organization whose total receipts (whether or not required to be deposited into its section 25F segregated account) for the most recent taxable year were more than $500,000 must hire an external, independent professional or accredited body that regularly assesses an organization's compliance, financial records, or processes (including internal controls) against specific standards to perform the audit required by this paragraph (e).

(ii) *Organizations with annual receipts of $500,000 or less.* An organization whose total receipts for the taxable year did not exceed $500,000 may use a committee of independent persons unrelated to the organization's management to conduct the audit required by this paragraph (e). The report must be signed under penalties of perjury by the persons preparing such report.

(3) *Content of audit.* The audit required by this paragraph (e) must cover, at a minimum:

(i) The organization's procedures for soliciting scholarship applications or otherwise identifying possible scholarship recipients from eligible students in the State, for verifying each such student's eligibility, and for processing scholarship applications;

(ii) The organization's procedures for selecting scholarship recipients, including procedures to establish priority for students previously awarded a scholarship and then any eligible students who have a sibling who was awarded a scholarship from such organization, and procedures to prevent the award of a scholarship to a disqualified person as defined in § 1.25F–3(d);

(iii) The organization's procedures for determining the amount of the scholarship awarded to each recipient;

(iv) The method(s) the organization uses to track how scholarship money for qualified elementary and secondary education expenses is paid (whether by direct payment, through a qualified digital wallet, or by reimbursement);

(v) Verification that scholarship expenses were qualified elementary and secondary education expenses;

(vi) Verification that the organization is located within the State; and

(vii) Verification that the organization met all of the operational requirements in § 1.25F–3(c).

(4) *Scope of audit.* The audit required by this paragraph (e) must assess compliance with the elements listed in paragraph (e)(3) of this section generally consistent with the scope of the reporting requirements applicable to the SGO. Thus, the audit regarding items described in paragraphs (e)(3)(i) through (vi) of this section should be done at the section 25F segregated account level, but the audit regarding the items described in paragraph (e)(3)(vii) of this section should be done consistent with the operational requirements set forth in § 1.25F–3(c)(1), (2), or (3), as applicable to the SGO.

(f) *Applicability date.* This section applies to taxable years ending on or after [date of publication of the final regulations in the **Federal Register**].

**§ 1.25F–5 State election, State SGO list, and certification of SGOs.**

(a) *Overview.* This section provides rules under section 25F(g) of the Internal Revenue Code (Code) for a State election and participation under section

25F. Paragraph (b) of this section describes the IRS State section 25F portal used for the submission of State elections and State scholarship granting organization (SGO) lists and the reporting of any changes to State SGO lists and other required information. Paragraph (c) of this section provides rules for the State election, including an advance election, and the provision of the State SGO list. Paragraph (d) of this section provides rules regarding State SGO lists. Paragraph (e) of this section provides general guidance regarding Federal review of the policies and procedures States adopt for SGOs.

(b) *IRS State section 25F portal*—(1) *In general.* A State that chooses to participate under section 25F must register in the IRS State section 25F portal in accordance with the instructions therein. Registration requires obtaining or being assigned a special-purpose employer identification number (EIN) in accordance with paragraph (b)(3) of this section and then providing the information required by paragraph (b)(4) of this section. At the conclusion of the registration process, a State will be able to electronically transmit through the IRS State section 25F portal its State election (including an advance election), State SGO list, any changes to the State SGO list, annual certifications, and any other information required by future guidance.

(2) *Delegation*—(i) *In general.* The Governor of the State or such other individual, agency, or entity as is designated under State law to make elections with respect to Federal tax benefits on behalf of the State may authorize up to two designated officials, as described in paragraph (b)(2)(ii) of this section, to register for and use the IRS State section 25F portal. The State must provide any information and documentation necessary, in accordance with future guidance, to establish an individual's authority to use the IRS State section 25F portal on behalf of the State.

(ii) *Designated officials.* A designated official for purposes of the delegation described in paragraph (b)(2)(i) of this section must be one of the following individuals:

(A) An elected official;

(B) The Director of Taxation; or

(C) An appointed official.

(3) *Special-purpose EIN.* Before a State may begin the registration process for the IRS State section 25F portal, the State must obtain or be assigned a special-purpose EIN, to be used only for purposes of section 25F, in accordance with applicable IRS guidance. The State may not obtain its own special-purpose EIN using the general guidance for obtaining an EIN set forth in § 301.6109–1(d)(2)(i) of this chapter. The special purpose EIN cannot be used for any other purpose under the Code.

(4) *Information required to complete registration.* A State must provide the following information to complete the registration process for the IRS State section 25F portal:

(i) The State's special-purpose EIN obtained or assigned in accordance with paragraph (b)(3) of this section;

(ii) Contact information, including the name, official title, telephone number, and email address of each of the State's designated officials (if any) authorized as provided in paragraph (b)(2) of this section; and

(iii) Any other information the IRS deems necessary for purposes of administering the requirements of section 25F as may be described in future guidance.

(c) *State election*—(1) *In general.* Except as provided in paragraph (c)(3)(i)(B) of this section (providing a special rule for the first year a State makes an election), a State election may be made either as an advance election that is perfected, as described in paragraph (c)(3) of this section, or as an election made as part of the submission of the State SGO list, as described in paragraph (c)(4) of this section. The State election is made only for a single calendar year, and all the requirements in this paragraph (c) must be satisfied for each year for which an election is made.

(2) *Authority to make a State's election.* A State election, including an advance election, must be made either by the Governor of the State (or the Mayor of the District of Columbia) or by such other individual, agency, or entity as is designated under State law to make such elections with respect to Federal tax benefits on behalf of the State.

(3) *Advance election*—(i) *Submission of advance election*—(A) *In general.* Except as provided in the transition rule in paragraph (c)(3)(i)(B) of this section (or as otherwise provided in guidance), a State may submit an advance election through the IRS State section 25F portal on or after January 2 and on or before September 30 of the calendar year immediately preceding the calendar year for which the election is being made. The IRS will acknowledge or otherwise confirm receipt of a State's advance election.

(B) *Transition rule for the first calendar year for which the State makes an election*—(*1*) *Calendar year 2027.* For calendar year 2027 only, a State must submit an advance election on Form 15714, *Advance Election to Participate Under Section 25F for 2027,* on or before January 1, 2027. The IRS will acknowledge or otherwise confirm receipt of a State's advance election.

(*2*) *Future years.* For calendar years after 2027, a State making its first election to participate under section 25F must submit an advance election as provided in future guidance.

(ii) *Perfection of advance election*—(A) *In general.* Except as provided in paragraph (c)(3)(ii)(B) of this section, if a State has submitted an advance election in accordance with paragraph (c)(3)(i) of this section, the State must perfect its election by providing its State SGO list for a calendar year, with the information and certifications required in paragraph (c)(5) of this section, on or before January 1 of that year, but not earlier than October 1 of the immediately preceding calendar year.

(B) *Transition rule for the first calendar year for which section 25F applies.* For calendar year 2027 only, a State may provide its State SGO list on or before February 15, 2027.

(C) *Failure to perfect.* Because a State that makes an advance election is required by section 25F(g) to provide its State SGO list as part of its State election, a failure to perfect its advance election within the time period set forth in this paragraph (c)(3)(ii) would result in a failure to meet the requirements of section 25F(g). Accordingly, no organization in that State would qualify as an SGO for the calendar year for which the advance election was not perfected.

(iii) *IRS advance election list.* The IRS will maintain and publish on *https://www.irs.gov* a list of States that have made an advance election.

(4) *Election with submission of the State SGO list.* Except for the first year for which the State makes its election (see paragraph (c)(3)(i)(B) of this section), a State may make its State election for a calendar year when the State submits its State SGO list for that year by providing its State election and State SGO list for that calendar year, with the information and certifications required in paragraph (c)(5) of this section, on or before January 1 of that year, but not earlier than October 1 of the immediately preceding calendar year.

(5) *Certifications and other required information.* As part of providing a State election and the State SGO list under this paragraph (c), the person with authority to make the State election, as described in paragraph (c)(2) of this section, or a designated official as described in paragraph (b)(2) of this section, must, in accordance with future guidance:

(i) Certify that the individual, agency, or entity making the State election has the authority to make the State election on behalf of the State;

(ii) Certify that the person authorizing any individuals as designated officials under paragraph (b)(2) of this section has the authority to do so;

(iii) Provide the enacted statutory or regulatory provisions that are binding on the State and establish the authority of an individual to make the election on behalf of the State, if the individual making the election is not the Governor of the State (or the Mayor of the District of Columbia);

(iv) Provide the information and certifications required by paragraphs (d)(2) and (3) of this section for each SGO on the State SGO list;

(v) Certify that the State SGO list includes every organization located in the State that is described in section 25F(c)(5)(A) and (B) and § 1.25F–3(b)(1) through (4) and (6), is seeking inclusion on the State SGO list, and is operating in a manner that satisfies the operational requirements in section 25F(d) and § 1.25F–3(c) and the applicable State requirements described in paragraph (e)(1) of this section;

(vi) Provide the certification of State procedures as required by paragraph (d)(6) of this section;

(vii) Describe any tax credit (including relevant State statutes, regulations, and other authoritative guidance) available under State law for contributions made to SGOs during the calendar year for which the State is electing to participate under section 25F; and

(viii) Provide any other information and certifications described in future guidance.

(d) *State SGO lists*—(1) *In general.* Except to the extent otherwise provided in future guidance, a State must provide its State SGO list and include the information and certifications required under paragraphs (d)(2) and (3) of this section as part of its State election. Paragraph (d)(4) of this section provides a transition rule for an organization that has not yet been required to provide information and certifications to the IRS. Paragraph (d)(5) of this section provides a procedure that applies when an organization's application for recognition of tax-exempt status is pending with the IRS. Paragraph (d)(6) of this section requires a State to provide a certification regarding its policies and procedures for determining whether an organization is included on the State SGO list. Paragraph (d)(7) of this section provides rules for changes to a State SGO list, and paragraph (d)(8) of this section provides rules for the removal of an SGO from the IRS SGO list. Paragraph (d)(9) of this section provides for the publication of the names of covered States and their State SGO lists on *https://www.irs.gov.*

(2) *Required SGO information.* For each organization named on the State SGO list, a State must provide:

(i) The name, EIN, address, and telephone number of the organization;

(ii) The Federal tax-exempt status of the organization, meaning that it either is currently described in section 501(c)(3), exempt from tax under section 501(a), and not a private foundation as defined in section 509(a), or, if paragraph (d)(5) of this section applies, that its application for recognition of tax-exempt status is pending with the IRS; and

(iii) Any other information the IRS deems necessary for purposes of administering the requirements of section 25F as may be described in future guidance.

(3) *Required SGO certifications.* Except as provided for the transition rule in paragraph (d)(4) of this section, for each organization named on the State SGO list, the State must certify that:

(i) The organization is located in the State;

(ii) The organization prevents the co-mingling of qualified contributions with other amounts by maintaining a section 25F segregated account, which must contain only qualified contributions and the earnings therefrom, depositing all qualified contributions into its section 25F segregated account and maintaining a complete set of books and records for its section 25F segregated account;

(iii) The organization meets all the operational requirements described in section 25F(d) and § 1.25F–3(c);

(iv) As part of the State's determination that an organization is or will be an SGO, the State has:

(A) Determined whether the organization is or will be a single-State SGO or a multistate SGO;

(B) Reviewed the annual financial and programmatic audit report the organization is required to provide to the State in accordance with § 1.25F–4(e);

(C) Reviewed the annual certifications and other information the organization is required to provide to the IRS in accordance with § 1.25F–4(d); and

(D) Investigated any failure by the SGO to provide the required certifications and other information in accordance with § 1.25F–4, and, with respect to any such failure, has become reasonably satisfied that the SGO has corrected the failure, if possible, or has put in place procedures to prevent future failures in a manner that satisfies the State that the SGO will satisfy the requirements to be an SGO located in the State; and

(v) The organization satisfies any other requirements the IRS deems necessary for purposes of administering section 25F as may be described in future guidance.

(4) *Transition rule for an organization that has not yet been required to provide information and certifications to the IRS.* Until an organization first provides the information described in § 1.25F–4(d) and (e), a State may rely, in determining whether the organization may be treated as an SGO, on the organization's governing documents or bylaws, written policies and procedures, and other documentation the organization provides to the State as part of its submission requesting inclusion on the State SGO list. However, for each year during this transition period for which the organization is listed as an SGO on the State SGO list, the State must:

(i) Determine that the SGO satisfies all requirements of section 25F(c)(5)(A) and (B);

(ii) Determine that the SGO's provisions, policies, and procedures expressly require (beyond a general requirement to comply with applicable law) the SGO to satisfy the operational requirements for an SGO in section 25F(d) and § 1.25F–3(c);

(iii) Determine that the documentation and information available to the State evidences the SGO's ability and intent to satisfy the operational requirements in section 25F(d) and § 1.25F–3(c); and

(iv) Require the SGO to concurrently provide the State with a copy of any information and certifications required to be provided to the IRS before the end of the transition period in accordance with § 1.25F–4(d).

(5) *Procedure that applies when an organization's application for recognition of tax-exempt status is pending with the IRS.* A State SGO list may include organizations whose applications for recognition of tax-exempt status are pending with the IRS as of the date of submission of the State SGO list if the State includes on its State SGO list all organizations seeking inclusion on the State SGO list whose application for recognition of tax-exempt status is then pending with the IRS, provides the information and certifications required under paragraphs (d)(2) and (3) of this section for each such organization, and certifies, for each such organization, that:

(i) The organization has applied for, but has not yet received, IRS recognition

of its status as an organization described in section 501(c)(3);

(ii) The organization's tax-exempt status, if granted, will be effective retroactively to a date that is on or before January 1 of the year for which the State SGO list applies;

(iii) The State SGO list indicates that such organization's tax-exempt status is pending IRS recognition; and

(iv) The State has complied with the requirements of paragraph (d)(4) of this section for each such organization.

(6) *Certification of State policies and procedures.* A State must certify that its policies and procedures, including its procedures for assessing and responding to audit results:

(i) Enable the State to make its own determination that each organization on the State SGO list is located in the State, is in compliance with the requirements of section 25F(c)(5)(A) and (B) and § 1.25F–3(b)(1) through (4) and (6), and is operating in a manner that satisfies the operational requirements in section 25F(d) and § 1.25F–3(c) and the applicable State requirements described in paragraph (e)(1) of this section;

(ii) Provide for the prompt removal of an organization from the State SGO list, and notification to the IRS through the IRS State section 25F portal, upon a determination that the organization does not satisfy each of the required criteria referenced in paragraph (d)(6)(i) of this section;

(iii) Require that any publicly available list of SGOs maintained by the State is identical to the most recently submitted State SGO list, includes the IRS SGO list's URL (Uniform Resource Locator), and states that a taxpayer may rely on an organization's inclusion on the IRS SGO list in accordance with § 1.25F–2(b); and

(iv) Ensure that the State's procedures before and after the removal of an organization from the State SGO list are fairly administered and afford due process in accordance with applicable Federal and State laws.

(7) *Changes to State SGO list*—(i) *Changes before the deadline for the elected calendar year.* A State may replace or supplement its State SGO list for a calendar year at any time before the deadline for perfecting or completing an election for that year by submitting the change in the IRS State section 25F portal in accordance with future guidance.

(ii) *Additions to State SGO list after the deadline for the elected calendar year.* Except to the extent provided otherwise in guidance, a State may not make any additions to the State SGO list for a calendar year after the deadline provided in paragraph (c)(3)(ii) or (c)(4) of this section, as applicable. Any additions a State seeks to make after that deadline may be included as part of the State's submission of its State SGO list for the following calendar year.

(iii) *Removal from State SGO list*—(A) *Removal request from SGO.* If an SGO requests to be removed from a State SGO list, a State must comply, indicate the removal and its effective date on that list, and promptly notify the IRS of that removal through the IRS State section 25F portal so the IRS can remove the SGO from the IRS SGO list for the current year.

(B) *State removal procedures.* A State may remove an SGO from its State SGO list if the State determines, through a procedure providing due process to the organization, that the SGO is not located in the State, or that the SGO does not satisfy the requirements for an SGO in section 25F(c)(5) or (d), § 1.25F–3(b) or (c), or the applicable State requirements described in paragraph (e)(1) of this section. The State must promptly notify the IRS of the removal and its effective date through the IRS State section 25F portal.

(8) *Removal of a non-compliant organization from the IRS SGO list.* An organization may be removed from the IRS SGO list, and will be shown on that list as having been removed as of the date the IRS removes the organization from that list, in the following circumstances:

(i) *Removal following change in tax-exempt status.* The IRS will remove an organization from the IRS SGO list if:

(A) The organization is not described in section 501(c)(3) and exempt from tax under section 501(a); or

(B) The organization is a private foundation.

(ii) *IRS determination of non-compliance with applicable requirements.* The IRS may remove an organization from the IRS SGO list following a determination that the organization has failed to comply with a requirement of section 25F or § 1.25F–3 (other than the tax-exempt status requirement in section 25F(c)(5)(A) and § 1.25F–3(b)(1)) or has failed to comply with the requirements in § 1.25F–4, including a failure to report qualified contributions in accordance with § 1.25F–4(c). Such an IRS determination is a Federal tax controversy under section 7803(e)(3), which gives the SGO an opportunity to seek review of the determination by the IRS Independent Office of Appeals in the time and manner prescribed in applicable forms, instructions, or other administrative guidance.

(iii) *Removal following State SGO status determination.—(A) In general.* If a State removes an SGO from its State SGO list in accordance with paragraph (d)(7)(iii) of this section, the IRS will remove an SGO from the relevant part of the IRS SGO list.

(B) *Multistate SGO.* If a State removes a multistate SGO from its State SGO list under paragraph (d)(7)(iii) of this section, but the SGO continues to satisfy all applicable requirements for an SGO in a different covered State on whose State SGO list it appears, as well as the applicable requirements as described in paragraph (e)(1) of this section in such other State(s), the SGO will remain on the IRS SGO list with respect to such other covered State(s), subject to any further discretionary examination of the SGO by such other covered States or the IRS.

(9) *Publication of covered States and State SGO lists*—(i) *In general.* The IRS will maintain and publish the IRS SGO list on *https://www.irs.gov.* For those SGOs that have authorized the disclosure of their information on the IRS SGO list, the IRS SGO list will contain each SGO included on a State SGO list for each of the covered States for the calendar year and reflect each removal from a State SGO list and the date of the removal. For donor reliance on the IRS SGO list, *see* § 1.25F–2(b).

(ii) *Addition of organizations with pending tax-exempt status to IRS SGO list.* Upon determining that an organization described in paragraph (d)(5) of this section qualifies for tax-exempt status and that the effective date of such tax-exempt status is on or before January 1 of the calendar year for which the State SGO list applies, the IRS will add the organization to the IRS SGO list for that year if and as soon as the organization authorizes publication of its information to be included on that list.

(e) *State administrative requirements*—(1) *In general.* Except as provided in paragraph (e)(2) of this section, a State must:

(i) Require that organizations meet all generally applicable State requirements for charitable organizations, including any State requirements that any organization must satisfy to be authorized to do business in the State and to solicit charitable contributions in the State; and

(ii) Require SGOs to comply with application, documentation, and financial reporting requirements that are reasonably tailored to:

(A) Support the State's certifications under paragraph (d)(3) of this section; and

(B) Facilitate the prevention and detection of fraud or abuse, including the misuse of scholarship funds, such as

through the duplication of scholarship awards to the same student for the same qualified elementary or secondary education expense.

(2) *Prohibition on additional State requirements or discretionary exclusions.* A State may not require SGOs to operate in a manner that is more restrictive than the requirements set forth in section 25F(c)(5) and § 1.25F–3(b) and (c), such as by limiting the type of school that scholarship recipients may attend or the types of qualified elementary or secondary education expenses for which scholarship funds may be used. Accordingly, the State requirements provided in paragraph (e)(1)(ii) of this section must be reasonably related to determining whether an organization is located in the State, meets the requirements of section 25F(c)(5) and § 1.25F–3(b) and the operational requirements in section 25F(d) and § 1.25F–3(c), and satisfies the generally applicable State requirements for charitable organizations.

(3) *Federal review.* The procedures a State implements in accordance with this paragraph (e) are subject to Federal review. Upon discovering a pattern of irregularities or noncompliance, the IRS, in its discretion, may require a State to modify its procedures to ensure that its determinations regarding an organization's satisfaction of the requirements in section 25F(c)(5) and (d) and § 1.25F–3(b) and (c) are being administered in accordance with the applicable statutory, regulatory, and appropriate State requirements.

(f) *Applicability date.* This section applies to taxable years ending on or after [date of publication of the final regulations in the **Federal Register**].

**Frank J. Bisignano,**

*Chief Executive Officer.*

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# FEDERAL REGISTER

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Part III

## Federal Reserve System

12 CFR Parts 225, 238, and 252
Enhanced Transparency and Public Accountability of the Supervisory Stress Test Models and Scenarios; Modifications to the Capital Planning and Stress Capital Buffer Requirement Rule, Enhanced Prudential Standards Rule, and Regulation LL; Interim Final Rule

**FEDERAL RESERVE SYSTEM**

**12 CFR Parts 225, 238, and 252**

**[Regulations Y, LL, and YY; Docket No R–1873]**

**RIN 7100–AH05**

# Enhanced Transparency and Public Accountability of the Supervisory Stress Test Models and Scenarios; Modifications to the Capital Planning and Stress Capital Buffer Requirement Rule, Enhanced Prudential Standards Rule, and Regulation LL

**AGENCY:** Board of Governors of the Federal Reserve System (Board).

**ACTION:** Final rule; amendments to policy statements.

**SUMMARY:** The Board of Governors of the Federal Reserve System (Board) has adopted final amendments to Regulations Y, LL, and YY to enhance the transparency and public accountability of the Board's stress testing framework. The Board is also finalizing amendments to the Policy Statement on the Scenario Design Framework for Stress Testing and the Stress Testing Policy Statement. The Board is also announcing that it is finalizing models for the 2027 stress test and proposing for public input additional changes to the stress test models for the 2027 stress test. Finally, the Board is finalizing changes to the stress test data collection (FR Y–14A/Q/M).

**DATES:** This final rule and policy statements are effective November 2, 2026.

**FOR FURTHER INFORMATION CONTACT:** Doriana Ruffino, Associate Director (202) 452–5235, Hillel Kipnis, Assistant Director, (202) 452–2924, John Simone, Manager, (202) 245–4256, and Theo Pistner, Financial Institution and Policy Analyst III, (202) 941–1825, Division of Supervision and Regulation; William Bassett, Senior Associate Director, (202) 736–5644, Bora Durdu, Deputy Associate Director, (202) 452–3755, and Anni Isojaervi, Senior Economist, (202) 596–4054, Division of Financial Stability; Asad Kudiya, Associate General Counsel, (202) 360–6887, Julie Anthony, Senior Special Counsel, (202) 658–9400, Jonah Kind, Senior Counsel, (202) 452–2045, Brian Kesten, Senior Counsel (202) 843–4079, Tara Hofbauer, Senior Attorney (202) 680–2503, and Rye Salerno, Attorney (240) 374–7788, Legal Division. Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551. For users of TDD–TYY, please call 711 from any telephone, anywhere in the United States.

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## I. Introduction

In October 2025, the Board invited public comment on changes to the Board's stress testing framework and the comprehensive model documentation for the 2026 stress test, which included proposed changes to the models relative to the 2025 stress test.[1] The comprehensive model documentation is available at *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2026.htm.* The Board also invited comment on the proposed scenarios for the 2026 stress test through a separate notice.[2] These proposals sought to improve the transparency and public accountability of the supervisory stress test, while retaining appropriate risk sensitivity and risk capture in the stress test, ensuring that the stress test remains an effective tool to understand and assess risk. The final rule, together with the finalization of the models for the 2027 stress test, advances these goals by adopting (1) incorporating public input into the final models for the 2027 stress test, and (2) disclosure and public input processes for the scenarios and models used in future stress tests.

### *A. Background on Stress Testing*

#### 1. Stress Testing Framework

Congress enacted the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) in the wake of the 2007–09 financial crisis.[3] Section 165 of the Dodd-Frank Act, as amended by section 401 of the Economic Growth, Regulatory Relief, and Consumer Protection Act,[4] requires the Board to establish enhanced prudential standards for nonbank financial companies supervised by the Board and bank holding companies with $250 billion or more in total consolidated assets.[5] The purpose of

[1] *See* 90 FR 51856 (Nov. 18, 2025) (the ''enhanced transparency and public accountability of the stress test'' proposal or the ''proposal''). Separately, in April 2025, the Board issued a proposal that would have amended the calculation of the stress capital buffer requirement to reduce the volatility of the requirement (the ''Volatility Proposal''). Final action related to that proposal is addressed in a separate **Federal Register** notice. *See* 90 FR 16843 (Apr. 22, 2025).

[2] *See* 90 FR 51762 (Nov. 18, 2025).

[3] Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010).

[4] Economic Growth, Regulatory Relief, and Consumer Protection Act, Public Law 115–174, 132 Stat. 1296 (2018).

[5] *See* 12 U.S.C. 5365(a). In addition, the International Lending Supervision Act of 1983

these enhanced prudential standards is to prevent or mitigate risks to the financial stability of the United States that could arise from the material financial distress or failure, or ongoing activities, of large, interconnected financial institutions.

Section 165(i)(1) of the Dodd-Frank Act requires the Board to conduct an annual supervisory stress test of nonbank financial companies supervised by the Board and bank holding companies with $250 billion or more in total consolidated assets to evaluate whether the firm has the capital, on a total consolidated basis, necessary to absorb losses as a result of adverse economic conditions.[6] Section 401(e) of the Economic Growth, Regulatory Relief, and Consumer Protection Act requires the Board to conduct periodic stress tests for bank holding companies with total consolidated assets between $100 billion and $250 billion.[7] Section 165(i)(1) of the Dodd-Frank Act requires the Board to publish a summary of the supervisory stress test results.[8] In 2012, the Board adopted a final rule implementing the stress test requirements established in the Dodd-Frank Act.[9]

The Dodd-Frank Act also requires bank holding companies with $250 billion or more in total consolidated assets, as well as nonbank financial companies supervised by the Board, to conduct company-run stress tests on a periodic basis.[10] Under the Board's rules, firms subject to Category I, II, or III standards must conduct company-run stress tests.[11] Company-run stress tests provide forward-looking information to supervisors to assist in their overall assessments of a firm's capital adequacy, help to better identify downside risks and the potential impact of adverse outcomes on the firm's capital adequacy, and assist in achieving the financial stability goals of the Dodd-Frank Act. Further, the company-run stress tests help improve firms' stress testing practices with respect to their own internal assessments of capital adequacy and overall capital planning.

Each June, the Board publishes the results of its annual supervisory stress test, including each firm's projected capital ratios, pre-tax net income, losses, revenues, and expenses, under hypothetical, severely adverse economic and financial conditions.[12] These disclosures provide the public with valuable information about each firm's financial condition and the ability of each firm to absorb losses considering a stressful economic environment. However, the supervisory stress test is not designed or intended to be predictive of future economic conditions.

Following the 2007–09 financial crisis, the Board also made changes to its capital rule to address weaknesses observed during the crisis.[13] These changes included the establishment of a minimum common equity tier 1 capital requirement and a fixed capital conservation buffer equal to 2.5 percent of risk-weighted assets.[14] Large firms also became subject to a countercyclical capital buffer requirement, and the largest and most systemically important firms—global systemically important bank holding companies, or GSIBs—became subject to an additional capital buffer based on a measure of their systemic risk, the GSIB surcharge.[15] In 2020, the Board adopted the stress capital buffer requirement for certain firms.[16] Because a firm's stress capital buffer requirement is informed by the firm's performance under the hypothetical economic conditions modeled by the supervisory stress test, each firm's stress capital buffer requirement is tailored to its risk profile.

Supervisory stress testing and stronger capital requirements have significantly improved the resilience of the U.S. banking system. Since 2009, the common equity capital ratios of firms subject to the test have more than doubled, with common equity capital of such firms increasing by over $1 trillion.[17] Greater transparency into the stress test and the calculation of the stress capital buffer requirement would allow firms to better understand the capital requirements associated with investment and expansion of different business lines and would facilitate more effective long-term capital planning. This, in turn, could enhance firms' ability to supply credit to households and businesses, ultimately supporting economic growth and financial stability.

### *B. Prior Supervisory Stress Disclosures and Policy Statements*

In addition to the annual stress test results disclosure, the Board has historically published detailed descriptions and information about the supervisory stress test scenarios and models. This section provides an overview of the Board's disclosures and policy statements prior to the proposal.

#### 1. Stress Test Scenarios

The Board's stress test rules have provided that the Board will notify firms, by no later than February 15 of each year, of the scenarios that the Board will apply to conduct its annual supervisory stress test and that firms must use to conduct their company-run stress tests.[18] The Board also has provided a narrative description of the scenarios no later than February 15 of each calendar year.[19]

In 2013, the Board increased the transparency of the scenarios by finalizing the Policy Statement on the

provides the Board with broad discretionary authority to set minimum capital levels for state member banks and certain affiliates of insured depository institutions, including holding companies, supervised by the Board. *See* 12 U.S.C. 3902(1); 3907(a); 3909(a). Under section 5(b) of the Bank Holding Company Act of 1956 (Bank Holding Company Act), the Board may issue such regulations and orders relating to capital requirements of bank holding companies as may be necessary for the Board to carry out the purposes of the Bank Holding Company Act. 12 U.S.C. 1844(b). Foreign banking organizations with a U.S. branch, agency, or commercial lending company subsidiary are made subject by the International Banking Act of 1978 (International Banking Act) to the provisions of the Bank Holding Company Act in the same manner as bank holding companies, *see* 12 U.S.C. 3106; therefore, the Board is also authorized under section 5(b) of the Bank Holding Company Act to impose these requirements on those foreign banking organizations, including on their U.S. operations. Similarly, with regard to savings and loan holding companies, section 10(g) of the Home Owners' Loan Act authorizes the Board to issue such regulations and orders relating to capital requirements as the Board deems necessary and appropriate to carry out the purposes of the Home Owners' Loan Act. *See* 12 U.S.C. 1467a(g)(1).

[6] 12 U.S.C. 5365(i)(1).

[7] 12 U.S.C. 5365 note (Supervisory Stress Test).

[8] 12 U.S.C. 5365(i)(1)(B)(v).

[9] *See* 77 FR 62378 (Oct. 12, 2012).

[10] 12 U.S.C. 5365(i)(2).

[11] *See* 84 FR 59032 (Nov. 1, 2019); 12 CFR 238.142; 12 CFR 252.53. State member banks with average total consolidated assets of greater than $250 billion must also conduct company-run stress tests. 12 CFR 252.13.

[12] A firm subject to Category I through III standards must participate in the supervisory stress test every year, while a firm subject to Category IV standards is generally required to participate only every other year. *See* 12 CFR 217.2; 12 CFR 238.10; 12 CFR 252.5; 84 FR 59032 (Nov. 1, 2019).

[13] See generally 12 CFR part 217.

[14] *See* 78 FR 62018 (Oct. 11, 2013); 12 CFR 217.11.

[15] See 80 FR 49082 (Aug. 14, 2015).

[16] In 2020, the Board finalized a rule to integrate supervisory stress test results into the capital framework, through the stress capital buffer requirement. *See* 85 FR 15576 (Mar. 18, 2020). The stress capital buffer requirement is calculated as the difference between a firm's starting and lowest projected common equity tier 1 capital ratio under the severely adverse scenario in the supervisory stress test plus four quarters of planned common stock dividends, expressed as a percentage of risk-weighted assets. *See* 12 CFR 225.8(f); 12 CFR 238.170(f). The stress capital buffer requirement framework generally applies to firms with $100 billion or more in total consolidated assets.

[17] Based on FR Y–9C (Consolidated Financial Statements for Holding Companies) filings.

[18] *See* 12 CFR 238.132(b); 12 CFR 238.143(b); 12 CFR 252.14(b); 12 CFR 252.44(b); 12 CFR 252.54(b).

[19] *See, e.g.,* Board, *2025 Stress Test Scenarios* (Feb. 2025), *https://www.federalreserve.gov/publications/files/2025-stress-test-scenarios-20250205.pdf.*

Scenario Design Framework for Stress Testing (Scenario Design Policy Statement), which articulated the Board's approach to scenario design for the supervisory and company-run stress tests, outlining the characteristics of the stress test scenarios, and explaining the considerations and procedures that underlie the formulation of these scenarios.[20] The Scenario Design Policy Statement also described the baseline and severely adverse scenarios, the Board's approach for developing these two macroeconomic scenarios, and the approach for developing any additional components of the stress test scenarios. The Scenario Design Policy Statement explained that the severely adverse scenario is designed to reflect conditions that have characterized post-war U.S. recessions (the recession approach). Historically, recessions have typically featured increases in the unemployment rate, contractions in aggregate incomes and economic activity, and declines in inflation and interest rates.

In the 2013 Scenario Design Policy Statement, the Board explained that, in light of the typical co-movement of measures of economic activity during economic downturns, such as the unemployment rate and gross domestic product, the Board would first specify a path for the unemployment rate and then develop paths for other measures of activity broadly consistent with the course of the unemployment rate in developing the severely adverse scenario. The 2013 Scenario Design Policy Statement also stated that economic variables included in the scenarios may change over time, and that the Board may augment the recession approach with certain salient risks, which would involve incorporating features that address aspects of the current economic or financial market environment that represent higher-than-normal risks to the condition of the banking system.

In 2019, the Board updated the Scenario Design Policy Statement, increasing the transparency and predictability of the scenarios. The updates allowed for a smaller-than-usual increase in unemployment if the stress test were to occur during an economic downturn, a change that would pass through to reduced severity of other key scenario variables due to the deference given to historical correlations. The 2019 update also introduced a formula with countercyclical features to guide the evolution of the ratio of housing prices to disposable income in the scenario, which provided more predictability in the way that the stress test would treat business lines affected by changes in house prices. However, the Board believes that the design of scenarios could be made more transparent and predictable through the use of additional guides for certain macroeconomic variables, and the disclosure of additional detailed information on the methodology used to create the global market shock component of the severely adverse scenario, as described below.

2. Trading and Counterparty Components

For a subset of firms, the severely adverse scenario also includes two additional components: the global market shock component and the largest counterparty default component.[21] The global market shock component is a group of hypothetical shocks to a large set of risk factors reflecting general market distress and heightened uncertainty that the Board may require certain firms to include in the severely adverse scenario.[22] The Board generally expects that firms with significant trading activity will consider the global market shock component as part of its severely adverse scenario and recognize associated losses in the first quarter of the projection horizon.[23] The global market shock component has been applied to asset positions held by the firms on a given as-of date.[24] In addition, for certain large and highly interconnected firms, the same global market shock component is generally applied to counterparty exposures under the largest counterparty default component.[25] The largest counterparty default component is intended to assess the potential losses and capital impact associated with the default of the largest counterparty of each applicable firm, and the as-of date aligns with that of the global market shock component.

The design and specification of the global market shock component differs from the design and specification of the severely adverse scenario in several respects. First, in alignment with U.S. generally accepted accounting principles (U.S. GAAP), profits and losses from trading and counterparty credit positions are measured in mark-to-market accounting terms in the global market shock, while revenues and losses from traditional banking activities, as generated under macroeconomic scenarios, are generally measured using the accrual accounting method. Second, the timing of loss recognition differs between the global market shock and the severely adverse macroeconomic scenario. The global market shock affects the mark-to-market value of trading positions and counterparty credit losses in the first quarter of the severely adverse scenario. This timing is based on an observation that market dislocations can happen rapidly and unpredictably at any time under stressed conditions. In addition, the severely adverse scenario has been applied as of December 31 of each year (the jump-off date), whereas the global market shock as-of date changes every year (within the window specified in the Board's stress test rules, as applicable) and does not necessarily coincide with the year-end. This timing is also based on a scenario assumption that market dislocations can happen rapidly and unpredictably at any time during the scenario horizon. Recognizing the global market shock in the first quarter helps ensure that potential losses from trading and counterparty exposures are incorporated into firms' capital ratios in each quarter of the severely adverse scenario.

[20] 12 CFR part 252, Appendix A.

[21] *See* 12 CFR 238.143(b)(2)(i); 12 CFR 252.14(b)(2)(i); 12 CFR 252.54(b)(2)(i). For more information on the scenarios and components, *see* Board, 2025 Stress Test Scenarios (Feb. 2025), *https://www.federalreserve.gov/publications/files/2025-stress-test-scenarios-20250205.pdf.*

[22] *Id.*

[23] The global market shock component of the company-run stress test may apply to firms subject to Category I, II, and III standards that have aggregate trading assets and liabilities of $50 billion or more, or trading assets and liabilities equal to or greater than 10 percent of total consolidated assets. *See* 12 CFR 238.143(b)(2)(i); 12 CFR 252.14(b)(2)(i); 12 CFR 252.54(b)(2)(i). The Board expects to require this group of firms with significant trading activities to include a trading and counterparty component in the severely adverse scenario for the supervisory stress test. *See* 12 CFR 252, Appendix A, sections 1(b) and 3.2(a).

[24] Under the Board's current stress test rules, the global market shock as-of date must occur between October 1 and March 1. *See* 12 CFR 238.143(b)(2)(i); 12 CFR 252.14(b)(2)(i); 12 CFR 252.54(b)(2)(i).

[25] The largest counterparty default component generally applies to all firms subject to the global market shock component, as well as firms with substantial processing and custodial operations.

3. Stress Test Models

Prior to 2019, the annual stress test results disclosure document contained an appendix describing the Board's supervisory stress test models.[26] In 2019, the Board increased the transparency of the supervisory stress test models by finalizing the Stress Testing Policy Statement [27] and the Enhanced Disclosure of the Models Used in the Federal Reserve's Supervisory Stress Test (Enhanced Model Disclosure).[28] The Stress Testing Policy Statement describes the Board's policies and procedures that guide the development, implementation, and validation of the models.[29] The Stress Testing Policy Statement also describes the Board's principles for stress test model design, namely that the system of models used in the supervisory stress test should result in projections that are (1) independent of firm projections; (2) forward-looking in that they project future losses and revenue; (3) consistent and comparable across firms; (4) generated from simple approaches, where appropriate; (5) robust and stable; (6) conservative; and (7) able to capture the effect of severe economic stress. The Board has developed stress test models in accordance with these principles, which are the foundation for the stress test modeling decisions described in the comprehensive documentation of the supervisory stress test models that the Board is publishing in conjunction with this proposal.

The Enhanced Model Disclosure supplemented prior public descriptions of the stress test models by providing some information about their structure and by including a list of key variables that influence the results of each model.[30]

*C. Supervisory Stress Test Modeling Framework*

The Board's stress test models take macroeconomic variables from the Board's severely adverse scenario and data from firms as inputs to produce each firm's projected capital ratios over a nine-quarter projection horizon (projection horizon). The minimum projected common equity tier 1 capital ratio is used to inform each firm's stress capital buffer requirement, which becomes part of a firm's capital conservation buffer.

The stress test models are intended to capture how a firm's regulatory capital would be affected by the macroeconomic and financial conditions described in the stress test scenarios, given the characteristics of the firm's business model and balance sheet composition. The Board uses a variety of statistical modeling techniques to produce the stress test results, including multivariate regression, which uses relationships in historical data to produce projections of a variable (such as a loss given default). These models are represented by a set of formulas and coefficients that produce the projections.

The Board estimates the effect of the severely adverse scenario on the regulatory capital ratios of firms by projecting revenues, expenses, and losses for each firm over the projection horizon. The projection horizon spans nine quarters to ensure that the firms can continue to provide credit and serve as financial intermediaries despite several quarters of adverse economic conditions, as well as to promote the forward-looking nature of capital planning by firms.

Projected net income, adjusted for the effect of taxes, is combined with assumptions regarding capital actions and other changes to regulatory capital to produce post-stress capital ratios. The Board's approach to modeling supervisory stress test results, including the calculation of post-stress capital ratios, is generally in alignment with U.S. GAAP and the regulatory capital framework.[31] However, the stress test models may deviate from U.S. GAAP and the regulatory capital framework, as circumstances warrant.

The Board established the Stress Testing Policy Statement modeling principles to ensure that the models are well suited for their purpose in the regulatory framework. In some cases, the Board's adherence to the principles limits modeling choices and results in certain common limitations across similarly constructed component models. For instance, consistent with the principles of independence, consistency and comparability, and simplicity, models are not designed to capture all firm-specific nuances, future strategic initiatives, or planned capital actions. Additionally, models may be limited by their reliance on historic relationships and by the nature of the data captured in firms' regulatory reports. Detailed assumptions and limitations for the models are discussed in the comprehensive documentation, which is available at *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2026.htm.*

Under the Stress Testing Policy Statement, the Board's projections also assume that a firm's balance sheet remains unchanged throughout the projection horizon.[32] This assumption seeks to help ensure that a firm cannot ''shrink to health'' and that it remains sufficiently capitalized to accommodate credit demand in a severe downturn.

*D. Stress Test Models*

The Board's stress test models comprise twenty-one component models that, when aggregated, produce projected regulatory capital ratios for each firm (see Table 1 below). The models can be grouped into four categories: credit risk, market risk, net revenue, and aggregation. These models enable the Board to estimate the effect of the scenarios on the regulatory capital ratios of firms participating in the stress test by projecting net income and other components of regulatory capital for each firm over a nine-quarter projection horizon.

Credit risk models capture losses associated with retail and wholesale loans that are held at amortized cost. Market risk models capture losses associated with trading and counterparty exposures, securities, and other assets held at fair value. Net revenue models capture income and expenses, including those related to operational risk, earned or incurred by a firm. Positive pre-provision net revenue typically offsets credit and market risk losses in the calculation of a firm's pre-tax net income. Aggregation models calculate a firm's pre-tax net income, which is then adjusted for other elements such as taxes and regulatory capital deductions to arrive at the projection of a firm's regulatory capital, which is used to calculate a firm's projected capital ratios. Additional detail about these component models is included in the comprehensive model documentation available at *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2027.htm.*[33]

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[26] *See, e.g.,* Board, *2018 Supervisory Stress Test Results* (Jun. 2018), *https://www.federalreserve.gov/publications/files/2018-dfast-methodology-results-20180621.pdf.*

[27] *See* 84 FR 6664 (Feb. 28, 2019).

[28] *See* 84 FR 6784 (Feb. 28, 2019).

[29] *See* 12 CFR 252, Appendix B.

[30] *See, e.g.,* Board, *2025 Supervisory Stress Test Methodology* (Jun. 2025), *https://www.federalreserve.gov/publications/files/2025-june-supervisory-stress-test-methodology.pdf.*

[31] *See generally* 12 CFR part 217.

[32] *See* 12 CFR 252, Appendix B, section 2.7.

[33] *See* Board, *2025 Supervisory Stress Test Methodology* (Jun. 2025), *https://www.federalreserve.gov/publications/files/2025-june-supervisory-stress-test-methodology.pdf;* Board, Dodd-Frank Act Stress Tests 2026 (Jun. 2026), *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2026.htm.*

**Table 1:** Summary of Stress Test Component Models

| Portfolio | Component Model | Description |
|---|---|---|
| Credit Risk Models | 1. Auto Model | Projects loan losses on domestic consumer loans held for investment at amortized cost that are extended for the purpose of purchasing new and used automobiles and light motor vehicles |
| | 2. Credit Card Model | Projects loan losses on domestic credit card exposures to individuals that are held for investment at amortized cost |
| | 3. First Lien Model | Projects loan losses on domestic first lien mortgages that are held for investment at amortized cost |
| | 4. Home Equity Model | Projects loan losses on domestic home equity exposures that are held for investment at amortized cost |
| | 5. Other Retail Model | Projects loan losses on loans in other retail loan categories that are held for investment at amortized cost |
| | 6. Corporate Model | Projects losses on corporate loans and leases that are held for investment at amortized cost |
| | 7. Commercial Real Estate Model | Projects losses on commercial real estate loans that are held for investment at amortized cost |
| Market Risk Models[34] | 8. Securities Model | Projects losses on available-for-sale debt securities, held-to-maturity debt securities, and equity securities with readily determinable fair values not held for trading |
| | 9. Fair Value Option Model | Projects gains and losses on loans subject to fair value accounting |
| | 10. Yield Curve Model | Projects Treasury, Secured Overnight Financing Rate (SOFR), and corporate yields by maturity |
| | 11. Private Equity Model | Projects losses on private equity investments |
| | 12. Trading Issuer Default Loss Model | Projects losses resulting from defaults of trading book credit positions |
| | 13. Trading Profit and Loss Model | Projects mark-to-market losses on trading positions in response to the global market shock component |
| | 14. Credit Valuation Adjustment Model | Projects counterparty credit risk losses in the global market shock component |
| | 15. Largest Counterparty Default Model | Projects losses from hypothetical default of largest counterparty |
| Net Revenue Models | 16. Operational Risk Model | Projects operational losses (e.g., losses stemming from events such as fraud, computer system failures, process errors, and lawsuits) |

| Portfolio | Component Model | Description |
|---|---|---|
| | 17. Pre-provision Net Revenue Model | Projects income from banking services, activities, and products, net of expenses related to the provision of these same services, activities, and products, and excluding loan loss provisions, operational losses, and net gains (losses) on sales of other real estate owned |
| Aggregation Models | 18. Balances Model | Produces flat-balance sheet input data |
| | 19. Retained Earnings Model | Projects retained earnings by combining supervisory projections of pre-tax net income, tax, and capital distribution items |
| | 20. Provisions Model | Projects credit loss provisions and allowances by combining supervisory projections of loan, lease, and securities credit losses |
| | 21. Capital Model | Projects change in regulatory capital and risk-weighted assets |

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*E. Overview and Purpose of the Proposal*

This section summarizes the contents and purpose of the proposal.

1. Overview of the Proposal

The Board proposed to codify an enhanced disclosure process that would build on the previous efforts that the Board has made to increase the transparency and public accountability of the supervisory stress test. Under this enhanced disclosure process, the Board would annually publish comprehensive model documentation on the stress test models, invite public comment on any material changes that the Board seeks to make to those models, and annually publish the stress test scenarios for comment. The Board would have also committed to responding to substantive public comments on any material model changes before implementing such changes. The proposal would have revised the Stress Testing Policy Statement to align with this enhanced disclosure process, as well as to amend the Board's general policy related to disclosing additional information directly to a firm about that firm's supervisory stress test results. To accommodate the annual comment process on the scenarios, the proposal would have also shifted the jump-off date of the supervisory and company-run stress tests from December 31 to September 30.

Additionally, the proposal would have amended the Scenario Design Policy Statement in several ways. The Board would have included in the Scenario Design Policy Statement detailed descriptions of additional guides that are used to inform the Board's choice of the values of the scenario variables along their scenario paths. The guides were designed to balance the competing objectives of predictability and transparency with the severity and relevance of the macroeconomic and financial market scenarios. Most of the proposed guides also incorporated features similar to the range of options in the existing unemployment guide or the automatic adjustment of the house price path to current housing market conditions in the existing house price guide. This approach would have allowed the Board to continue to adjust the severity of those variables as necessary to avoid inducing greater procyclicality in the financial system and macroeconomy.

Similarly, the Board proposed to incorporate additional information into the Scenario Design Policy Statement about the framework used to create the global market shock component of the severely adverse scenario. This information included, but was not limited to, details on the logic underlying the severity of the shocks and a description of the processes used to generate the shock values. The Board also proposed to update the global market shock methodology to simplify the scenario and better align certain elements of the global market shock with the nature of an ''instantaneous'' shock. The proposal would have also revised the stress test rules to improve the risk capture of the supervisory stress test by widening the as-of date window for the global market shock.

The proposal also would have made changes to the FR Y–14A/Q/M reports to remove items and documentation requirements that would no longer be needed to conduct the supervisory stress test, as well as to collect additional data to improve risk capture.

The Board also published comprehensive documentation on the stress test models on the Board's website, which is available at *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2026.htm*. This documentation contains information on the models that produce the results of the supervisory stress test, including the equations, variables, and coefficients used in each model (where applicable); assumptions and limitations of each model; rationales for modeling decisions; and discussions of alternative models. Section VI.A of this **SUPPLEMENTARY INFORMATION** summarizes changes to the models, relative to the 2025 stress test, that the Board plans to implement in the 2027 stress test cycle; Section VI.B of this **SUPPLEMENTARY INFORMATION** contains an analysis of the potential effects of these proposed model changes. Detailed documentation on these changes is also provided on the Board's website, at *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2027.htm*.

[34] The Trading Issuer Default Loss Model, Trading Profit and Loss Model, Credit Valuation Adjustment Model, and Largest Counterparty Default Model apply only to a subset of firms. *See* Section II.B of this **SUPPLEMENTARY INFORMATION**.

2. Purpose of the Proposal

The purpose of this proposal was to provide the public with more information about the stress test models and scenarios and to help ensure that the public has an opportunity to comment on the models and scenarios. While the Board has increased the transparency of the stress test models over time, disclosing additional information about the models and their underlying methodologies will further increase transparency and improve public accountability. At the same time, these changes were intended to improve the risk capture of the supervisory stress test and ensure the test's ability to capture changes in risks in the financial industry over time.

As described in the proposal, publishing detailed descriptions of the stress test models for comment, as well as committing to future enhanced disclosures, has benefits. First, the increase in transparency would increase public accountability and instill confidence in the fairness of the supervisory stress tests. Second, the disclosure process would create a new mechanism for obtaining feedback from the public, including academics, financial analysts, and firms, on the design and specifications of the models, which should lead to model improvements. Third, a firm would have a better sense of how its risk profile would factor into its stress test results and stress capital buffer requirement, which would reduce the likelihood of unanticipated stress test results and allow for better capital and business planning by firms. Finally, the public disclosure of additional information about supervisory stress tests should strengthen market discipline, because investors, counterparties, and rating agencies would be able to better assess a firm's risk profile.[35] The costs and benefits of publishing descriptions of the models and committing to future enhanced disclosures were described in Section X of the **SUPPLEMENTARY INFORMATION** in the proposal.

With respect to the proposed amendments to the Scenario Design Policy Statement, the proposal also built on the contents of the current Scenario Design Policy Statement and would have amended it to provide additional transparency, public accountability, and predictability in the variable paths. The changes would have supported the Board in developing scenarios, inviting comment on those scenarios, incorporating input from commenters, and maintaining the current schedule for release of the final scenarios. Despite the increased predictability in the scenarios, the proposed framework would have remained flexible enough to suitably assess whether firms could maintain an adequate amount of loss-absorbing capital to stay above minimum regulatory requirements and continue financial intermediation during periods of stress. Further, the proposed framework would have promoted the scenario design principle of avoiding adding procyclicality to the financial system. In practice, the scenarios resulting from the revised framework were expected to remain consistent with the current Scenario Design Policy Statement and should not have resulted, on average over a typical business cycle, in materially different scenarios than would have been designed previously.

Taken together, these changes were intended to improve transparency, public accountability, and predictability of the supervisory scenarios, while ensuring the supervisory stress test's ability to capture changes in risks in the financial industry over time.

*F. General Summary of Comments*

The Board received 30 comments on the proposal from banking organizations, trade associations, public interest groups, and private individuals.[36] Most commenters were supportive of the proposal's objective of enhancing the transparency and public accountability the stress test models and scenarios while also ensuring the supervisory stress test's ability to capture changes in the risks in the financial industry over time. However, some commenters objected to the increased transparency of the stress test, stating that it would undermine the effectiveness and dynamism of the test. Commenters provided a range of views on the proposed changes to the stress test rules, policy statements, and the scenarios and models.

With respect to the proposed changes to the Board's stress testing rules, including the annual calendar of stress test disclosures and results and capital planning submissions, the Board received comments that supported scenario disclosure only after the stress test jump-off date. However, some commenters suggested an alternative schedule that would accommodate the public comment period on scenarios and material model changes while retaining the December 31 jump-off date. One commenter recommended the inclusion of additional scenarios with more severe assumptions and also recommended that the Board introduce a qualitative objection process. Another commenter recommended that the Board adopt quantitative parameters that govern scenario and shock design. Commenters also provided input on the applicability of the global market shock component and the dividend add-on to different categories of firms. Some commenters also recommended that all model changes be published for public input, not just material model changes.

Commenters provided general support and input on the proposed changes to the Stress Test Policy Statement and Scenario Design Policy Statement. Commenters also provided input on the proposed modifications to the FR Y–14A/Q/M reports, while suggesting additional changes to the reporting forms that would enhance the granularity of certain stress test models or reduce regulatory burden.

[35] *See, e.g.,* N. Gambetta, M.A. García-Benau, and A. Zorio-Grima, *Stress test impact and bank risk profile: Evidence from macro stress testing in Europe,* International Review of Economics & Finance 61 (2019), 347–54; I. Goldstein and Y. Leitner, ''Stress test disclosure: theory, practice, and new perspectives,'' *Handbook of Financial Stress Testing* (2022), 208–223.

[36] *See* Enhanced Transparency and Public Accountability of the Supervisory Stress Test Models and Scenarios; Modifications to the Capital Planning and Stress Capital Buffer Requirement Rule, Enhanced Prudential Standards Rule, and Regulation LL [R–1873], *https://www.federalreserve.gov/apps/proposals/FR-2025-0063-01/details.*

With respect to the proposed models for the 2026 stress test, commenters provided a mix of comments that expressed general support for the proposed models, as well as suggestions for additional changes, including many conceptual and technical adjustments. In general, many commenters recommended increasing the complexity and granularity of the models to better reflect differences across the firms subject to the stress test. For instance, some commenters suggested significant changes to the pre-provision net revenue (PPNR) models related to noninterest income and noninterest expense. Several of these commenters also recommended the Board adjust its modeling approach to better reflect risk mitigants on firms' balance sheets in stress test results, such as through broader consideration of hedging instruments in the stress test models. Several commenters also suggested implementation of additional stress test components that would capture risks related to digital assets or climate events.

Finally, commenters also provided input on other proposals and their interaction with this one, such as the Board's Volatility Proposal and the Board's recent capital proposals.[37] To the extent those comments were relevant to this proposal, they are addressed in the Supplementary Information below.

*G. Overview of the Final Rule and Final Policy Statements*

The Board is finalizing the rule and the policy statements largely as proposed, but with several modifications. These revisions would further improve the transparency and public accountability of the stress test, while maintaining the dynamism and risk sensitivity of the stress test framework.

1. Key Changes in Response to Comments

In considering the comments provided by the public and the purposes of the proposal, the Board determined to make several key changes to the final rule relative to the proposal.

Stress Testing Calendar

The Board proposed to revise several dates in the annual stress test cycle and sought feedback on revising other dates to comport with any final changes to cycle deadlines. For the final rule, the Board determined to revise several dates that are set out in the stress test rule and policy statements. The Board proposed to move the annual jump-off date to September 30 from December 31 to accommodate a public input period without requiring any accompanying changes to the rest of the stress test calendar. However, the Board is finalizing this rule without changing the current stress test jump-off date given concerns from commenters about operational burden and data integrity related to existing year-end processes. Retaining the December 31 jump-off date requires several adjustments to the annual cycle to enable public input on stress test scenarios, as described below.

With respect to model disclosure, the Board did not propose a single date by which the Board would publish material model changes for comment. However, the Board is finalizing August 31 of the year prior to the stress test as the date by which the Board will publish any such proposed changes for public input. This date will ensure that the Board can meaningfully engage with public comments before implementing material model changes.

With respect to scenario disclosure, the Board proposed to disclose scenarios for public input on October 15 of the year prior to the stress test, but it will adopt January 10 of the year of the stress test in this final rule so that the scenarios are proposed after the jump-off date. Disclosing proposed scenarios after the jump-off date prevents firms from adjusting their exposures based on the published scenario information. In addition, to ensure that a firm subject to Category IV standards must decide whether to participate in the stress test in an odd-numbered year prior to the disclosure of the proposed scenarios, the final rule would move the date by which these firms must make that determination from January 15 to January 5.[38] Next, the Board proposed a public input period of at least 30 days for proposed scenarios, and it has retained this proposed public input period in this final rule to ensure the public has time to consider the proposed scenarios and provide input, as appropriate. Relatedly, the Board proposed to retain the February 15 date to publish final scenarios, but it is revising this date to February 28 to ensure that the Board has sufficient time to consider public input prior to finalizing the scenarios.

The Board also did not propose changes to the capital plan submission deadline or to the date by which firms subject to Category I–III standards must conduct company-run stress tests, but it is adopting April 30 as the deadline for both of these requirements under the final rule to ensure firms have sufficient time to submit capital plans and conduct company-run stress tests following the publication of the final scenarios.

The Board did not propose changes to the 15 calendar day timeframe in which a firm can request reconsideration of its stress capital buffer requirement. However, to provide firms with more time to consider whether to request reconsideration, the Board is revising this timeframe to 15 business days. The Board also did not propose revising the date by which it must disclose final stress capital buffer requirements, which is currently August 31. However, the final rule moves this date to September 30 to better ensure that the Board can adequately assess reconsideration requests before disclosing final stress capital buffer requirements.

Finally, as part of a separate final rule associated with the Volatility Proposal, the Board is moving the effective date of firms' stress capital buffer requirement from October 1 to January 1 to allow firms more time to comply with their new requirement. While not discussed in this final rule, this effective date change is included in Table 2 for completeness.

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[37] 91 FR 14908 (Mar. 27, 2026); 91 FR 14952 (Mar. 27, 2026); and 91 FR 15332 (Mar. 27, 2026) (together, the ''2026 Capital Proposals'').

[38] Category IV firms generally are not required to participate in the supervisory stress test during odd-numbered years. 12 CFR 252.44(d)(1). However, Category IV firms may elect to participate in the stress test in a year ending in an odd number by providing notice to the Board. 12 CFR 252.44(d)(2)(ii).

**Table 2:** Comparison of Existing Annual Stress Test Dates and Final Rule Dates

| Annual Stress Test Milestone | Existing Rule | Final Rule |
|---|---|---|
| Request public input on material model change prior to implementation | N/A[39] | August 31 |
| Public input period length for material model changes | N/A | At least 30 days |
| Scenario jump-off date | December 31 | December 31 |
| Firms subject to Category IV standards opt into stress test in odd-numbered year | January 15 | January 5 |
| Disclosure of proposed scenarios | N/A | January 10 |
| Public input period length for scenarios | N/A | At least 30 days |
| Disclosure of final scenarios | February 15 | February 28 |
| Stressed counterparty data submission deadline[40] | April 5 | April 5 |
| Capital plan submission and company-run stress test deadline[41] | April 5 | April 30 |
| Final model disclosure | N/A | May 15 |
| Results disclosure and preliminary stress capital buffer requirement notification | June 30 | June 30 |
| Adjusted Capital Actions Deadline | 2 business days after results disclosure | 2 business days after results disclosure |
| Reconsideration Deadline | 15 calendar days after results disclosure | 15 business days after results disclosure |
| Final stress capital buffer requirement disclosure | August 31 | September 30 |
| Stress capital buffer requirement effective date | October 1 | January 1 |

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Material Model Changes

The Board also proposed to introduce a material model change definition, which would have required the Board to publish for public input prior to implementation certain model changes that could have, in the Board's estimation, an impact on the post-stress common equity tier 1 capital ratio of any firm, or on the average post-stress common equity tier 1 capital ratios of all firms required to participate in the upcoming stress test cycle, based on the prior year's severely adverse scenario and prior year's input data, equal to (i) a change of 20 basis points or more in the projected common equity tier 1 ratio of any firm participating in the upcoming stress test cycle; or (ii) a change of 10 basis points or more in the average of the absolute value of each firm's change in projected common equity tier 1 ratio. In the final rule, the Board is revising this proposed definition so that the criteria to determine whether a model change would be published for public input

[39] Previously, the Board's practice was to publish all material model changes in the annual model methodology document and phase in material model changes over two years. *See, e.g.*, Board, 2025 Supervisory Stress Test Methodology (Jun. 2025), *https://www.federalreserve.gov/publications/files/2025-june-supervisory-stress-test-methodology.pdf*. *See also* 12 CFR 252, Appendix B, section 2.3.

[40] Submission of FR Y–14A data needed for the Board to calculate stress test losses related to the global market shock component would also continue to be due on this date.

[41] Submission of FR Y–14A data not needed to calculate stress test losses related to the global market shock component would also be due on this date.

prior to implementation is based on the post-stress common equity tier 1 capital ratio of each of the firms subject to the supervisory stress test, as described below in Section II.C of this **SUPPLEMENTARY INFORMATION**. As a result, the Board will consider a model change's impact on all firms that have at least $100 billion in total consolidated assets, and which have completed transition arrangements and continue to be subject to the stress test, regardless of whether those firms are actually required to participate in the upcoming stress test cycle. More specifically, this revision would ensure that the potential capital impact on all such firms is considered when determining whether a model change would be material.

Other Changes

Additionally, the Board is finalizing the proposed changes to the FR Y–14A/Q/M forms with some additional changes. To reduce reporting burden, the final rule would remove items, schedules, and supporting documentation requirements that are no longer needed to conduct the supervisory stress test, largely as proposed. The final rule would also add a limited number of items to enable implementation of the models for the 2027 stress test, as well as to allow for potential future model enhancements.

Finally, the Board is also making additional changes to the global market shock component of the severely adverse scenario, which is set out in the final rule for company-run stress tests and the Scenario Design Policy Statement. These changes concern the date range in which the global market shock as-of date must occur and the number of global market shock scenarios for a given stress test, both of which improve the risk capture of the global market shock component. The Board proposed to revise the date selection range of the GMS as-of date to be a full year, between October 1 of two years prior to a given stress test cycle to October 1 of the year prior to a given stress test cycle. The final rule adopts a date selection range of nine months, between April 1 and December 31 of the year prior to the stress test. This nine-month range would allow the Board to consider a wider array of market conditions for the as-of date of the global market shock component than is possible using the current range of five months. Additionally, the revised Scenario Design Policy Statement will explain that the Board expects to establish two different GMS scenarios on a single date for a given annual stress test, which would differ from the current approach of having one GMS scenario on a single date.

The Board is also finalizing the Board's Stress Testing Policy Statement and Scenario Design Policy Statement largely as proposed, but with several modifications. With respect to the Stress Testing Policy Statement, the Board is amending this policy statement to affirm its expectation to continue providing the enhanced firm and public disclosure processes described in this notice. With respect to the Scenario Design Policy Statement, the Board is finalizing the proposal's substantive and technical changes to the policy statement that provide additional transparency into the Board's scenario design process, with several technical adjustments relative to the proposal.

2. Purpose of the Final Rule and the Final Policy Statements

As stated above, the purpose of the proposal was generally to increase transparency and public accountability while improving the risk capture of the supervisory stress test and ensuring the test's ability to capture changes in risks in the financial industry over time.

The Board received a range of comments on the purposes of the proposed rule, which the Board considered in evaluating policy options for this final rulemaking.

Many commenters supported the Board's actions to increase the transparency of the stress test, stating that improved transparency would support the predictability of the stress test. Increased predictability would improve capital allocation and planning at firms subject to the stress test. One commenter also stated that predictable stress tests would improve market discipline, as investors, counterparties, and analysts would be better able to understand stress test results, while also improving the public's confidence in the stress test.

Commenters that supported the purposes of the proposal specifically highlighted the proposed public input processes for stress test scenarios and models. Commenters suggested that the public input process would improve model quality by enabling public input in identifying weaknesses or challenging assumptions in the models. One commenter stated that the increased transparency would lower risk in the financial system by improving the risk capture of the stress test models.

Commenters also suggested that the proposal would, if finalized, reduce the volatility of stress capital buffer requirements. According to these commenters, reducing the volatility of the stress test would support effective capital planning and the deployment of capital and liquidity into the broader economy, which would improve the availability and cost of credit for businesses and households because firms would be able to better anticipate volatility in stress capital buffer requirements.

Other commenters opposed the proposal and its purpose to increase the transparency of the stress test. Some commenters stated that the proposal would increase the predictability of the stress test, which would reduce the dynamism of the stress test and limit its ability to capture salient and unseen or under-appreciated risks by making the annual test more repetitive. These commenters generally expressed concern that model and scenario disclosure would enable or incentivize firms to limit their stress test losses by adjusting their balance sheets. These commenters argued that firms would be able to optimize their balance sheets for the stress test, which would enable them to lower their stress capital buffer requirements without necessarily reducing the riskiness of their portfolios. Some commenters expressed concern that model disclosure would lead to ''model monoculture,'' whereby firms adjust their internal models to adopt the Board's stress test models and miss specific risks that would be relevant to a given firm or set of firms. However, another commenter argued that concerns about ''model monoculture'' and balance sheet optimization are misplaced, and that supervisory attention and firm incentives eliminate any realistic possibility of balance sheet optimization based on the disclosed models.

Commenters also provided feedback on the Board's retained discretion in model and scenario design, and they suggested that the Board take steps to prevent model arbitrage and balance sheet optimization, and to continuously evaluate the impacts of the transparency introduced by the proposal, including through publication of model and scenario specifications prior to the stress test jump-off date. One commenter offered suggestions for adjusting the global market shock component so that it incorporates two shock scenarios in order to mitigate these risks. Commenters also suggested that the Board provide additional explanation of how it would balance the transparency of the proposal with the integrity of the stress test, or how the Board would exercise its discretion with respect to certain modeling decisions, such as modeling changes that would occur after the publication of the model

documentation. Some commenters also suggested that the Board retain the confidentiality of some information related to the models and scenario specifications and rationales, or that the Board publish this information on a delayed basis, to mitigate the risk that firms tailor portfolios to the stress test models rather than underlying risks.

After considering input from the public, the Board remains committed to the proposal's goals of increasing transparency and public accountability while improving the risk capture of the supervisory stress test and supporting the broader goals of the stress test program. The Board expects that, under the final rule, the stress test models and scenarios will remain robust and effectively able to capture risks to the financial system. As described in the proposal, seeking public input on the scenarios and models has several benefits, including increased public accountability and confidence in the fairness of the stress test, improved scenarios and models that incorporate public feedback, improved capital planning due to the reduced likelihood of unanticipated stress test results, and stronger market discipline, as the public will be able to better assess a firm's risk profile. Together with enhancements to the Board's models and scenario design framework, and the Volatility final rule, the Board expects this final action will improve the transparency and public accountability of the stress test, while enabling the Board to continue to meet the goals of the stress test.

The Board's response to comments on specific aspects of the proposal, as well as its rationale for the final rule and policy statements, are described below.

*H. Interactions With Other Proposals*

The Board has published other policy actions for public comment and received input on those proposals, including the Volatility Proposal and the 2026 Capital Proposals. Some commenters on those proposals also provided comments on the enhanced transparency and public accountability of the stress test proposal, including with respect to interactions between these proposals. For example, some commenters suggested that the Board should consider overlaps between the risks captured by the Board's stress test models and the 2026 Capital Proposals, and that the Board should develop an implementation timeline that considers effective dates of each proposal. The Board addressed comments on the Volatility Proposal in the final action described in a separate **Federal Register** notice. The Board has addressed comments on this enhanced transparency and public accountability of the stress test proposal in this notice, and will address comments on the 2026 Capital Proposals in any final action on those proposals.

**II. Enhanced Disclosure Process**

Under the proposal, the Board would have codified an enhanced disclosure process. As part of this process, the Board would annually publish comprehensive documentation on the stress test models, invite public input on any material changes that the Board seeks to make to those models, and annually publish the stress test scenarios for comment. The Board is finalizing this aspect of the proposal, with several enhancements and adjustments.

*A. Annual Disclosure of Models*

Under the proposal, the Board would have annually published the models used to conduct the supervisory stress test. The form of this disclosure would be similar to the comprehensive documentation on the stress test models that was published with the proposal at *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2026.htm*. The Board would have been required to disclose its models by May 15 of the year in which the stress test is performed, and the models described in the documentation would be used to produce the stress test results disclosed by the Board by June 30 of that year. In addition, the Board would seek public input, and respond to such substantive public input, on any material changes to the models before implementing those changes in a stress test. Material model changes are discussed in more detail in Section II.C of this **SUPPLEMENTARY INFORMATION**. To implement this enhanced disclosure process, the Board proposed to revise Regulations YY and LL, as well as the Stress Testing Policy Statement.

The Board received many comments on the proposal to annually disclose the models used in the stress test as well as the date of disclosure. Commenters provided a range of feedback on the Board's approach to model disclosure. As described above in Section I.G of this **SUPPLEMENTARY INFORMATION**, many commenters supported the Board's actions to increase the transparency of the stress test, stating that improved transparency would support the predictability of the stress test for firms subject to the stress test, which would improve capital allocation and planning.

Conversely, some commenters opposed the enhanced model disclosures described in the proposal, stating that these disclosures would increase the predictability of the stress test, reduce the dynamism of the stress test, and limit its ability to capture salient and unseen or under-appreciated risks by making the annual test more repetitive. These commenters expressed concerns that these disclosures would enable firms to adjust their balance sheets to reduce their stress capital buffer requirements without necessarily reducing actual risks. These commenters also expressed concern that model disclosure would lead to ''model monoculture,'' whereby firms adjust their internal models to adopt the Board's stress test models and miss specific risks that would be relevant to a given firm or set of firms. One of these commenters further stated that while disclosure of the conceptual bases for the models would be appropriate, certain operational details may need to be held as confidential to avoid creating incentives for firms to tailor their exposures to the stress test models rather than the firm's assessment of risk. Another commenter recommended that the Board also disclose other model details, such as validation information, to better facilitate public comment. One commenter suggested that the Board align its disclosure practices with international peers and establish a review mechanism where independent experts would periodically evaluate the Board's stress test methodologies.

With respect to the May 15 model disclosure date, one commenter stated that the Board should publish the final model documentation prior to the capital plan submission date, which was set as April 5 of each year under the current stress testing rules.[42] This commenter stated that it would be important for firms to understand the models used in the stress test prior to submitting their capital plans, and that the Board's approach would not comply with the Board's legal obligations under the Administrative Procedure Act and the Due Process Clause of the U.S. Constitution.

One commenter stated that establishing a set timeline for model disclosure could leave models outdated as financial markets and risk profiles can change rapidly. This commenter suggested that the Board adopt a mechanism for expedited procedures for urgent model updates that respond to threats to financial stability. This commenter also expressed concern that the annual stress test cycle would be compressed further by incorporating

[42] An adjustment to this aspect of the Board's stress testing rules is described in Section II.E of this **SUPPLEMENTARY INFORMATION**.

public input on the models, which could limit the Board's ability to incorporate feedback without disrupting the annual stress test cycle.

The Board is adopting this aspect of the proposal, with one change to enable disclosure of necessary additional adjustments to models that may occur after May 15.

As described above in Section I.G of this **SUPPLEMENTARY INFORMATION**, the Board is committed to enhancing the transparency and public accountability of the stress test, including through disclosure of the models the Board uses in the annual stress test. The Board has considered the risks identified by commenters in disclosing the Board's stress test models and has implemented several mitigating measures in this final action, as described throughout this **SUPPLEMENTARY INFORMATION**, and also retained certain mitigating measures, such as the Model Validation Council, which is a council of external academic experts that provides independent advice on the Board's process to assess models used in the supervisory stress test and is described in the Stress Testing Policy Statement.[43]

The Board considered comments about milestones in the broader stress test cycle, discussed throughout this **SUPPLEMENTARY INFORMATION**, and determined that a May 15 disclosure date would best balance the public's interest in timely disclosure with the operational demands of the stress test cycle, particularly in implementing an additional public input process into the annual cycle. Disclosure of stress test models before May 15 would not allow the Board to adequately develop, propose, and evaluate public input on changes to the stress test models for use in that year's stress test, or to update model parameters based on recent data submissions. Further, material model changes will be disclosed for public input well in advance of May 15 each year, providing firms and the public with a reasonable sense of the impacts to results of any such adjustments to the Board's models.

Additionally, in a change from the proposal and in consideration of comments received, the Board is adopting a process by which the Board could make non-material, technical changes after the final models have been disclosed, including after May 15. Such adjustments would be limited to fixing clear errors, making technical changes, and addressing circumstances where the Board determines that a change in the models is necessary to accurately determine firms' stress test losses. These types of post May 15 changes and disclosures would ensure that the Board can correct identified errors in the stress test models or documentation and would ensure the effective administration of the stress test before stress test results are finalized. These changes would be published so that the public could understand the changes and firms could understand their results. In this situation, the Board would publish a description of the model updates no later than June 30.

Additionally, the Board considered whether it could be appropriate to retain the confidentiality of certain aspects of the Board's models at this time or in the future. The Board has provided detailed descriptions of its stress test models and has not determined to implement a mechanism that would establish that certain aspects of the Board's models would remain confidential. However, the Board has not disclosed some information related to the models, such as the firm-specific fixed effects and third party vendor information. The Board does not view publishing this information as necessary to meet the goals of this final rule. However, the Board is committed to the transparency of the stress test, and will continue to consider any appropriate disclosure enhancements in the future.

*B. Model Changes*

The proposed rule would have defined a ''model change'' to mean ''the introduction of a new model or a conceptual change to an existing model.'' The Board's proposed definition of ''model change'' is an important component of the Board's proposed definition of ''material model changes,'' which is discussed in greater detail in Section II.C. of this **SUPPLEMENTARY INFORMATION**. As explained in the proposal, the Board would publish ''material model changes'' for public input prior to implementing those changes in the supervisory stress test. To balance the benefit of public feedback with the operational and resource costs of seeking such feedback and to allow the Board to ensure reasonable results, the Board would not formally invite public comment on model adjustments or updates that are not new models or conceptual changes to existing models before implementing them in the stress test; however, the Board would welcome public feedback on these and all other aspects of the stress test models once they are published.

Some commenters suggested that all changes to the models should be published for comment before they are implemented, with one commenter suggesting they be published by August 31 for a 60-day comment period. One commenter said that the Board's definition of ''model change'' is unduly narrow and argued that the Board should revise the definition to capture any change to the modeling process that affects results, including changes to methodology, removal of firm data, re-estimation of model parameters, or changes to the scope of a model's use.[44] As described below in Section II.C of this **SUPPLEMENTARY INFORMATION**, the Board also considered comments that stated the Board's approach would violate the Administrative Procedure Act and the Due Process Clause of the U.S. Constitution.

The Board is finalizing this aspect of the proposal as proposed, with technical adjustments to the regulation text definition of ''model change'' to incorporate descriptive language which had been included in the proposal's preamble.

As explained in the proposal, a ''new model'' means a model that fully replaces one of the twenty-one component models described in this Section of this **SUPPLEMENTARY INFORMATION**, or is added to the modeling suite (*e.g.,* a 22nd component model). Conceptual changes to existing models would include changes to model assumptions, incorporation of a new statistical technique, or the addition or deletion of any model components or sub-components that currently inform a firm's stress capital buffer requirement.

Model changes would not include changes resulting from updates or adjustments to input data, such as firm data, third-party vendor data, and scenario data, including any re-estimation based on this data, as well as changes related to accounting definitions or to the mechanical implementation of federal, state, or local laws that are directly embedded in a stress test model (*e.g.,* the federal statutory tax rate). In this final rule, the Board is including this detail regarding the Board's definition of ''model change'' directly in the regulation text, in order to promote the clarity and predictability of this definition. As is current practice, the Board would generally continue to implement changes in accounting definitions or regulatory capital rules and model parameter re-estimation based on newly available data with immediate effect. These types of adjustments would not be considered model changes because

[43] 12 CFR 252, Appendix B, section 3.

[44] Re-estimation comprises updates to model parameters based on consideration of different input data (*e.g.,* incorporating the most recent year's data as a model input, or incorporating data from new stress test entrants or from mergers).

they do not substantively change the form of the stress test models as described in the documentation. For example, the Board re-estimates many of its models with updated data each year when it runs the supervisory stress test. This re-estimation may result in changes to the statistical coefficients produced by some of the models, even though the Board has made no conceptual changes to the models. Under the proposed definition of model change, such re-estimation would not be viewed as a model change because the resulting changes stem solely from updated data and not from a conceptual change to the models. Similarly, changes to the estimation sample periods would not be considered model changes. Finally, the definition of model changes would exclude model adjustments made in response to a reconsideration request granted by the Board.

The Board considered the range of comments on this aspect of the proposal, including those that suggested that all changes to the Board's stress test models should be published for comment, as well as other comments that suggested that none of the models should be put out for comment, or only a portion of the models or aspects of the models.

The Board is committed to enhancing the transparency and public accountability of the stress test, and the Board is balancing those considerations with practical operational challenges of administering the annual stress test. Under the approach finalized here, the public is able to provide input on the most important changes to the models before they are implemented, while other necessary and appropriate adjustments to the models will continue to occur without disrupting or disincentivizing model improvements within and across the annual stress test cycles.

As explained in the proposal, the Board will annually disclose adjustments to the models that are not ''model changes'' and will welcome public feedback, whether within a public input period on proposed material model changes or informally, on these adjustments and all other aspects of the stress test models as they are published. Notably, firms will be able to review these changes prior to the deadline to submit requests for reconsideration of their stress capital buffer requirements. In considering these comments, the Board determined that adopting the proposed definition of ''model change,'' with additional clarification, as part of the regulation text rather than solely in this **SUPPLEMENTARY INFORMATION**, appropriately balances the public's interest in transparency with the goals and operational challenges of the stress test program.

The Board also considered comments suggesting that it should disclose adjustments to models that do not meet the definition of model changes and provide a measurement of their expected impact. The Board is not adopting a formal template or criteria for disclosing these adjustments. Rather, the Board expects to continue to use the existing format for identifying adjustments to the models, which best balances the public's interest in transparency with the practical limitations of an annual stress test, the complexity of the Board's stress test models, and the potential to refine disclosures over time. Consistent with the disclosure methods described in this Section and Section II.A of this **SUPPLEMENTARY INFORMATION** to provide transparency on adjustments to the models year to year, these adjustments will be included in applicable model documentation published by May 15.[45]

Finally, the Board also considered comments that stated the Board's approach would violate the Administrative Procedure Act and the Due Process Clause of the U.S. Constitution. These comments are discussed below in Section II.C of this **SUPPLEMENTARY INFORMATION**.

*C. Material Model Changes*

The proposal would have established a definition of ''material model change,'' so that such material model changes would be published for public input prior to implementation in the annual stress test. This approach would balance the public's interest in commenting on the most important changes to the Board's stress test modeling framework with the importance of maintaining a dynamic stress test modeling framework that achieves the goals of the Board's stress test program, and operational burden in administering the program.

The Board proposed to define a ''material model change'' as a model change that could have, in the Board's estimation, an impact on the post-stress common equity tier 1 capital ratio of any firm, or on the average post-stress common equity tier 1 capital ratios of all firms required to participate in the upcoming stress test cycle, based on the prior year's severely adverse scenario and prior year's input data, equal to (i) a change of 20 basis points or more in the projected common equity tier 1 ratio of any firm participating in the upcoming stress test cycle; or (ii) a change of 10 basis points or more in the average of the absolute value of each firm's change in projected common equity tier 1 ratio.[46] The Board proposed to apply this definition of a material model change such that the individual materiality threshold would apply to all firms required to participate in the next stress test, and such that the Board's estimation of whether a change meets the aggregate materiality threshold would be determined across all firms required to participate in the next stress test.

The proposed rule did not establish a specific deadline by which the Board would publish material model changes for public input or the length of the public input period. However, the proposal asked for public feedback on the appropriate length of the public input period.

The Board received many comments on this aspect of the proposal. Several commenters supported publishing material model changes for comment, as described below in Section II.E and Section III.B of this **SUPPLEMENTARY INFORMATION**. With respect to the proposed definition of ''material model change,'' some commenters disagreed with the inclusion of a materiality threshold, suggesting that the Board instead publish all changes to the models for comment, as described above in Sections II.A and II.B of this **SUPPLEMENTARY INFORMATION**. One commenter stated that the Board's proposed definition of ''material'' model change does not capture all changes that could result in significant effects on stress test results. The commenter argued that, if the Board retains the materiality threshold, it should be revised to capture changes to models that are significant in aggregate for one year or over multiple cycles and that the aggregation should be based on absolute value of all changes rather than net impact. The commenter recommended a threshold of a 10 basis point change in the aggregated impact of the absolute value of changes for any particular firm. Without the aggregate impact, the commenter asserted that the Board could influence what is proposed as ''material'' based on its definition of an individual change. The commenter also

[45] As noted in Section II.A of this **SUPPLEMENTARY INFORMATION**, the Board could correct errors and make technical changes to the models, as well as address circumstances necessary to accurately determine firms' stress test losses, potentially after May 15. In such cases, documentation of the updates would be published no later than the date of results disclosure.

[46] The Board would take the absolute value of each firm's change in projected common equity tier 1 ratio, then average those values. If the average is 10 basis points or greater, the change would constitute a material model change.

recommended that the Board disclose the impact of each change. The commenter suggested that the Board's definition of ''material changes'' should include changes that are below the capital materiality threshold but have a substantial effect on losses associated with a particular asset or exposure, which could potentially disincentivize stress tested firms' participation in affected markets. The commenter also proposed certain principles for defining materiality, including that immaterial changes should not affect a firm's capital requirement; that immaterial changes should not affect the incentives that firms have to enter or exit a particular business; and that materiality analysis should be robust to different scenarios and jump-off data.

Other commenters opposed subjecting material model changes to public input because the increased transparency would reduce the dynamism of the stress test and undermine its purposes. These commenters noted that the public comment process would slow the development of the Board's models, making them out-of-date and therefore unable to capture salient and evolving risks. The Board also considered comments discussed above in Section II.A and Section II.B of this **SUPPLEMENTARY INFORMATION**, which raised concerns that the model disclosure process would pose risks to the Board's stress testing program, and that the public input process could introduce challenges in completing the annual stress test cycle. Additional discussion of comments regarding the purposes of the proposal are described above in Section I.E–G of this **SUPPLEMENTARY INFORMATION.**

Commenters also provided feedback on how the Board would calculate materiality. One commenter stated that the Board should use two years of data in the materiality analysis because materiality could change based on the scenario or jump-off data. Alternatively, the commenter proposed that the Board could periodically conduct and publish sensitivity analysis on material changes. Another commenter stated that the proposed definition of ''material model change'' would be defined based on the firms that are required to participate in a given year's stress testing cycle, which excluded firms subject to Category IV standards in years when those firms are not required to participate in the stress test. The commenter recommended that the effects of a model change on firms subject to Category IV standards be reflected in the materiality analysis, including in years when a firm subject to Category IV standards is not required to participate in the stress test.

With respect to the proposed public input process for material model changes, several commenters supported the Board's proposal to respond to substantive comments on material model changes. One commenter suggested that the Board publish proposed model changes by August 31 of the year prior to the stress test, and adopt a 60-day comment period for proposed model changes. One commenter suggested that the Board adopt a phased disclosure process that initially presents only high-level information to mitigate the risk that firms reverse-engineer the results of the stress test. Another commenter suggested that the Board codify the timing for proposing material model changes and disclosing all other changes. The commenter also recommended that the model disclosure timeline be revised so that final models are published in advance of capital plan submission dates, which is discussed below in Section II.E of this **SUPPLEMENTARY INFORMATION.**

As described above in Section II.B of this **SUPPLEMENTARY INFORMATION**, the Board also considered comments that stated the Board's approach would violate the Administrative Procedure Act and the Due Process Clause of the U.S. Constitution. This commenter asserted that limiting proposed model changes to only those that are material violates the APA and the Due Process Clause of the U.S. Constitution. The commenter argued that the models themselves are legislative rules, and thus they can only be amended by a legislative rule. The commenter further asserted that a materiality threshold is inconsistent with the letter and spirit of the APA and noted that the APA allows flexibility (like interim final rules or direct final rulemaking) for rare cases when the Board would need to make urgent changes. The commenter argued that the Board should publish the full suite of stress test models each year but should still specify the changes made and the impact from each change.

In addition, the commenter argued that limiting proposed model changes to only those that are material is ambiguous and increases administrative burdens on the Board and firms, and further said that the Board would need to determine and explain the scope of ''model change'' and ''material model change.'' The Board also considered comments discussed above in Section II of this **SUPPLEMENTARY INFORMATION**, which raised concerns that the model disclosure process would pose risks to the Board's stress testing program, and that the public input process could introduce challenges in compressing the annual stress test cycle. The Board also received comments on the proposal's definition of ''model change'' together with comments on the proposal's definition of ''material model change,'' which are addressed here and above in Section II.B of this **SUPPLEMENTARY INFORMATION.**

The Board is finalizing this aspect of the proposal with adjustments, as explained below. In considering the comments on the proposal, the Board is revising the proposal's definition of ''material model change'' to include all of the firms subject to the stress test, as described below, rather than only those firms subject to the stress test in a given year. This approach expands the set of firms considered and is expected to result in more model changes meeting the threshold for a ''material model change.'' Under this approach, a ''material model change'' will be defined as any model change resulting in either (i) an impact of 20 basis points or more to the projected common equity tier 1 capital ratio of any ''materiality determination company'' (as defined below), or (ii) a change of 10 basis points or more in the average of the absolute value of changes in the projected common equity tier 1 capital ratio for all materiality determination companies.[47] The Board is defining a materiality determination company to mean any company that (1) in at least one of the past two stress test cycles, has been subject to the Board's stress test analysis, (2) in both the year prior to the year in which the stress test is performed and the year in which the stress test is performed, is subject to the stress test rules, and (3) has average total consolidated assets of at least $100 billion, as of the date of disclosure of material model changes. The Board is also establishing that material model changes will be published for public input by August 31 of the year prior to the year in which the stress test will be administered, for a period of at least 30 days.

As described above in Section II.B of this **SUPPLEMENTARY INFORMATION**, the Board considered the range of comments on this aspect of the proposal, including those that suggested that all changes to the Board's stress test models should be published for public input, as well as other comments that suggested that none of the models should be put out for comment, or that only a portion of the models or aspects

[47] Regarding (ii), the Board will take the absolute value of each materiality determination company's change in projected common equity tier 1 ratio, then average those values. If the average is 10 basis points or greater, the change will constitute a material model change.

of the models should be published for public input.

As described in the proposal, a materiality threshold is important because many adjustments to models and model changes are necessary to ensure that the models remain dynamic (*i.e.,* can be enhanced to capture emerging risks), produce reasonable results, identify salient risks at firms, and maintain an optimal level of robustness and stability. Many of these adjustments typically occur throughout the annual stress test cycle, including after scenarios are published. This threshold allows the Board to refine and enhance its models to reflect advances in modeling techniques, respond to model validation findings, incorporate richer and more detailed data, or identify more stable models or models with improved performance, particularly under stressful economic conditions. The Board's process for making these adjustments is an important aspect of the modeling framework and helps to ensure that the stress test models can more quickly capture changes in borrower and lender behavior, as well as in bank business practices.

In addition, the Board has sometimes needed to make changes to its stress test models while the stress test is ongoing. These changes have often been in response to unforeseen events or circumstances and are necessary to ensure that model output is reasonable. For example, during the COVID–19 pandemic, the vacancy rates for hotel properties were unprecedented, and the Board made certain adjustments to yield sensible commercial real estate loan losses in the model output. Without these in-cycle changes, the results of the stress test would have been irrational and may have led to stress capital buffer requirements that were not commensurate with certain firms' risk profiles, including results that may have overstated firm risk profiles.

In the Board's judgment, it is not necessary or practical to solicit public input on every adjustment and model change before implementing them in an annual stress test. The Board proposed and received input on the comprehensive disclosure of all of the stress test models as part of the proposal in 2025. While the Board is establishing a process to ensure that material model changes will be published for input before implementing them in the future, repetition of a comprehensive model publication, comment, and review process every year is not necessary for the models that have already received public input. An annual process for commenting on all of the stress test models would significantly increase the uncertainty related to the stress test models year to year, reduce the focus of the public input process on any material model changes, and demand significant resources from firms and the Board to administer each year.

As explained above in Section II.B, the public disclosure process for other, non-material changes or adjustments to the models will provide an appropriate level of transparency and opportunity for feedback on these changes without posing significant operational challenges or resulting in excessive volumes and publications within each stress test cycle. This approach balances the benefit of public feedback with the operational and resource costs of seeking such feedback. It also allows the Board to make timely model adjustments to ensure reasonable results, consistent with the purposes of the stress test program. For example, many econometric models are updated annually to ensure that they are relevant and incorporate data that reflects the current business environment.

Notably, the Board would not implement any in-cycle adjustments that are considered material model changes prior to seeking public input on the adjustments. In addition, the Board would review and respond to all substantive public input on material model changes before implementing the changes in the stress test.

With respect to the specific thresholds in the definition of materiality, the Board considered the comments and determined to keep the proposed threshold of a 20 basis point change in the common equity tier 1 capital ratio for individual firms. This threshold will ensure that the public can comment on any change likely to affect a firm's stress capital buffer requirement prior to its implementation. Considering the history of recent model changes, and the finalization of the Volatility Proposal, a threshold of 20 basis points would generally scope in model changes that involve conceptual enhancements to model specifications, such as to incorporate improved modeling techniques or to capture emerging risks. It would scope out those changes that are simpler model refinements, such as those implemented to ensure that the models maintain consistency given changing requirements (*e.g.,* refinements made to accommodate the transition from the London Interbank Offered Rate to SOFR). Therefore, changes of smaller magnitudes would be unlikely to impact a firm's stress capital buffer requirement, particularly because the Board has also adopted the proposed two-year averaging approach to calculate a firm's stress capital buffer requirement.[48]

The Board is also finalizing the threshold of a 10 basis point average change in the absolute value of the change to each firm's projected common equity tier 1 capital ratio. The Board will take the absolute value of each firm's change in projected common equity tier 1 ratio following a specific model change, then it will average those values. If the average is 10 basis points or greater, the change would constitute a material model change. This additional threshold covers cases when a model change has minimal individual impacts but has a notable aggregate impact on the firms subject to supervisory stress test requirements. The Board selected 10 basis points for this aggregate prong because a model change of this size would be likely to impact the aggregate projected common equity tier 1 capital ratio decline, which is rounded to 0.1 percent or 10 basis points. The aggregate projected CET1 capital decline is a frequently cited metric from the annual stress test and a salient measure of the health of the banking system. A change that satisfies one or both of the materiality thresholds would be considered a material model change. The Board considers this two-prong approach to be reasonable and appropriate for identifying the most important model changes that should receive public input prior to implementation.

In a change from the proposal, the Board adjusted the scope of firms included in the materiality analysis to include firms that (1) in at least one of the past two stress test cycles, have been subject to the Board's stress test analysis, (2) in both the year prior to the year in which the stress test is performed and the year in which the stress test is performed, are subject to the stress test rules, and (3) have average total consolidated assets of at least $100 billion, as of the date of disclosure of material model changes. Under this approach, the Board will consider a model change's impact on all firms that have at least $100 billion in total consolidated assets, and which have completed transition arrangements and continue to be subject to the stress test, regardless of whether those firms are actually required to participate in the upcoming stress test cycle. This approach will increase the operational burden associated with administering this aspect of the stress test program, but it will help ensure that firms and the public can provide input on adjustments to the Board's stress test

[48] *See* 90 FR 16843 (Apr. 22, 2025).

models that materially affect a firm's results, even if that firm is not participating in the current year's test.

The Board also considered comments that recommended that the Board conduct the materiality assessment at a more granular level or that the Board disclose additional information about the analysis in its disclosures. As explained in the proposal, the Board proposed conducting the materiality assessment without aggregating or netting across component models. The Board is finalizing this materiality assessment as proposed. For example, if the Board proposed a change to both the Pre-Provision Net Revenue Model and Corporate Model in the same stress test cycle, the Board would estimate the effects of each change separately for purposes of determining materiality. Similarly, for purposes of assessing materiality, model changes would not be aggregated or netted within component models. For example, if the Board proposed two changes to a component model, the Board would evaluate the materiality of each change separately. Conducting the assessment without aggregating or netting across component models will better ensure that the impact of each model change is considered individually, and that the public will have an opportunity to provide input on material model changes.

With respect to the form of disclosure of material model changes, the Board considered comments suggesting that the Board should disclose all model adjustments and provide a measurement of their expected impact. Consistent with the description above in Sections II.A–B of this **SUPPLEMENTARY INFORMATION**, the Board is not adopting a formal template or criteria for disclosing these adjustments. Rather, the Board expects to continue to utilize the existing format for identifying model adjustments. The model documentation is maintained on the Board's website and includes a document describing model changes year to year.[49] Consistent with the disclosure methods described in this Section and Section II.A of this **SUPPLEMENTARY INFORMATION**, in order to provide transparency about adjustments to the models year to year, the Board will propose material model changes each year by August 31, and then, as appropriate, include such changes in applicable model documentation published by May 15.[50] Additionally, the Board expects to provide a measurement of impact for proposed material model changes during a given year.

Additionally, the final rule specifies that the public input period for material model changes will be at least 30 days. The Board will evaluate the nature and extent of any material model changes that are proposed for public input and may select a longer comment period if a longer period more appropriately balances the public's interest in a reasonable opportunity to provide input with the Board's operational limitations within the annual stress test cycle. In most cases, a comment period for 30, 45, or 60 days is expected to be reasonable and practical for these purposes. However, the Board considered that the volume and nature of material model changes will vary year to year, and therefore determined that a degree of flexibility in this process would best ensure that the public has a reasonable public input period for material model changes for a given year.

Finally, as described above in Section II.B of this **SUPPLEMENTARY INFORMATION**, the Board also considered comments that stated the Board's approach would violate the Administrative Procedure Act and the Due Process Clause of the U.S. Constitution. The Board considered these comments and determined to finalize as proposed the form of the models, scenarios, scenario guides, and other aspects of the stress capital buffer requirement determination process. The structure of the Board's existing stress capital buffer requirement determination process allows the Board to ensure the stress test can meet its statutory and regulatory objectives by remaining robust, flexible, and able to address changing market conditions. In reaching this determination, the Board considered the public's interest in transparency, the goals of the stress test, and the Board's legal obligations. The purposes of this final rule are described in greater detail in Section I.G of this **SUPPLEMENTARY INFORMATION**.

*D. Annual Disclosure of Scenarios*

Under the proposal, the Board would have annually published for public input the proposed stress test scenarios by October 15 of the calendar year prior to the stress test, for at least a 30-day period. This approach was intended to permit sufficient time for the Board to consider and respond to comments and to finalize the scenarios within the current window for publication by February 15 of each annual stress test cycle.[51] This disclosure, along with the implementation of additional scenario variable guides and revisions to the Scenario Design Policy Statement, were intended to meaningfully improve the transparency, public accountability, and predictability of the annual stress tests, while mitigating risks that could materialize if the proposed scenarios were disclosed prior to the jump-off date of the supervisory stress test. The Board explained the purpose of the proposal's timeline and its interactions with other parts of the stress test calendar, as well as asked several questions in order to solicit public input on other changes to the stress test calendar that could be necessary to incorporate annual disclosure of scenarios.[52]

The Board received several comments on this aspect of the proposal. Two commenters recommended that the Board publish proposed stress test scenarios by January 5 each year, with final scenarios published by February 28 of each year. These commenters recommended that the Board retain the current December 31 jump-off date, as discussed in Section II.E of this **SUPPLEMENTARY INFORMATION**, and also recommended that the comment period for scenarios not begin until after the jump-off date has occurred. These commenters stated that the scenario comment period should be at least 15 days to accommodate publication of final scenarios in February. One of these commenters noted that this timeline would provide the Board with 40 days to consider and respond to any comments on the proposed scenarios. Another commenter agreed that the Board should retain the December 31 jump-off date with the Board publishing the proposed scenario in early January and completing the annual stress test by June 30. The Board also considered comments that provided input on whether the Board should publish scenarios for public input, which is discussed in greater detail in Section II.D of this **SUPPLEMENTARY INFORMATION**.

The Board is finalizing this aspect of the proposal with changes to accommodate the public input process while retaining the December 31 stress test jump-off date, as described in greater detail in Section II.E.1 of this

[49] *See, e.g.,* Board, Dodd-Frank Act Stress Tests 2026 (Jun. 2026), *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2026.htm.*

[50] As noted in Section II.A of this **SUPPLEMENTARY INFORMATION**, the Board could make late-stage updates to the models, potentially after May 15. In these cases, documentation of the updates would be published no later than the date of results disclosure.

[51] Trading or other components of the scenarios, and any additional scenarios used by the Board, would continue to be communicated by March 1 of the calendar year in which the stress test is performed. 12 CFR 238.132(b); 12 CFR 238.143(b)(2)(i); 12 CFR 252.14(b)(2)(i); 12 CFR 252.44(b); 12 CFR 252.54(b)(2)(i).

[52] 90 FR 51856, 51873 (Nov. 18, 2025).

**SUPPLEMENTARY INFORMATION.** Under the final rule, the Board will propose scenarios for the stress test by January 10, with final scenarios published by February 28. The Board will provide a public input period of at least 30 days. The final rule establishes that the publication of final scenarios will occur by February 28, which will provide the Board with sufficient time to respond to public input and update applicable materials between the end of the public input period and the publication date.

The Board determined that it would publish the proposed scenarios only after the annual stress test jump-off date to mitigate the risk that firms could adjust their balance sheets after the publication of the proposed scenarios. As a result, to retain the December 31 jump-off date, the Board recognized that it would be necessary to provide a limited period for input on annual scenarios in order to minimize adjustments to, and operational risks for, the remaining milestones in the annual stress test.

The Board selected January 10 for the disclosure of proposed scenarios. The Board did not select an earlier date to limit potential operational challenges at the beginning of the calendar year. When possible, the Board will publish proposed scenarios prior to this date but after December 31 of the previous calendar year. The Board selected February 28 as the publication date for final scenarios in order to provide the public with additional time to review the proposed scenarios, and for the Board to consider any comments received and adjust the scenarios due to incoming data, as necessary and appropriate. When possible, the Board will publish final scenarios in advance of February 28. If this timeline presents challenges for the public or the Board, the Board will consider and propose additional adjustments to these dates in a future action.

As explained in the proposal, by designing and publishing the revisions to the Scenario Design Policy Statement, including the guides described in Section VI.G of this **SUPPLEMENTARY INFORMATION**, the Board expects that the annual severely adverse scenarios will generally be more consistent and predictable year-to-year. As a result, the Board weighed whether publishing the annual scenarios for comment in a typical year would contribute meaningful additional accountability that would improve the stress test program, and whether the Board should limit publication of the annual scenarios for public input to situations where the Board is proposing to incorporate a salient risk into the scenarios that is not described in this proposal. However, in the interest of enhancing transparency and public accountability, the Board determined to finalize a process that involves the publication of proposed and final annual scenarios and the receipt of public input, with the process formalized through changes to Regulations LL and YY. Additionally, the Board is updating its existing delegations of authority to be consistent with this revised process, so that a joint determination by the Director of the Division of Supervision and Regulation and the Director of the Division of Financial Stability, with the concurrence of the Chair of the Board's Committee on Supervision and Regulation, would continue to apply to the proposed and final scenarios that may be published in the **Federal Register** going forward.[53]

*E. Other Revisions to the Stress Testing and Capital Plan Rules*

The Board also proposed to revise the stress testing and capital plan rules to reflect the Board's efforts to disclose more information about the stress test scenarios and allow time for those additional processes. The Board is finalizing this aspect of the proposal, with several enhancements and adjustments to accommodate the public input process, as described in Section III of this **SUPPLEMENTARY INFORMATION**, and the retention of the current stress test jump-off date.

1. Stress Test Jump-Off Date Change

Under the proposal, the Board would have modified the jump-off date of the supervisory and company-run stress tests from December 31 to September 30, while leaving unchanged the other dates associated with publication of the final scenario and stress test results.[54] In the proposal, the Board explained that the disclosure of the proposed scenarios prior to the jump-off date of the supervisory stress test could incent firms to temporarily modify their businesses to affect the results of the stress test without changing the actual risk profile of the firms. Such changes to firm business profiles could also result in greater than typical quarter-to-quarter variability in the banking books of firms. The Board proposed moving the jump-off date to September 30 to address this potential risk associated with increased transparency. In the proposal, the Board also acknowledged that this change would affect other aspects and dates in the established annual stress test cycle, such as the capital plan submission dates, and also requested feedback from the public on whether it would be appropriate to implement other modifications to limit the ability of firms to adjust their balance sheets in response to the proposed scenario prior to the jump-off date of the stress test.

Two commenters supported the proposed jump-off date of September 30, stating that the change would prevent firms from adjusting their exposures based on the proposed scenarios, and that the additional full quarter of execution time would reduce operational burden without compressing the capital planning cycle or interfering with year-end reporting.

However, many other commenters opposed the proposed change and suggested that the Board retain December 31 as the jump-off date. These commenters generally stated that the proposal would increase operational burden for firms subject to the stress test, as other stress testing regulations promulgated by other federal agencies would be expected to continue to use December 31. Some commenters stated that the approach would add an additional quarter of staleness into the stress test, which would result in a less accurate measure of bank resilience, or that a September 30 date would introduce more seasonable variability into the stress test, causing volatility in results. Other commenters noted that an advantage of the December 31 jump-off date is that it aligns with other year-end reporting obligations, as well as capital and liquidity planning milestones, for firms subject to the stress test.

Many commenters that opposed changing the jump-off date suggested that it was unnecessary to mitigate risks that firms could adjust their balance sheets after the publication of the proposed scenario. These commenters argued that it would be impractical for firms subject to the stress test to make meaningful balance sheet adjustments after the publication of the proposed scenario.

Some of these commenters also recommended that the Board consider alternative approaches to achieve its goals of collecting public input and avoiding incentivizing firms to adjust their balance sheets. These alternative approaches are discussed in greater detail in Section II.E.2 and II.E.3 of this **SUPPLEMENTARY INFORMATION**.

[53] *See* 12 CFR 265.7(c)(11); 12 CFR 265.13(a)(1).

[54] The Board has experience operating the annual supervisory stress test with a September 30 jump-off date. *See, e.g.,* Board, 2015 Supervisory Scenarios for Annual Stress Tests Required under the Dodd-Frank Act Stress Testing Rules and the Capital Plan Rule (Oct. 23, 2014), *https://www.federalreserve.gov/newsevents/pressreleases/files/bcreg20141023a1.pdf*.

The Board will not adopt the proposed jump-off date of September 30, and will retain the December 31 date in the final rule. However, as described in Section III of this **SUPPLEMENTARY INFORMATION**, the Board is making additional adjustments to the stress test calendar in order to accommodate the public input process while mitigating risks that firms could adjust their balance sheets following the disclosure of a proposed scenario.

In considering the comments on the proposal, the Board recognized that the shift to September 30 was likely to introduce significant operational and administrative burden for most firms subject to the stress test. Furthermore, a December 31 jump-off date better aligns with most firms' year end processes and capital planning activities, and it ensures that the stress test is based upon more recent and relevant data. However, the Board considers it necessary to make additional adjustments to the annual stress test cycle in order to accommodate the public input process and mitigate risks that firms adjust their balance sheets due to the publication of proposed components of the stress test prior to the jump-off date. These additional adjustments are described in Section II.E of this **SUPPLEMENTARY INFORMATION**.

2. Global Market Shock Scenarios, Date, Notifications, and Applicability

The global market shock (GMS) component has historically been applied to market risk positions held by firms on a given as-of date.[55] Under the Board's regulations, the GMS component can apply to both the supervisory stress test and the company-run stress test for applicable firms.[56] The Board also has authority to require a covered company to include one or more additional components in its severely adverse scenario in the stress test required by this section based on the company's financial condition, size, complexity, risk profile, scope of operations, or activities, or risks to the U.S. economy.[57]

Under the proposal, the Board would have revised the date range for the GMS as-of date to occur between (inclusive of) October 1 of the calendar year two years prior to the year in which the stress test is performed to (exclusive of) October 1 of the calendar year one year prior to the year in which the stress test is performed. The current GMS as-of date range is established for company-run stress tests, and extends between (inclusive of) October 1 of the year prior to the stress test to (exclusive of) March 1 of the year of the stress test.[58] In the proposal, the Board explained that a wider date range would allow the Board to capture a broader set of market risks across different time periods, thereby improving the risk capture of the global market shock. The Board has historically selected a cycle-specific as-of date each year and, typically, announced it to firms about two weeks later to ensure that firms retain necessary data. The as-of date is expected to change from year to year to avoid creating potential incentives for firms to take temporary trading positions. However, in practice, there is a comprehensive date selection process that shortens the actual window during which the GMS as-of date is generally selected. As described in this Section of the **SUPPLEMENTARY INFORMATION**, certain changes are implemented through revisions to the Board's stress test regulations, while other changes are implemented through revisions to the Board's Scenario Design Policy Statement or the model documentation for the global market shock component.[59]

For the supervisory stress test and the company-run stress test, the Board has generally provided each affected firm with a description of the GMS scenario and with the specific GMS as-of date by March 1 of the year in which the stress test occurs.[60] For the company-run stress test, the Board is generally required to also notify each affected firm by December 31 of year preceding the stress test that the firm is required to include additional components or scenarios in its company-run stress test.[61] To align the GMS component with the other proposed changes to the annual stress test cycle, the Board proposed to change the date by which the Board needs to notify affected firms of this as-of date from March 1 of the year in which the stress test occurs to October 15 of the calendar year one year prior to the year in which the stress test is performed. Finally, the Board also proposed to change the date by which the Board must notify firms that they are required to include additional components or scenarios in their company-run stress test from December 31 to September 30 of the year preceding the stress test. This change would have ensured that firms are aware of the components to which they would be subject prior to the annual publication of the proposed scenarios.

As part of the proposal, the Board did not propose to change the number of GMS components applied to firms' positions. However, the Board sought comment on whether it should consider alternative approaches to increase the risk captures of the GMS, including by applying the GMS to more than one as-of date or using more than one set of shocks in a given stress test.

The Board received many comments on this aspect of the proposal. With respect to the proposed one-year window for the GMS component as-of date, most commenters recommended that the Board retain the current five-month window. These commenters stated that the proposed one-year window would increase burden and operational complexity for firms subject to the supervisory stress test. They stated that the longer window would require firms to calculate and maintain records of daily portfolio compositions and price sensitivities. One commenter explained that a one-year cycle could cause firms to rely on manual controls to preserve trading and counterparty information needed to calculate the GMS data that firms must provide to the Board, which could complicate model governance and could introduce additional volatility in stress test results.

Other commenters suggested that the Board adopt alternative GMS windows. One commenter suggested that the Board adopt a different window, from May to October of the year prior to the year of the stress test, to improve the Board's flexibility without imposing additional challenges and burdens on firms subject to the stress test. Another commenter suggested that the Board shift the window to August 1 to December 31, stating that any concerns about balance sheet adjustments following the publication of stress test scenarios could be mitigated through ongoing monitoring and supervision.

Other commenters opposed the expansion of the GMS window because the one-year period would permit the Board to conduct the GMS component using firm data and market conditions that would be relatively more stale. One of these commenters asserted that this issue would be further compounded if the Volatility Proposal were to be adopted because that proposal would

[55] *See, e.g.,* 12 CFR 238.143(b)(2); 12 CFR 252.14(b)(2); 12 CFR 252.54(b)(2).

[56] *Id.*

[57] 12 CFR 252.14(b)(2)(ii); 12 CFR 252.54(b)(2)(ii); 12 CFR 238.143(b)(2)(ii).

[58] *See, e.g.,* 12 CFR 238.143(b)(2); 12 CFR 252.14(b)(2); 12 CFR 252.54(b)(2).

[59] Current and historical documentation is available on the Board's website. *See, e.g.,* Board, Dodd-Frank Act Stress Tests 2026 (Jun. 2026), *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2026.htm.*

[60] *See, e.g.,* 12 CFR 238.132(b); 12 CFR 238.143(b)(2); 12 CFR 252.14(b)(2); 12 CFR 252.44(b); 12 CFR 252.54(b)(2).

[61] *See, e.g.,* 12 CFR 238.143(b)(4)(i); 12 CFR 252.14(b)(4)(i); 12 CFR 252.54(b)(4)(i).

average the results of two consecutive stress tests to inform stress capital buffer requirements.

With respect to the number of GMS scenarios, one commenter recommended retaining the Board's current approach of using a single GMS scenario. As an alternative, the commenter also recommended adopting a two-month window with two GMS scenarios applied on a single as-of date. The commenter suggested that two GMS scenarios would sufficiently capture trading book dynamics while balancing burden and the Board's principle of simplicity. Other commenters expressed concern about ''window dressing,'' whereby firms could temporarily adjust their balance sheets to reduce losses from the GMS component without reducing actual risk. These commenters recommended that the Board apply two GMS scenarios with the same as-of date. One commenter further recommended that if the Board adopted a second GMS scenario, then the Board should average the results of the two scenarios to calculate GMS losses in the stress test, while another commenter suggested that the Board use the results of the scenario that showed greater losses to calculate GMS losses in the stress test. Another commenter opposed an approach where the Board would adopt two GMS scenarios, stating that it would add significant costs without advancing the objectives or usefulness of the supervisory stress test. One commenter suggested that, if the two GMS scenarios approach were adopted, the Board should eliminate exploratory scenarios, which do not impact stress test results, and reduce data requests.

Regarding the proposed changes to GMS component notifications, one commenter recommended disclosing the GMS as-of date, once chosen, publicly rather than only to firms subject to the GMS. The commenter stated that some firms voluntarily run the GMS scenario and would benefit from earlier knowledge of the as-of date. Two commenters asked that the Board codify its usual practice of providing notice of the GMS as-of date within two weeks of that date. These commenters noted that codifying the period would provide certainty to firms about when they must preserve trading and counterparty data, which is important given the costs of data retention.

Commenters also provided feedback on a question raised by the Board in the proposal that requested feedback on the current applicability of the GMS component to firms subject to Category I, II, and III standards that have aggregate trading assets and liabilities of $50 billion or more, or trading assets and liabilities equal to or greater than 10 percent of total consolidated assets. Commenters generally recommended that the Board reconsider these thresholds or recalibrate them. One commenter stated that the GMS component imposed an outsized burden on intermediate holding companies of foreign banking organizations because these entities are generally smaller than their domestic counterparts subject to the GMS component, but compliance costs represent a fixed cost for each such firm.

Some commenters recommended that the $50 billion threshold be revised to account for economic growth and inflation, including through an automatic mechanism to adjust the threshold over time. Commenters also suggested that the GMS threshold should be tailored across the firms subject to Category I, II, and III standards, so that the GMS would apply differently to those firms based on their respective category in a way that balances the prudential benefits of the GMS component with the burdens imposed on firms. One commenter suggested that the Board revise the threshold to $200 billion or more, arguing that firms below this threshold face a high operational burden if they are subject to the GMS component. This commenter also stated that changes to the Basel capital framework would sufficiently capture market risks for firms below a $200 billion threshold. Another commenter suggested increasing the threshold to $100 billion, with further indexing to account for inflation and economic growth.

Other commenters suggested removing the prong of the threshold that applies the GMS to firms with aggregate trading assets and liabilities equal to 10 percent or more of total consolidated assets. One commenter stated that this prong was not relevant to determining the systemic risk that a firm might pose, and that for firms that meet this threshold but do not pose risks to financial stability, the existing market risk capital requirements and the other components of the severely adverse scenario already ensure sufficient capital. This commenter stated that the ongoing operational burden of the GMS component was not justified by the incremental capital effect of the GMS component. This commenter suggested that the Board replace the existing thresholds with other objective criteria to determine which firms have substantial trading or custodial operations. Another commenter suggested removing U.S. Treasury securities from the calculation of trading assets and liabilities, arguing that they do not pose the same risks as other trading assets and are not subject to the same regulatory treatment.

After considering the comments, the Board is adopting this final rule with three changes from the proposal to improve risk capture, in alignment with the Board's stress testing principle of conservatism, and to mitigate compliance burden. First, the final rule includes a 9-month GMS as-of date window, spanning from April 1 to December 31 of the calendar year prior to the year the stress test is administered. Second, the final rule codifies the practice that the Board notify applicable firms of the GMS as-of date within two weeks after the date. Third, the revisions to the Scenario Design Policy Statement specify that the Board expects to have two GMS scenarios on a single as-of date for a single stress test, and that the Board will use the maximum loss of the combined trading and counterparty results across both GMS scenarios to determine a firm's stress test results. These changes are discussed below.

Separately, the Board is not adopting any changes to the GMS applicability threshold as part of this final rule, nor is the Board adjusting the Board's ability to conduct other analysis to inform supervision or risks to financial stability, such as through exploratory scenarios.

a. GMS as-of Date Window

After considering comments regarding the operational and data retention burden of a 12-month GMS as-of date window, the Board is adopting this final rule with a 9-month GMS as-of date window. By way of example, this change would mean that for the 2028 supervisory stress test, the GMS as-of date could fall on any date from April 1, 2027, to December 31, 2027. Table 3 below describes the date ranges associated with the current practice, the proposal, and the final rule.

**Table 3:** Summary of Date Range of As-of Date Window

| | **Date Range** |
|---|---|
| Current practice | Length: 5 months<br>First possible as-of date: October 1 of the year prior to the stress test year<br>Last possible as-of date: March 1 of the stress test year |
| Proposal | Length: 12 months<br>First possible as-of date: October 1 of two years prior to the stress test year<br>Last possible as-of date: September 30 of the year prior to the stress test year. |
| Final Rule | Length: 9 months<br>First possible as-of date: April 1 of the year prior to the stress test year.<br>Last possible as-of date: December 31 of the year prior to the stress test year. |

Adopting the 9-month as-of-date window in the final rule improves risk capture compared to the current 5-month window. The 9-month window will enable the Board to consider a wider array of potential GMS as-of dates, especially because, in practice, the comprehensive selection process eliminates a range of potential dates within the current window. This wider set of potential dates will allow the as-of date to occur under various economic and financial conditions and will avoid creating potential incentives for firms to take temporary trading positions in anticipation of the as-of date. Given the fluctuations in firms' trading positions, the 9-month window provides the Board the flexibility to capture a wider range of firms' portfolio compositions and risk sensitivities. Additionally, the 9-month window would include only dates prior to the release of the given stress test cycle's GMS scenario for public input. Therefore, firms subject to the GMS would not be able to use their knowledge of the GMS as-of date to optimize their balance sheet positions or adjust their portfolios based on the proposed GMS scenario.

The Board recognizes the potential operational burdens associated with the 12-month as-of-date window in the proposal, as expressed by some commenters. The 9-month window will best balance the objective of improving risk capture with the potential operational burden that firms could face. The 9-month window is longer than those recommended by many commenters, but shorter than the 12-month window put forth in the proposal. The window also does not extend as far back into the past as put forth in the proposal, reducing the potential for staleness of the stress test results. Compared to the 12-month window, the 9-month window reduces the operational burden associated with long-term data maintenance.

b. Two GMS Scenarios

As discussed above, the Board received several comments on the possibility of having more than one GMS scenario. After considering these comments, the Board is revising the Scenario Design Policy Statement to state that the Board expects to select up to two GMS scenarios that occur on a single as-of date for each annual stress test. Historically, the Board has generally disclosed a single GMS scenario for each stress test, and this component has been used to calculate trading and counterparty losses. However, the single GMS scenario has limited capability to capture risks in firms' portfolios because different firms may be exposed to different directions of shocks on the same as-of date. For example, one firm may experience losses when the U.S. dollar appreciates compared to the Japanese Yen, while another firm may experience gains in this situation. A second GMS scenario will improve the risk capture of the stress test by allowing the Board to capture a wider range of firms' vulnerabilities with opposite directions of shocks.

Additionally, introducing a second GMS scenario is likely to reduce year-over-year volatility in trading and counterparty losses. Under a single GMS scenario, a change in the direction of the shocks from one year to the next could lead to substantial variation in losses because a firm's portfolio may be particularly exposed to shocks in one direction. Due to differences in GMS scenarios from year to year, this variability can occur even if a firm's portfolio remains unchanged. The use of two GMS scenarios with potentially directionally opposite shocks can mitigate this concern because both directions of the exposures can be tested. With the introduction of a second GMS scenario, the Board expects trading and counterparty losses to be more stable over time and also more reflective of the changes in firms' risk exposures instead of changes in scenarios.

The Board determined to use the largest combined trading and counterparty losses across the two scenarios in each firm's stress test results and to inform each firm's stress capital buffer requirement. The Board also considered the option of averaging the GMS losses across the two scenarios but determined that this approach would not sufficiently reflect firms' vulnerabilities to a severe market shock. Therefore, having two GMS scenarios in one stress test with the maximum losses determining stress test results better ensures that firms are appropriately capitalized to a broader range of market events. This approach is discussed further in Section VI of this **SUPPLEMENTARY INFORMATION**.

c. Codification of GMS Notification Date

While not currently required by the stress test rules, the Board typically notifies applicable firms of the GMS as-of date within two weeks after the as-of date. This notification ensures that these firms can preserve trading and counterparty data for the as-of date. The final rule codifies this practice so that the Board would be required to notify firms subject to the GMS component of the date no later than two weeks after the as-of date. The notification ensures that firms subject to the GMS component retain necessary data, and reduces firms' data retention burden. The public and all firms not subject to the GMS component will continue to be notified of the as-of date when the

scenarios are proposed for a given stress test.

d. GMS Applicability Threshold

The Board considered comments on the current thresholds for applicability of the GMS component. The current threshold includes firms that have aggregate trading assets and liabilities of $50 billion or more, or trading assets and liabilities of 10 percent of total assets. This approach captures firms where market risk is a key risk. With respect to the aggregate size of $50 billion or more, at this time, the Board considers this threshold to be reasonably appropriate to capture trading activities that are significant to the firm and to markets. Any changes to this threshold would be accomplished through a specific proposed rulemaking. With respect to the 10 percent prong, this proportion represents a significant portion of the firm's total assets, and it continues to be appropriate for the GMS component to apply to these firms to more accurately identify the firm's trading asset and liability risks. At this time, the Board considers it appropriate to retain this threshold as an applicability criterion. The Board expects any future changes to the GMS threshold to be preceded by a proposal for public comment.

3. Other Adjustments to the Stress Test Cycle

As described in Section II of this **SUPPLEMENTARY INFORMATION**, the proposal would have moved the jump-off date of the annual stress test to September 30 to accommodate the public input process and mitigate the risk of firms adjusting their balance sheets following the publication of proposed scenarios prior to the jump-off date. Because the Board is retaining the December 31 as-of date in this final rule, the Board is also implementing additional changes to the annual stress test cycle to complement this decision and support the goals of the rulemaking.

As mentioned in Section II.E.1 of this **SUPPLEMENTARY INFORMATION**, commenters suggested many alternative approaches to the proposed September 30 jump-off date. These alternatives generally involved additional changes to key dates in the annual stress test cycle. Two commenters suggested that the Board retain the December 31 as-of date and adjust the existing and proposed dates for several components of the annual stress test, the capital plan submission deadline, and the deadline to request reconsideration. One commenter also recommended that preliminary stress capital buffer requirements, including any enhanced disclosures, should be published by June 30, 2027, for the 2027 stress test cycle. The Board also considered input from one commenter that stated that a compressed timeline for scenario development and public comment within the annual stress test cycle could impose challenges for the Board, including the Board's ability to substantively incorporate feedback within an annual cycle.

The Board is finalizing several additional changes to milestones in the annual stress test cycle as part of this final rule. While the proposal did not include specific adjustments to these components of the stress test rules, the Board asked detailed questions on the annual stress test cycle, including many of the aspects described below, and indicated that the Board was considering revisions to its rules to achieve the purposes of the proposal. Furthermore, many commenters provided suggestions to improve the annual stress test cycle and align it with other changes to dates in the proposal. The changes described below take into account the comments received, reduce regulatory burden, and support the goals of the rulemaking and the stress test program.

a. Biennial Opt-In for Category IV Firms

Under the current stress testing rules, Category IV bank holding companies, Category IV U.S. intermediate holding companies, and Category IV covered savings and loan holding companies subject to the supervisory stress test may elect to have the Board conduct a stress test with respect to that company in a year ending in an odd number by January 15.[62] This timing enables firms to consider their balance sheets as of the stress test jump-off date (December 31) but prevents these firms from considering the scenario when determining whether to opt into the stress test. As explained above in Section II.D of this **SUPPLEMENTARY INFORMATION**, the Board proposed to adjust the jump-off date for the supervisory stress test in order to implement the annual disclosure of scenarios for public input, while mitigating risks that could materialize if the proposed scenarios were disclosed prior to the jump-off date of the supervisory stress test. The Board asked several questions in order to solicit public input on other changes to the stress test calendar that could be necessary to incorporate annual disclosure of scenarios for all of the firms subject to the supervisory stress test.[63]

The Board did not propose to change this opt in date and did not receive any comments regarding this date. However, to accommodate the publication of proposed scenarios by January 10, the final rule moves the opt in date to January 5. This timing will enable firms to continue to consider their balance sheets as of the stress test jump-off date (December 31), but it will not allow them to consider the variable paths specified in the proposed scenario.

b. Capital Plan Submission and Company-Run Stress Test Dates

The Board did not propose to change the April 5 submission date for firms' annual capital plans or for firms subject to Category I–III standards to conduct company-run stress tests. However, two commenters recommended that the Board move the capital plan submission deadline to April 30 of each year so that firms would have ample time to create and review their capital plans following the publication of the final scenarios. The process for proposing and finalizing scenarios is described above; these commenters had recommended moving the final scenario publication date to February 28 to accommodate a 15-day public input period. In recommending that the Board move the capital plan submission date to April 30, these commenters argued that certain elements of the annual capital plans rely on information provided in the final scenarios publication. One of these commenters recommended a capital plan submission date of April 30 and the disclosure of final models for a given stress test by March 31. This commenter argued that this sequencing would improve capital plans because firms would have ample time to review the final scenarios and model documentation prior to submitting their annual capital plans.

In response to these comments, the final rule moves the deadline for annual capital plan submissions and date by which applicable firms must conduct company-run stress tests to April 30 to provide firms with sufficient time to submit capital plans and conduct company-run stress tests following the publication of the final scenarios. Firms need information from the final scenarios to prepare annual capital plan submissions and to conduct company-run stress tests, and these deadlines give firms additional time to meet these requirements. Relatedly, due to the connection between the data reported on the FR Y–14A report and the data

[62] 12 CFR 252.44(d)(2)(ii); 12 CFR 238.132(c)(2)(ii).

[63] 90 FR 51856, 51873.

submitted in firms' annual capital plans and in company-run stress tests, the final rule also moves the submission date for all FR Y–14A data not needed to calculate trading and counterparty losses in the stress test to April 30. The FR Y–14A data needed to calculate trading and counterparty losses will continue to be due April 5. Further discussion of changes in FR Y–14A reporting requirements is discussed in Section IV of this **SUPPLEMENTARY INFORMATION**.

c. Adjusted Capital Actions Deadline

Currently, firms subject to the supervisory stress test must notify the Board of any adjustments to their planned capital actions within two business days of receipt of notice of a stress capital buffer requirement.[64] The Board received one comment suggesting that the Board revise this deadline to provide firms with 10 business days, in order to reduce burden for firms and avoid rushed decision making.

Under the final rule, the Board is retaining the requirement for firms to notify the Board of any adjustments to their planned capital actions within two business days of receipt of notice of their stress capital buffer requirement. In the Board's experience, the current deadline for adjustments to planned capital actions provides firms with sufficient time to confidentially determine whether they wish to submit adjusted capital actions and to support alignment of firm capital actions and any applicable securities reporting obligations.

d. Final Stress Capital Buffer Requirement Notification Date

Currently, the Board provides firms subject to the supervisory stress test with their final stress capital buffer requirements and confirmed planned capital distributions by August 31 of the calendar year that a capital plan was submitted.[65] The Board received comments on the stress capital buffer reconsideration request process that suggested that the Board retain the August 31 calendar date unless the stress capital buffer effective date is moved to January 1 of the year after a capital plan was submitted. The commenter stated that if the effective date of the stress capital buffer requirement is moved, then the August 31 deadline should be extended by at least 30 days.

Under the final rule, the stress capital buffer requirement notification deadline will occur by September 30. This change is appropriate to account for the revisions described above that grant additional time for firms to submit reconsideration requests, while also enabling the Board to process any such requests efficiently. It also retains sufficient time between the notification date and the effective date to allow firms to prepare for any changes in capital requirements.[66] Additional discussion of the Board's adjustment of the effective date is included below and in the Volatility final rule.

e. Stress Capital Buffer Effective Date

Finally, the Board is also revising the stress capital buffer effective date, which is currently October 1, in a separate rulemaking.[67] As explained in the notice for the Volatility Rule, that final rule revises the effective date to be January 1.

4. Amendment to the Dividend Add-On Component Calculation

Under the proposal, the Board would have adjusted the dividend add-on component of the stress capital buffer to align with the proposed change to the jump-off date from December 31 to September 30. To maintain alignment between the dividend add-on component of the stress capital buffer requirement and the one-year period during which the requirement is typically effective, the Board proposed to change the dividend add-on component to cover dividends issued in quarters five through eight, instead of quarters four through seven, of the planning horizon of the supervisory stress test. This change would have involved updates to the capital plan rules, at Regulation Y and Regulation LL, to any references to the relevant quarters of the planning horizon.[68]

The dividend add-on component of the stress capital buffer requirement currently comprises planned dividends in the fourth through seventh quarters of the planning (or projection) horizon of the supervisory stress test.[69] Under the current framework, the planned dividends that are incorporated in the stress capital buffer requirement align with the effective date of the stress capital buffer requirement (that is, October 1 as the first day of the fourth quarter of the existing planning horizon) and last for the one-year period through which the stress capital buffer requirement is expected to be effective (that is, through the seventh quarter of the existing planning horizon, after which the following year's stress capital buffer requirement would be expected to take effect).

Commenters did not provide input on this specific aspect of the proposal, but they did provide other feedback related to the dividend add-on component. Several commenters recommended that the Board eliminate the dividend add-on component of the stress test. These commenters stated that this component is overly conservative and causes firms to duplicate their capitalization of dividends, particularly with the capital conservation buffer requirement and existing firm capital management buffers. One commenter argued that the Board's previous rationale for the dividend add-on component, which referenced historical experience from the 2007–2009 financial crisis, was no longer relevant.

Several commenters representing foreign banking organizations specifically commented that the dividend add-on component should be eliminated for foreign banking organizations with intermediate holding companies. These commenters stated that dividends from the intermediate holding company serve a different function for these foreign banking organizations compared to domestic firms, as the dividends are primarily a mechanism to upstream surplus capital to the foreign banking organization parent. Noting that the dividend add-on component does not apply to share repurchases, these commenters also stated that the exclusion of share repurchases is not beneficial for intermediate holding companies, giving domestic firms an advantage over foreign banking organizations. Commenters also stated that dividends do not pose the same reputational or systemic risk concerns for foreign banking organizations as for domestic firms. These commenters suggested that, if the Board retains the dividend add-on component, the Board should adopt alternative approaches, such as scaling the component for intermediate holding companies or using a discount approach to the component for intermediate holding companies that is consistent with recent domestic bank activity. Others suggested alternatives that would involve recalibrating the dividend add-

[64] 12 CFR 225.8(h)(2)(ii); 12 CFR 238.170(h)(2)(ii).

[65] 12 CFR 225.8(h)(4)(i); 12 CFR 238.170(h)(4)(i).

[66] The period between the notification and effective dates of the stress capital buffer requirements would go from one month under the current rule (August 31 to October 1) to three months under this rule and the Volatility Rule (September 30 to January 1).

[67] 12 CFR 225.8(h)(4)(ii)(A); 12 CFR 238.170(h)(4)(ii)(A).

[68] 12 CFR 225.8(f)(2)(i)(C)(1); 12 CFR 225.8(f)(4); 12 CFR 225.8(h)(2)(ii)(A); 12 CFR 225.8(h)(2)(ii)(B); 12 CFR 225.8(k)(2); 12 CFR 238.170(f)(2)(i)(C)(1); 12 CFR 238.170(f)(4); 12 CFR 238.170(h)(2)(ii)(A); 12 CFR 238.170(h)(2)(ii)(B); 12 CFR 238.170(k)(2).

[69] *See* 12 CFR 225.8(d)(16); 12 CFR 238.130. The planning (or projection) horizon for the supervisory stress test is nine consecutive quarters starting on the jump-off date of the supervisory stress test.

on to reduce it as dividends are actually paid out over time.

The Board is declining to adopt the proposed change to the quarters subject to the dividend add-on component in the final rule. As explained in the proposal, this change to the dividend add-on component was contingent upon changing the jump-off date to September 30. Accordingly, the Board is not adjusting the planning horizon period for planned dividends in this final rule.

Additionally, the Board is not eliminating the dividend add-on component in response to comments. Removing the dividend add-on component of the stress capital buffer was outside of the scope of the proposal.

To align with the Board's principle of consistency and comparability across firms, including intermediate holding companies of foreign banking organizations, to ensure that all firms subject to the stress test engage in appropriate capital planning, and to limit procyclical aspects of the stress test, the final rule maintains that the dividend add-on component applies to all firms and that it remains constant over the period that a firm's applicable stress capital buffer requirement is in effect.

*F. Stress Capital Buffer Requirement Reconsideration Process*

The Board did not propose to amend the Board's capital planning rules that govern firm requests to reconsider the Board's calculation of preliminary stress capital buffer requirements. The current rules require firms to request reconsideration within 15 calendar days of receiving notice of the preliminary requirement.[70] Firms may also request informal hearings with the Board to discuss reconsideration requests.[71] Though the Board did not propose any changes to this process, the proposal requested public input on potential enhancements to the stress capital buffer requirement reconsideration process, including whether additional enhancements to this process would be appropriate.

The Board received several comments on the reconsideration request deadline, as well as the reconsideration request process itself. Regarding the reconsideration request deadline, several commenters suggested that the Board extend this deadline to either 15 business days or 30 days or more, particularly if the stress capital buffer effective date is moved to January 1, as was proposed in the Volatility Proposal. These commenters stated that the Board's reconsideration process should better align with the Board's supervisory appeals process, and they stated that additional time would improve the arguments presented by firms in their reconsideration requests, which would reduce the risk of calculation errors while improving the transparency, integrity, and credibility of the stress capital buffer framework. Commenters also emphasized that reconsideration requests should be due a reasonable period of time after firms receive firm-specific results disclosures.

Regarding the Board's reconsideration request review process, several commenters suggested that the Board provide additional information or introduce new guardrails to the Board's review process. Some commenters stated that the reconsideration process was inadequate for firms to challenge stress capital buffer determinations. These commenters recommended that the Board expand the scope of appealable issues to include instances where results are unrealistic, overly conservative, inconsistent with empirical performance, or conflict with the Board's Stress Testing Policy Statement principles, even if no modeling errors are identified. One commenter added that a firm should be able to request reconsideration for any adjustment applied to its results. One commenter further suggested that the Board codify the permissible basis for which a firm could request reconsideration and that the Board codify that the window for the request begin when firm-specific disclosures are provided. The commenter suggested that the Board publish a list of research issues identified in reconsideration request letters and identify whether any changes to models were made in response to reconsideration requests. Two commenters requested that the Board define the criteria it considers in granting an informal hearing in response to reconsideration requests. Another commenter suggested that the Board create a transparency framework to track, implement, and disclose the outcomes of all reconsideration requests, and that the Board provide a response to each reconsideration request with the Board's rationale for its decision making. Another commenter recommended that the Board establish specific review timelines for reconsideration requests.

The Board is revising the deadline by which a firm subject to the supervisory stress test must request reconsideration. Under the final rule, this request must occur within 15 business days after the preliminary stress capital buffer notification occurs, replacing the current deadline of 15 calendar days. This change is expected to reduce burden on firms subject to the supervisory stress test while also providing the Board with sufficient time to consider any such requests and make appropriate adjustments prior to the disclosure and effective date of final stress capital buffer requirements. The Board addressed comments related to enhanced results disclosures in Section II.A of this **SUPPLEMENTARY INFORMATION**.

With respect to comments suggesting changes to the Board's reconsideration request review process, beyond those regarding the window to request reconsideration, the Board is not adopting any changes at this time. The current capital plan rules do not provide a limit on the scope of a firm's reconsideration request. Instead, the rules provide that, ''a request for reconsideration must include a detailed explanation of why reconsideration should be granted.'' [72] The Board has not established a scope of appealable issues and will continue to implement a flexible approach that enables firms to request reconsideration for any aspect of their stress capital buffer requirement and on any basis. While the Board recognizes that establishing a certain set of criteria or basis for reconsideration could provide firms and the public with greater transparency around the Board's reconsideration review process, the Board considers the current broad scope appropriate to enable the Board to continue to engage with firms in the reconsideration request process on an unrestrained scope of issues identified by firms. Therefore, in the final rule, the Board does not codify the scope of issues for which a firm could request reconsideration of its stress capital buffer requirement. Additionally, the Board anticipates that the public input process for stress test models and scenarios will provide an appropriate and effective avenue for firms and the public to provide feedback on aspects of the stress test program that apply to each firm's stress test results, which will help ensure the consistency and fairness of the stress testing program.

With respect to additional disclosures or timelines related to the Board's reconsideration request review process, the Board considered the comments and its experience administering the reconsideration request process. At this time, the Board is not adopting additional changes to this process, which effectively balances interests in transparency with the Board's need to handle confidential materials

[70] 12 CFR 225.8(h)(2)(i); 12 CFR 225.8(i)(2); 12 CFR 238.170(h)(2)(i); 12 CFR 238.170(i)(2).

[71] 12 CFR 225.8(i)(3)(ii); 12 CFR 28.170(i)(3)(ii).

[72] 12 CFR 225.8(i)(3)(ii), 12 CFR 238.170(i)(3)(ii).

appropriately and conduct a fair and efficient stress capital buffer determination process for each firm within the constraints of the annual stress test cycle. Under the Board's rules, the Board notifies each firm of the Board's decision to affirm or modify the firm's preliminary stress capital buffer requirement within 30 calendar days of receipt of the reconsideration request.[73] Typically, the Board responds to the firm through a letter; in the past, a version of the letter that redacts confidential supervisory information has also typically been released publicly with a press release. To preserve confidentiality and flexibility, the Board is not making additional changes to the reconsideration process or disclosures at this time beyond extending the window for submission of reconsideration requests.

Additionally, the Board considered a comment that suggested that the Board should define criteria for granting an informal hearing. Under the Board's stress test rules, a request for reconsideration may include a request for an informal hearing on the firm's request for reconsideration; the Board may, in its sole discretion, order an informal hearing if the Board finds that a hearing is appropriate or necessary to resolve disputes regarding material issues of fact.[74] Given the wide range of reasons why a firm may request reconsideration and what information such a request could encompass, establishing a set criteria could narrow the scope of bases for granting an informal hearing. As a result, the Board is not defining criteria for granting an informal hearing.

## III. Revisions to the Stress Testing Policy Statement

Under the proposal, the Board would have made changes to the Stress Testing Policy Statement to (i) amend the section related to disclosure of information related to the stress test; and (ii) to align the Stress Testing Policy Statement with the proposed enhanced disclosure process. The Board is adopting these changes largely as proposed, with adjustments as described below.

### *A. Supervisory Stress Test Results Disclosures*

To provide additional transparency, the Board proposed to revise the Stress Testing Policy Statement to clarify that the Board will generally disclose information directly to a firm about the firm's supervisory stress test results that is not available to the broader public, so long as the Board discloses similar information to the other firms participating in a given stress test cycle. In the proposal, the Board explained that, for example, the Board may provide a firm its common equity tier 1 capital ratio during all quarters of the projection horizon. Providing firm-specific results directly to the affected firms even when that information is not disclosed to the broader public was expected to allow firms to better understand their results while preventing potentially sensitive information about a firm from being shared with competitors. Under the proposal, the Board would have continued to disclose the supervisory stress test results to the public.

The Board received three comments suggesting that the Board codify a requirement that the Board transmit certain non-public information to firms in their results disclosures, while another commenter also suggested that the Board codify the type of information that the Board provides to firms when transmitting the firms' results. In particular, this commenter suggested that the Board provide firms with a firm-specific, granular breakdown of projections and a quarter-by-quarter view of the results. The commenter stated that this disclosure should, at a minimum, be similar to the Board's disclosure of aggregate stress test results related to the 2025 stress test.[75] Two commenters stated that the disclosures should include model-level impacts to the firm from any model changes that are significant to a specific firm, as well as model adjustments, such as overlays, including the rationale for any adjustments.

One commenter further recommended that the Board provide firms with more model details in private disclosures, such as the firm-specific fixed effects for applicable models. Another commenter had a similar sentiment, stating that the Board should provide firms with more information about projections and quarter-by-quarter results of component models (*e.g.,* noninterest income), as opposed to projections and results of broader modeling areas (*e.g.,* total pre-provision net revenue). These commenters explained that these disclosures and processes would improve firms' understanding of the Board's modeling methodology and the firms' results, which would therefore improve firms' capital planning.

The Board is finalizing this aspect of the proposal without changes. The Board's current approach is flexible and enables the Board to tailor its firm-specific results disclosures to changes in the stress test over time. Establishing detailed requirements for firm-specific results disclosures could constrain the Board's ability to provide detailed disclosures or change the format of the disclosures over time. Additionally, the Board recognizes that increasing the granularity of firm-specific disclosures within the annual stress test cycle would proportionally increase the operational burden and complexity of administering the stress test, particularly within the compressed time available to the Board to conduct the stress test. Within each cycle, the Board aims to provide results that balance these challenges with the benefits of additional disclosures, while ensuring consistency in results reporting so that firm-specific results would not advantage individual firms. As a result, the Board is not implementing a change to the Board's stress test rules to require a specific format or contents for firm-specific results disclosures.

### *B. Other Revisions to the Stress Testing Policy Statement*

In addition, the Board proposed to revise the Stress Testing Policy Statement to align it with the proposed enhanced disclosure process, such as to reflect the model disclosure and public input process for material model changes.

The Board did not receive comments on this aspect of the proposal. Other comments related to the proposed enhanced disclosure process are addressed in Sections II of this **SUPPLEMENTARY INFORMATION**.

The Board is finalizing this aspect of the proposal without changes.

Separately, two commenters provided their views on the Board's ''flat balance sheet'' assumption, which is described in the Board's Stress Testing Policy Statement. One commenter asserted that the assumption distorts estimated capital levels under stress, and recommended that the Board's projections should instead allow for balance sheet growth. Another commenter stated that this assumption is overly simplified, unsupported by empirical evidence, and leads to higher borrowing costs and reduced credit availability for consumers.

The Board did not propose to adjust this assumption in the proposal and the Board is not adopting changes to the flat

[73] 12 CFR 225.8(i)(5), 12 CFR 238.170(i)(4).

[74] 12 CFR 225.8(i)(3)(ii); 12 CFR 225.8(i)(4); 12 CFR 238.170(i)(3)(ii); 12 CFR 238.170(i)(4).

[75] *See* Board, 2025 Detailed Nine Quarter Paths, available at *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2026.htm; see also* Board, 2025 Detailed Hypothetical Nine Quarter Paths Under Proposed Models, available at *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2026.htm.*

balance sheet assumption as part of this final rule. The existing balance sheet assumption aligns with the Board's principles of simplicity, as well as consistency and comparability, and also ensures that firms do not reduce the supply of credit under a stress scenario.

## IV. Revisions to the FR Y–14A/Q/M

To reduce regulatory reporting burden, support the proposed model changes, and improve risk capture, the Board proposed to adopt several revisions to the FR Y–14A/Q/M. To reduce regulatory reporting burden, the Board proposed to remove items and documentation requirements that are no longer needed to conduct the supervisory stress test. These revisions, as well as other revisions incorporating feedback from public comments, are described in this Section of this **SUPPLEMENTARY INFORMATION.**

Commenters broadly supported the proposed revisions to the FR Y–14. Commenters also recommended that additional items be added to the FR Y–14 reports to support suggested changes to the models, as well as recommended areas that could be further streamlined. After considering these comments, the Board is adopting the revisions largely as proposed, and it is also adopting other changes to the FR Y–14 reports following consideration of these comments, as described below and in the Board's 2027 Model Review of Comments and Summary of Changes, available on the Board's website.[76]

### *A. FR Y–14 Supporting Documentation*

#### FR Y–14A

To ensure that the FR Y–14A requirements do not capture information that is no longer needed and to reduce reporting burden, the proposal would have removed Appendix A ''Supporting Documentation'' from the FR Y–14A report. Commenters supported this proposed removal as it would decrease reporting burden and requested that the Board clarify response times for potential additional requests from supervisors during the annual capital plan review.

In connection with the supervisory review of capital plans, recent practice has been to communicate the focus of each year's review and anticipated targeted required information in detail through examination first-day letters prior to the submission date. This process is intended to minimize follow-up requests after the submission date, and supervisors tailor the suggested turnaround times based on the size and nature of the request. In addition, supervisors may incorporate input from supervised firms on the nature and timing of large follow-up requests, as appropriate. With this clarification, the final rule removes Appendix A from the FR Y–14A.

#### FR Y–14Q

To streamline FR Y–14Q, Schedule L (Counterparty) and reduce reporting burden, the proposal would have replaced the existing Schedule L supporting documentation with a more limited set of questions that is relevant for supervisors to assess Schedule L data. Similarly, the proposal would have introduced supporting documentation for FR Y–14Q, Schedule F (Trading) that includes five questions related to a firm's trading projections and Schedule F submissions.

Commenters opposed these changes, as they believe they would significantly increase reporting burden. Additionally, commenters stated that Schedule F collects information on firms' trading exposures, not trading projections, so it would not be appropriate to collect information on projections in connection with Schedule F. Finally, to reduce reporting burden around the timing of FR Y–14Q submissions, commenters recommended that, if adopted, the Schedule L supporting documentation be due at least 30 days after the submission of data.

The Board recognizes that Schedule F does not collect projection data, and the final notice does not adopt the Schedule F supporting documentation requirement, though, supervisors may request additional information from firms to better understand their trading exposures and projections. However, the underlying methodology for stressed counterparty data is necessary to understand firms' Schedule L submissions, so the final notice adopts a revised Schedule L supporting documentation requirement. To be responsive to the commenters' burden concerns, the final notice streamlines the supporting documentation requirement by removing or simplifying questions, and by offering additional time to provide responses to certain requests, where appropriate.

### *B. Collection of Mailing Address Information*

The proposal would have removed item 6 (Mailing Stress Address), item 7 (Mailing City), item 8 (Mailing State), and item 9 (Mailing Zip Code) from FR Y–14M, Schedule C (Address Matching). Commenters supported these proposed removals and asked that the Board retire the entire Schedule C asserting that it does not provide unique information. The final notice removes these mailing address items from Schedule C but does not implement further changes, as the schedule collects important information that is not available elsewhere, such as property address data. This information is needed to match junior and senior loans that use the same collateral.

### *C. Private Equity*

The proposal would have revised FR Y–14Q, Schedule F.24 (Private Equity) in four ways: (1) to have private equity reported as of December 31, (2) to have carry values reported net of embedded goodwill or investments in the capital of unconsolidated financial institutions that are deducted from CET1 capital, (3) to collect data on private equity hedges, and (4) to introduce a materiality threshold for reporting private equity exposures that aligns with other banking book portfolios.

Commenters suggested that the Board modify certain aspects of the proposed private equity revisions to clarify the instructions or simplify reporting. For example, commenters requested the Board clarify how to define a material private equity portfolio, add items to capture capital deduction items associated with private equity separately instead of reporting carrying value offset of these deductions, revise the instructions to reflect the capital deduction thresholds based on those applicable to the reporting firm, and introduce a separate version of Schedule F to capture private equity exposures and their associated hedges. As these recommendations would simplify reporting and not impact the Board's ability to model private equity losses, the final notice incorporates revisions based on these comments. Finally, as proposed, the Board is revising Schedule F.24 to be reported as of quarter-end for each quarter, instead of the GMS as-of date for the fourth quarter submission.

### *D. Hedges*

The proposal would have revised Schedule F, which is currently subject to a materiality threshold, to capture data on hedges from any firms with reportable hedges. As proposed, firms, including those not required to submit Schedule F, could submit a version of Schedule F to report hedges but would not be required to do so. Commenters requested that the Board clarify the expectation of when hedges are to be

[76] The documentation is available on the Board's website. *See* Board, 2027 Model Review of Comments and Summary of Changes, *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2027.htm.*

reported on Schedule F, asserting that the language in the proposed instructions was unclear. To provide clarity, the final notice revises the instructions to indicate that submissions of Schedule F for hedges are optional except that, if a firm chooses to report a given hedge type (for example ''AL Hedges''), then all relevant worksheets within Schedule F must be reported with respect to that hedge type. Additionally, the final notice clarifies that once that hedge type has been reported for a given reporting quarter, it must be reported for each subsequent quarter.

Additionally, to improve the risk capture of the supervisory stress test by incorporating the effects of additional hedges, the proposal would have revised FR Y–14Q, Schedule B.2 (Investment Securities with Designated Accounting Hedges) to capture all qualified accounting hedges. The proposal would have also implemented a new schedule to more comprehensively map hedging relationships (FR Y–14Q, Schedule B.3—''Investment Securities with Designated Accounting Hedge Mapping''). Commenters recommended various changes to Schedule B, including expanding the scope of reportable hedges on Schedule B.2 to capture all economic hedges, adding a clean present value field to Schedule B.2, and introducing a new sub-schedule to better map long-term debt/borrowings.

To improve and clarify the reporting of hedges, the final notice largely incorporates these recommended changes into the Schedule B instructions. However, the Board has determined that a dedicated sub-schedule for long-term debt/borrowings is not needed at this time. These revisions will enable the Board to better assess firm hedges.

*E. Exchange Traded Funds*

To ensure consistent reporting, the proposal would have clarified Schedule F instructions such that all exchange traded funds (ETFs) would be reported in the Schedule F worksheet that corresponds to the underlying asset class and risk exposure. One commenter stated that it is not practical to decompose all positions in funds, including ETFs, and recommended that firms be allowed to treat non-decomposed funds as a single name equity reported in the equity worksheet.

The Board is cognizant of reporting burden; however, it is important that exposures are reported consistently and based on their underlying risk. Therefore, the final notice adopts the proposed instructional clarification. However, to address the commenter's concern, the final instructions indicate that reporting can be based on the primary underlying asset class and risk exposure, if decomposition is not possible.

*F. Credit Card Revenue and Loss Sharing Agreements*

The proposal solicited public comment on two versions of a credit card revenue and loss sharing (RLSA) collection on FR Y–14M, Schedule D (Credit Card): one that would have captured portfolio-level details and one that would have captured agreement-level details. Commenters supported the portfolio-level approach, asserting it would increase standardization across firms while providing the Board with appropriately granular information. Commenters also recommended additional changes such as clarifying certain items, introducing a materiality threshold, and adding new items. Additionally, one commenter requested that firms be provided 12 months to implement the necessary reporting system changes.

As discussed in the Retail section of the Review of Comments documentation, the Board has determined that portfolio-level, rather than agreement-level, reporting is appropriate for collecting information on RLSAs and has adopted the proposed portfolio-level approach, with certain adjustments in response to comments.

To align with the final PPNR models that rely on data reported on FR Y–14Q, Schedule G (PPNR), the Board has removed items from FR Y–14M, Schedule D.3 that capture data associated with RLSA payments and added new items to FR Y–14Q, Schedule G to collect RLSA payment amounts that are reflected in interest income, noninterest income, and noninterest expense. For consistency between reports, the Board is also adding these items to FR Y–14A, Schedule A.7.a (PPNR Projections) and Schedule A.7.b (PPNR Net Interest Income), as applicable. Additionally, the Board has clarified Schedule D.3 to implement consistency in charge-off and recovery reporting and firm accounting practices. To avoid imposing reporting burden on firms with small RLSA balances, the Board has implemented a materiality threshold for Schedule D.3 such that firms that either report $5 billion or more in total partnership agreement balances or have total partnership agreement balances exceeding 5 percent of the firm's total domestic consumer bank card balances at quarter-end must report Schedule D.3. To further reduce reporting burden, the Board has revised the cadence of Schedule D.3 reporting such that it is submitted quarterly instead of monthly. Finally, the Board is adopting the RLSA reporting revisions for the December 31, 2027, as-of date to provide firms the time necessary to submit accurate data.

*G. Stress Test Date Changes*

To align with proposed changes to the stress test calendar, the proposal would have revised the FR Y–14A jump-off date to be September 30 and modified the submissions of FR Y–14 such that, for the quarter containing the GMS component as-of date, the submission of data associated with the GMS component would be submitted as of the date instead of quarter-end. As discussed in Section II.E of this **SUPPLEMENTARY INFORMATION**, the Board is not revising the FR Y–14A jump-off date.

Therefore, the final notice does not alter the current December 31 jump-off date for the FR Y–14A. Additionally, as discussed in Section II.E of this **SUPPLEMENTARY INFORMATION**, the final rule adopts an as-of date window for the GMS component of April 1 to December 31 of the year preceding the stress test. Consistent with this expanded as-of date window, the final notice revises the FR Y–14 instructions such that, for the quarter containing the GMS component as-of date, the submission of data associated with the GMS component is submitted as of that date, instead of quarter-end.

Finally, as discussed in Section II.E of this **SUPPLEMENTARY INFORMATION**, the Board is adopting several changes to dates in the annual stress test cycle. For example, the due date for annual capital plan submissions and for applicable firms to conduct company-run stress tests is April 30, instead of April 5. However, the timely submission of certain FR Y–14 data is critical to ensure that the stress test results are final by June 30. Specifically, the stressed submission of FR Y–14Q, Schedule L (Counterparty) and alternative starting values for certain capital deduction items on FR Y–14A, Schedule A.1.d (Capital) are necessary to calculate projected losses under the GMS component. Therefore, the Board is retaining an April 5 due date for these items but revising the due date of the remaining FR Y–14A data to April 30, consistent with the revised due date of firms' capital plans and the date to conduct a company-run stress test.

*H. Other FR Y–14 Revisions and Comments*

*Comments on Further Reporting Reductions*

As described above, the proposal included revisions that would have reduced reporting burden. Commenters provided several recommendations as to how this burden could be further reduced. For example, one commenter asked that the Board conduct a line-by-line inventory of all FR Y–14 items and explain which are used in the supervisory models or are necessary for supervision and regulation, or to otherwise justify collecting that data. The commenter suggested that any items not on either list be retired. The commenter recommended that the Board consider developing materiality frameworks for firms to consider for reporting the FR Y–14Q and FR Y–14M reports. The commenter suggested that collecting data on only material items would reduce burden on firms. Alternatively, the commenter suggested that the Board identify critical data elements and make the non-critical elements optional or best efforts. Another commenter recommended that the Board reconsider the reporting frequency for certain areas, such as the FR Y–14M report, and consider limiting historical data requirements for firms newly subject to reporting FR Y–14Q schedules.

The Board is cognizant of regulatory reporting burden and has already undertaken significant steps to reduce reporting burden by retiring supporting documentation, line items that are no longer necessary, and historical data requirements that are no longer necessary. Additionally, while an item may not be an input to the stress test models, it is important that the Board receive fulsome data to support model monitoring or other supervisory activities. Further, a materiality framework or reporting on a best efforts basis could result in critical data not being reported, which could hinder supervisory activities. Therefore, the Board is not removing additional items from the FR Y–14 at this time. The Board will continue to assess whether it is appropriate to retire select items or requirements that are no longer necessary.

Comments on Reporting in Connection With Modeling Suggestions

Additionally, in response to the proposed models, commenters recommended that the Board improve aspects of the models, and some of these recommendations would require the collection of additional data. Further, commenters recommended that specific schedules be modified or clarified to improve reporting. Comments that suggested additional data collections to support commenter recommendations to revise model specifications or improve reporting are discussed in the Board's 2027 Model Review of Comments and Summary of Changes, available on the Board's website.[77]

## V. Changes to the Stress Test Modeling Framework

The Board proposed to use the models described in the documents posted on the Board's website to generate results for the 2026 supervisory stress test. Included in these descriptions were some model specifications that were not used to conduct the 2025 supervisory stress test but were proposed to be used for the 2026 supervisory stress test. Section V.A of this **SUPPLEMENTARY INFORMATION** discussed the model changes adopted at this time and Section V.B of this **SUPPLEMENTARY INFORMATION** provides an updated analysis of the potential effects of the changes, as compared to the proposal. Based on this analysis, implementing the final model changes and final revisions to the GMS scenario design in the 2024, 2025, and 2026 stress tests would have, independent of other factors, increased the aggregate projected CET1 stress ratio, on average, by 17 basis points.[78]

*A. Changes to Stress Test Models*

The Board proposed a series of changes to the Board's stress test models in the proposal, which were described in the proposal and in greater detail in the documentation published on the Board's website.[79] The Board received many comments on the proposed changes to stress test models described in the proposal. As described above in Section I.F of this **SUPPLEMENTARY INFORMATION**, commenters provided a mix of comments that expressed general support for the proposed models, as well as suggestions for additional changes to these proposed models, including many conceptual and technical adjustments. The Board considered these comments and addressed them in the Board's Review of Comments, available on the Board's website.[80]

With respect to the credit risk models, the Board proposed to change how it uses geography in scenario variables (First Lien, Home Equity, Credit Cards, Auto, and Commercial Real Estate Models); change how it treats foreclosures under judicial supervision (First Lien and Home Equity Models); change how it calculates loss given default for international loans (Commercial Real Estate and Corporate Models); change how it includes losses attributable to accrued interest and carrying costs (First Lien and Home Equity Models); change how it uses multipliers in the Provisions Model; revise the mortgage loss given default model in the First Lien Model; revise the bank card model in the Credit Card Model; change how it projects losses on auto leases in the Auto Model; and update the probability of default, loss given default, and exposure at default components in the Corporate Model. The Board is finalizing these changes largely as proposed.

[77] The documentation is available on the Board's website. *See* Board, 2027 Model Review of Comments and Summary of Changes, *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2027.htm.*

[78] The Board is separately finalizing the Volatility Proposal in order to reduce the volatility of stress capital buffer requirements. Section II of that final rule's preamble includes an estimate of its impact on required capital. *See* [**Federal Register** notice for Volatility final rule, section II].

[79] Board, Model Changes 2025 to 2026 (Oct. 24, 2025), available at *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2026.htm.*

[80] The documentation is available on the Board's website. *See* Board, 2027 Model Review of Comments and Summary of Changes, *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2027.htm.*

With respect to the market risk models, the Board proposed to update several of its market risk models for the 2026 stress test, including to simplify the Yield Curve Model; adjust its process for projecting credit valuation adjustments for derivative positions in the Credit Valuation Adjustment Model; lower the loss given default assumption amount and loan equivalent factor parameter in the Fair Value Option Model; update and simplify the Securities Model; and exclude additional counterparties in the Largest Counterparty Default Model. The Board is also finalizing these changes largely as proposed.

With respect to the net revenue models, the Board proposed an alternative suite of pre-provision net revenue component models that depart from the current panel regression-based approach. This alternative suite was described in the Pre-provision Net Revenue Model documentation, available at *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2026.htm.* The Board also proposed to discontinue the current regression model used to project operational risk losses and instead project losses with a distributional model. This alternative model was described in the Operational Risk Model documentation, also available at *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2026.htm.* The Board is finalizing some of these changes at this time, and is also proposing further changes to the adopted noninterest income expense model.

The Board received detailed feedback on the proposed model changes for the 2026 stress test, and on the model documentation as a whole. The Board has considered these comments and described its rationale for the final models for the 2027 stress test, as well as additional proposed changes to the noninterest income expense model for the 2027 stress test, in documentation on the Board's website, available at *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2027.htm.*

*B. Analysis of Final Model Changes*

This section describes illustrative analysis of how the model adjustments described above could have affected past stress test results. As discussed in Section V.A of the **SUPPLEMENTARY INFORMATION**, the Board is adopting several model changes in response to public comments, as well as changes to the GMS scenario design described in Section II.E of this **SUPPLEMENTARY INFORMATION**. For example, the final FVO models would adopt more risk-sensitive loss given default assumptions for corporate and commercial real estate loans. Similarly, the pre-provision net revenue models would adopt several revisions, such as changing the base rate assumption for fixed-rate wholesale loans in the interest income on loans model and anchoring each firm's projected efficiency ratio to its own recent experience to better incorporate business heterogeneity in the noninterest expense model. All model changes adopted as part of this final notice are discussed in the model documentation available on the Board's website.[81]

In aggregate, these changes are not expected to materially change capital requirements for firms subject to the supervisory stress test, across various stress scenarios and jump-off conditions at the start of the test. As in the proposal, to illustrate the effect of these model changes, the Board's analysis estimated the impact of these model changes on the CET1 stress ratio for a balanced sample of 30 firms subject to the 2024 stress test, then aggregated the averages.[82] Using this analysis, table 4 illustrates the potential impact of these changes for each risk stripe across various stress test scenarios and jump-off dates. Based on this analysis, the final model changes can be expected to result in slightly lower projected common equity tier 1 (CET1) capital ratio declines compared to the proposed models, mostly due to the updated calculation of the valuation allowance for deferred tax assets to better align with U.S. GAAP accounting practices.

**Table 4:** Estimated Aggregate Effect of Final Model Changes on Projected CET1 Ratio Declines, by Model Type

| Model Type | CET1 Ratio Effect (basis points) | | | |
|---|---|---|---|---|
| | 2026 | 2025 | 2024 | Average |
| Credit Risk | -7 | -4 | -2 | -4 |
| Securities | 6 | 6 | 2 | 5 |
| Market Risk | 0 | 4 | 3 | 2 |
| Ops Risk | 0 | 0 | 0 | 0 |
| PPNR | -14 | -6 | 6 | -5 |
| Aggregation | -18 | -17 | -9 | -15 |
| All Changes | -33 | -17 | 0 | -17 |

Table 5 below provides a separate analysis of estimates of stress losses across firm types that are subject to the stress capital buffer requirement. The analysis shows that the reduction in projected CET1 capital ratio declines due to the final model changes is concentrated at larger firms.

[81] *See* Board, Dodd-Frank Act Stress Tests 2026 (Jun. 2026), *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2026.htm.*

[82] This analysis used the 2024, 2025, and 2026 scenarios, respectively, and the same data used for those years' stress tests. The estimated impact of these changes remains highly sensitive to the stress test scenario and firm-specific data for each year. In addition, the estimated impact of the changes to the GMS scenario design relies on additional counterparty modeling assumptions, since the historical data alone cannot incorporate these changes. While the precise impact will vary each year based on stress test scenarios and specific firm data, Board analysis across a range of conditions shows that capital requirements should remain essentially unchanged.

**Table 5:** Estimated Aggregate Effect of Final Model Changes on Projected CET1 Ratio Declines, by Firm Category

| Firm Type | CET1 Ratio Effect (basis points) | | | |
|---|---|---|---|---|
| | 2024 | 2025 | 2026 | Average |
| Cat I/II | -15 | -24 | -38 | -26 |
| Cat III-IV | 30 | -4 | -21 | 2 |
| All Firms | -2 | -17 | -33 | -17 |

Table 6 illustrates the estimated impact of the model changes described in this notice, updated to include the results of the 2026 stress test.

As indicated, the Board's analysis estimates that the impact of the model changes adopted for the 2027 stress test, could lower the common equity tier 1 capital requirements of Category I and II firms by 0.9 percent. Similarly, the impact could lower the common equity tier 1 capital requirements for Category III and IV firms by 2.0 percent. Relative to the results from the 2024, 2025, and 2026 stress testing cycles, the analysis estimates that the adopted changes could have reduced aggregate stress capital buffer requirements by approximately 1 percent of required common equity tier 1 capital.

**Table 6:** Estimated Cumulative Change in Aggregate CET1 Capital Requirements

| | **Stress Test Proposal (2024-2025)** | | **Stress Test Proposal (2024-2026)** | | **Stress Test Final Rule, With Adopted Model Changes (2024-2026)** | |
|---|---|---|---|---|---|---|
| | **Category I/II** | **Category III/IV** | **Category I/II** | **Category III/IV** | **Category I/II** | **Category III/IV** |
| **Stress Test Changes** | -2.4% | -2.2% | -1.2% | -0.4% | -0.9% | -2.0% |

**VI. Changes to the Scenario Design Policy Statement**

The Board also proposed several changes to its Scenario Design Policy Statement. This section describes those changes, and summarizes and responds to comments received on those changes.

*A. Changes to the Background and Overview and Scope Sections*

The Board proposed to make limited changes to the first two sections of the Scenario Design Policy Statement, which address background and overview and scope topics, respectively. In the Background section, the Board proposed to clarify that the stress tests primarily focus on credit risk, operational risk, and market risk. The inclusion of operational risk in this list was intended to help clarify the Board's continued focus on designing a supervisory tool that makes a valuable forward-looking assessment of large financial companies' capital adequacy under hypothetical economic and financial market conditions. The Board proposed to also clarify that it expected to provide only two different sets of macroeconomic scenarios for both the supervisory and company-run stress tests: the baseline and severely adverse scenarios. This change would clarify the quantity of macroeconomic scenarios the Board expects to provide, consistent with the previous removal of a separate adverse scenario.[83]

In the Overview and Scope section, the Board proposed to make conforming edits to the description of the organization of the Scenario Design Policy Statement to reflect the changes discussed earlier in this proposal.

The Board did not receive comment on these technical changes, and is finalizing, as proposed, changes to the Background and Overview and Scope section of the Scenario Design Policy Statement.

*B. Changes to the Content of the Stress Test Scenarios Section*

The Board proposed to make two general changes to this section, which describes the Board's expectations for the content of the published stress test scenarios. First, this section would have been amended to make clarifications that the Board expects to generally publish two different macroeconomic scenarios: the baseline and severely adverse scenarios. This section would also have been revised to clarify that the Board expects to invite comment on severely adverse scenarios. Second, as described in Sections II.E and VI.H of this **SUPPLEMENTARY INFORMATION**, the Board proposed to make certain changes related to the global market shock component. See Sections II.E and VI.H of this **SUPPLEMENTARY INFORMATION** for a discussion of those changes. Comments related to the public input period for proposed scenarios are discussed above in Section II.D of this **SUPPLEMENTARY INFORMATION**.

One commenter suggested that the Board design a matrix of all possible values to use for the variables in scenario design and run the stress test on every possible scenario.

Another commenter, providing research in support of their claims, recommended that the Board incorporate climate tail scenarios into the stress test, which would enable the Board to capture tail amplification, nonlinear effects, and cross-bank differences to extreme weather exposures. Another commenter stated that the limited incorporation of climate-related financial risks is a

[83] 84 FR 59032, 59061 (Nov. 1, 2019).

significant gap in the Board's scenario design and that the Board should consider how climate factors might interact with traditional economic and financial stresses to improve the forward-looking nature of the stress test.

The Board has considered the comments submitted and has determined to finalize, as proposed, the changes to the Content of the Stress Test Scenarios section described in the proposal.

The Board considered comments requesting that the stress test feature a matrix with all possible variables that could be used in scenario design, with the stress test run against all possible scenarios. This approach would be operationally burdensome, particularly within the revised stress testing calendar. Further, it would be impractical to seek public input on an approach that uses all possible scenarios, and the approach would not align with the Board's scenario development process as described by the Scenario Design Policy Statement.[84]

Regarding comments recommending that the stress test include climate-related financial risks and climate tail scenarios, the Board finds that the final stress test scenarios are well-suited to capture various types of shocks contained within the historical data, and to meet the Board's scenario design goals. Additionally, the existing and final scenario design principles ensure that the Board strives to ensure that scenarios are sufficiently severe.[85]

*C. Approach for Formulating Macroeconomic Assumptions in the Baseline Scenario*

The Board proposed to provide additional details describing the process by which the Board would set the paths of the variables in the baseline and severely adverse scenarios. In particular, the amendments reflected the publication, on the Board's website, of a description of the macroeconomic model utilized to support the construction of the baseline and severely adverse scenarios in the annual stress test (the ''macroeconomic model for stress testing'').[86] By posting a description of this model on the Board's website, the Board expected to improve the transparency, public accountability, and predictability of the Board's scenario design framework, particularly with respect to the baseline scenario and certain variables in the severely adverse scenario. These models are used solely for stress testing purposes and the output is not a forecast of the Board.

One commenter asserted that the Board did not provide sufficient transparency or guardrails regarding how the Board would determine the final jump-off values for each year's scenarios. The commenter recommended that the Board further explain how it would revise the jump-off values for these variables, and that the final scenarios should be broadly aligned with the proposed scenarios in terms of overall severity.

The Board has considered the comments submitted and has determined to finalize, as proposed, the changes to the Approach for Formulating Macroeconomic Assumptions in the Baseline Scenario section described in the proposal.

To increase transparency into how the Board determines final jump-off values, the Board has previously supplemented the explanation in the Board's macroeconomic model for stress testing to clarify the methodology the Board used to determine the jump-off values in the final 2026 scenario.[87] In addition, the Board had updated this documentation to clarify how the determination of jump-off values may have been affected by the 2025 government shutdown.[88]

*D. Scenario Narrative, the Recession Approach, and Salient Risks*

In this section of the Scenario Design Policy Statement, the Board has provided a description of how it expects to incorporate a recession approach into the annual scenario narrative, and how the Board could incorporate salient risks into that annual scenario. The proposed scenario design principles are discussed below in Section VI.F of this **SUPPLEMENTARY INFORMATION**, and the construction of certain variables and description of certain variable guides are described below in Sections VI.E and VI.G of this **SUPPLEMENTARY INFORMATION**, respectively.

The Board proposed to continue to use a recession approach to develop the severely adverse scenario. Under the recession approach, the Board expected to specify the future paths of variables to reflect conditions that characterize post-war U.S. recessions, generating either a typical or specific recreation of a post-war U.S. recession; and that the Board expects that there will be some important instances when it will be appropriate to augment the recession approach with salient risks, and in some cases, set variable values outside of the ranges and values provided in the guides in the Scenario Design Policy Statement. As explained in the proposal, recessions have historically differed in cause, character, and consequence—from oil price shocks and housing slumps to asset-price busts and pandemics, from short to long, and from mild to moderate to severe—therefore, the Board augments the basic recession approach with an annual scenario narrative. The annual scenario narrative provides qualitative direction on how the Board builds that year's severely adverse scenario. Under the proposal, the Board expected that the macroeconomic scenario used in the Board's annual supervisory severely adverse scenario would begin with a sudden and significant increase in uncertainty and associated rapid deterioration in risk appetite that, together, cause a spike in financial market volatility and a sharp decline in many U.S. and foreign financial assets.

Additionally, in the proposal, the Board explained that it continued to expect that there would be some important instances when it would be appropriate to augment the recession approach with salient risks, and in some cases, set variables' values outside of the ranges and values provided in the guides in the Scenario Design Policy Statement. As a result, each year, the Board proposed to consider particular risks to the financial system and to the domestic and international macroeconomic outlook identified by its economists, bank supervisors, and financial market experts.

In the proposal, the Board proposed two changes to its consideration of salient risks in the severely adverse scenario. First, the Board would remove paragraph 4.2.4(d) from the Scenario Design Policy Statement in order to improve the transparency of the scenario design process by limiting the Board's expectations for considering risks of uncertain significance. Second, where the Board does consider salient risks in designing the severely adverse scenario, the Board would endeavor to disclose and explain the Board's reasoning in the publication of the annual stress test scenarios, and would subsequently adjust those aspects of the scenario, if necessary, in response to those comments.

One commenter, expressing general concern with the publication of the

[84] *See* 12 CFR 252, Appendix A, section 1(a).

[85] *See* 12 CFR 252, Appendix A, section 4.2.2(f)(1).

[86] *See* Board, Macroeconomic Model Guide (Oct. 2025), *https://www.federalreserve.gov/supervisionreg/files/macroeconomic-model-guide.pdf.*

[87] The documentation is available on the Board's website. *See* Board, Dodd-Frank Act Stress Tests 2026 (Jun. 2026), *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2026.htm.*

[88] *See* Board, Macroeconomic Model Guide (Feb. 2026), *https://www.federalreserve.gov/supervisionreg/files/2026-final-macroeconomic-model-guide.pdf.*

annual scenarios and the Proposed 2025 Scenario Design Policy Statement, argued that the proposal would reduce the dynamism of the stress test and limit the Board's ability to capture salient and unseen or under-appreciated risks. Another commenter expressed concern with the proposed amendments to the Scenario Design Policy Statement, indicating that the framework, including through the Board's identification of salient risks, would permit deviation from the ranges and values provided in the proposed guides, without being thoroughly described and explained in the proposed scenarios. Another commenter stated that, because stress test models and scenarios are highly complex, they require a degree of Board judgment that warrants retaining discretion for aspects of scenario design. This commenter suggested that the Board clarify how it will apply its discretion and justify any departures from specified ranges.

The Board has considered the comments submitted and has determined to finalize, as proposed, the scenario narrative and recession approach, and amendments to the salient risk framework described in section IX.D of the proposal's **SUPPLEMENTARY INFORMATION** (Scenario Narrative: Refinement to the Recession Approach).

As described in the proposal, the Board expects that the severely adverse scenario would be developed each year to reflect the current level of vulnerabilities or risks to the banking sector that are apparent in relevant indicators of economic and financial conditions. The Board also anticipates that the finalized guides for scenario variables described below provide an appropriate range of values to design the severely adverse scenario in most years. The waxing and waning of relevant indicators of economic and financial conditions will inform the Board's decisions about where to set the value of those parameters within those ranges for each variable.

However, the Board continues to expect that there will be some important instances when it will be appropriate to augment the recession approach with salient risks, and in some cases, set variables values outside of the ranges and values provided in the guides in the Scenario Design Policy Statement. As a result, each year, the Board will consider particular risks to the financial system and to the domestic and international macroeconomic outlook identified by its economists, bank supervisors, and financial market experts. The Board, using its internal analysis and supervisory information and in consultation with the Federal Deposit Insurance Corporation and the Office of the Comptroller of the Currency, will then determine whether any of those risks appear significantly more elevated than usual or, conversely, whether risks are unusually low at a particular time, such that they cannot be appropriately reflected by choosing values within the ranges of the final guides. In those cases, which it expects to be infrequent, the Board will make appropriate adjustments to the paths of specific economic variables, and will explain any deviations from the guides as part of the proposed scenarios for that year's stress test. The scenario variable values and associated rationale for guide deviations will be subject to public input prior to finalization. These adjustments will not always be reflected in the general severity of the recession and, thus, all macroeconomic variables; rather, the adjustments will sometimes apply to a subset of variables to reflect co-movements in these variables that are historically less typical.

To assist the public in assessing the use of salient risks in the scenario, the Board considered the following examples, which were discussed in the proposal. A stress test initiated in a period of unusually high uncertainty and rapid deterioration in economic and financial conditions, such as the first quarter of 2009 or the first quarter of 2020, likely would prove challenging for the ranges in this proposed framework. In each case, the prevailing conditions made it plausible that key variables would settle beyond the range of their previous peak or trough values, on which the guides for the variables in the severely adverse scenario are calibrated. Although the unemployment guide remained flexible enough to respond to the spike in the unemployment rate to nearly 15 percent during the first months of the COVID–19 pandemic-related business closures in 2020, the paths of other variables may have needed to be adjusted more severely if the economy had not recovered as quickly as it did.

As another example, the Board may become increasingly concerned about vulnerabilities related to a particular asset class that is experiencing rapid and persistent price increases supported by increasingly leveraged investors. Those circumstances existed in the housing market in the early 2000s and may have tested the credibility of a guide framework based solely on past performance of home prices, given that up until then, the price index for homes the Board uses for stress testing had rarely experienced a decline.[89]

Sometimes, the salient risk may arise within a particular subset of an asset class. The Board most recently incorporated this type of salient risk in the severely adverse scenario for the 2024 supervisory stress test. That year, the Board noted unusually high vulnerabilities in types of commercial properties that could be most at risk for a sustained drop in income and asset values due to the prevalence of remote work.[90]

The Board has considered comments submitted on the proposal and has determined to finalize, as proposed, the scenario narrative and recession approach, and amendments to the salient risk framework as described in Section VI.D of the proposal's **SUPPLEMENTARY INFORMATION**.

### *E. Changes to Construction of Certain Variables in the Severely Adverse Scenario*

The Board proposed to maintain existing guides for setting the size of the maximum change in the unemployment rate and the timing of its peak, as well as the size of the maximum decline in house prices in the severely adverse scenario and the timing of their trough; introduce guides that would be used to set the changes in the values, and the timing of those changes, for more variables in the severely adverse scenario; and provide additional context for the path of each variable before it reaches the maximum change both for the existing unemployment rate and house price guides as well as the new guides introduced for other scenario variables. In addition, the Board separately disclosed a specific macroeconomic model used to translate the paths of certain variables that are set using the proposed guides into internally consistent projections for the remaining variables, such as the 3-month Treasury bill rate, gross domestic product (GDP), Disposable Personal Income (DPI), and inflation.[91] The additional introduced guides addressed each of the following variables: equity prices; the VIX index; 5-year Treasury yields; 10-year Treasury yields; BBB corporate bond yields; mortgage spread;

[89] The Board uses the Price Index for Owner-Occupied Real Estate, Z.1 Release (Financial Accounts of the United States), Federal Reserve Board (series FL075035243.Q).

[90] *See* Board, 2024 Stress Test Scenarios (Feb. 2024), at 6–7, *https://www.federalreserve.gov/publications/files/2024-stress-test-scenarios-20240215.pdf.*

[91] *See* Board, Macroeconomic Model Guide (Oct. 2025), *https://www.federalreserve.gov/supervisionreg/files/macroeconomic-model-guide.pdf.*

commercial real estate prices; and the international scenario values. Comments on these specific proposed guides are discussed in Section VI.G of this **SUPPLEMENTARY INFORMATION.**

One commenter recommended adding the price of bitcoin as a scenario variable in the macroeconomic scenarios, allowing firms to directly model exposures without reliance on different price assumptions across firms. The same commenter advocated for several methods for determining the price path of bitcoin, such as historical characteristics, regime switching, and jump-diffusion modeling, if adopted into the macroeconomic scenarios or global market shock. The commenter indicated that bitcoin has an unstable relationship with other macroeconomic variables and can be a material driver of market and counterparty risk, and these modeling approaches would be able to incorporate this variability.

The Board has considered the comments submitted and has determined to finalize, as proposed, changes to the construction of certain variables in the severely adverse scenario.

The proposed and final guides include all but one of the financial market variables typically included in the domestic severely adverse scenario disclosure each year (the exception being the 3-month Treasury bill rate, which is informed by the Board's macroeconomic model for stress testing [92]). The Board considered the commenter's recommendation, but determined that the existing set of variables used in the severely adverse scenario is representative of macroeconomic conditions, and implementing the recommendation at this time would add model complexity and reporting burden without adding commensurate benefits.

*F. Scenario Design Principles Derived From Stress Testing Literature: Severity, Credibility, and Not Adding to Procyclicality*

In formulating the proposed guides, the Board described three principles suggested by the literature that inform the Board's scenario design framework: the importance of severity, the importance of credibility, and the importance of not adding to procyclicality.[93]

One commenter welcomed the introduction of scenario design principles as a step towards systemic, rules-based scenario development. The commenter stated that these transparent principles reduce a perception of arbitrariness and inform stakeholders. However, this commenter advised that the final principles should not be overly rigid, as the Board must retain flexibility to design scenarios that capture novel risks and tail events that may not fit established patterns. As support, the commenter noted that financial crises consistently involve unexpected combinations of stresses, which may not be captured by a constrained scenario design approach. The commenter suggested that the Board specify criteria for invoking expedited procedures to update scenarios when necessary, such as when the Financial Stability Oversight Council identifies systemic risks or when material changes in financial conditions occur.

The Board also considered comments on the nature of the guides and their role in the scenario design framework as relevant to these principles. One commenter explained that, in their view, the proposed guides would make the severely adverse scenario in future stress tests more predictable and therefore, more easily gamed by firms subject to the supervisory stress test. In the commenter's view, the predictability of the scenarios would also provide ''false comfort'' to the public that firms had sufficient capital.

One commenter suggested that using both guide- and model-based types of variables could reduce the coherence of the supervisory stress testing narrative, and at times may require trade-offs between scenario consistency and other design principles, such as severity. The commenter stated that the Board must sufficiently explain and justify its design choices with respect to a given scenario to allow the public to assess trade-offs between scenario design principles. This commenter also stated that the Board should reflect the structural and regulatory changes that distinguish historical periods of stress from stress that is plausible after intervening reforms in determining values for its scenario guides. This commenter also asserted that the use of unemployment and house prices as main variables to determine the path of other macroeconomic variables is not conceptually sound, particularly as it would violate the principle of avoiding adding sources of procyclicality. To the extent the Board intends to use unemployment rate and house prices to determine the path of other variables, the commenter recommended that the Board consider additional data points to capture the idiosyncratic nature of those other variables (*e.g.,* spot prices, year-over-year trends).

One commenter, while supporting the Board's objective of preserving flexibility and allowing supervisory judgment in severity calibration, stated that scenario guides should support predictability while preserving the Board's ability to adjust severity to avoid reinforcing economic contractions. This commenter also stated that scenario design should mitigate, not exacerbate, procyclicality, and that rigid scenario design or overly mechanical modeling could amplify procyclicality by tightening capital in times of stress. One commenter recommended that the Board provide plain-language explanations of why the scenarios are chosen, how they relate to evolving risks, and how the severity of scenarios avoids becoming procyclical.

The Board has considered the comments submitted and has determined to finalize, as proposed, scenario design principles derived from stress testing literature: severity, credibility, and not adding to procyclicality.

The Board has recognized that the academic literature and some commenters highlight the need for stress tests to avoid adding to other sources of procyclicality in the financial system.[94] Despite the increased predictability in the scenarios, the new framework would remain flexible enough to suitably assess whether firms can maintain an adequate amount of loss-absorbing capital to stay above minimum regulatory requirements and continue financial intermediation during periods of stress, as well as adjust features that might add to existing procyclicality in the financial system, as appropriate.[95] In practice, the scenarios resulting from the revised framework are expected to remain consistent with the prior and current Scenario Design Policy Statement and, on average over a typical business cycle, should not result in materially different scenarios than would have been designed previously. The Board understood these comments to also implicate the Board's proposed principle of flexibility.

Additionally, as explained in the proposal, the guides and the macro model for Stress Testing are constructed to remain flexible enough to ensure that the Board can adjust the severely adverse scenario to capture emerging risks and changes in the level of systemic risk since the previous stress test in a timely fashion. This flexibility

[92] This approach is consistent with how the Board has designed recent stress test scenarios. *See* 84 FR 6651, 6659 (Feb. 28, 2019).

[93] *See* Section IX.F of the **SUPPLEMENTARY INFORMATION** in the proposal.

[94] *See, e.g.,* 12 CFR 252, Appendix A, section 4.2.2(g); 90 FR 51856, 51877 (Nov. 18, 2025).

[95] *Id.*

includes the ability to increase scenario severity when systemic risks may have built up during robust economic expansions or periods when risk appetite is high or to avoid adding sources of procyclicality through the stress test. The final rule helps ensure that the scenarios continue to maintain a minimum severity level, even when economic and financial conditions are strained.

As discussed in greater detail in the proposal, in designing the guides for the construction of the severely adverse scenario presented in this framework, the Board is informed by the stress testing literature,[96] which provides certain principles for scenario design also reflected in the Board's Stress Testing Policy Statement.[97] First, the literature emphasizes the need for adequately severe scenarios, even when the economy and financial system are in a stressed condition—complementing the Board's principle of conservatism.[98] Second, the literature offers insights on how historical data should inform the design of an adequately severe scenario, augmenting the Board's recession approach. Third, the literature highlights the need for stress tests to avoid adding to other sources of procyclicality in the financial system.

Further evidence for the importance of sufficiently stressful scenarios to maintaining public credibility comes from past U.S. stress tests. For example, the rapid deterioration in the U.S. economy in early 2009 led to realized unemployment rates that approached the peak of the unemployment rate path in the severely adverse scenario used for the Supervisory Capital Assessment Program (SCAP) in 2009.[99] As described in the proposal, this example helps demonstrate the importance of the principle of severity when considering historical data and current conditions in the construction of an adequately severe scenario.[100]

That experience reinforces the need for the framework to support variable paths that exceed levels observed in the historical data. Choosing a historical scenario has a price—''it does not test for anything new.'' [101] While the recession approach dictates that variable movements follow historical recessions, when current conditions are already extreme, a credible scenario may replicate historical recessions in terms of the size of movements previously observed, leading to levels of variables that may exceed historical levels. Several of the guides in this framework allow, at times, for variables to exceed their historical range, either in levels or in magnitude of changes, in order to maintain adequate severity.

At the same time, the Board recognizes that the severity of the annual stress tests potentially can have unintended effects on firms' operations. For instance, the academic literature finds that stress tests improve financial stability by reducing riskier bank lending.[102] Ensuring that firms are appropriately capitalized for the risks they are taking is a goal of stress testing; however, if those effects are not well aligned with the true riskiness of a particular type of loan, then stress tests could unintentionally reduce banks' credit supply. For instance, some evidence exists that counties in which stress tested banks had high market share may have experienced a lower supply of credit to small and young businesses, which are generally considered riskier than established businesses but can generate a disproportionate share of growth in employment and income.[103]

However, other research concludes that businesses largely offset the reduction in loans from banks that participate in the stress tests with other sources of credit. Those sources include loans from smaller banks not in the stress tests,[104] debt issuance in capital markets, or loans from nonbank financial institutions.[105] Moreover, these potential unintended effects on credit supply by stress tested firms must be weighed against the benefits, discussed above, that more credible stress tests bring to the economy and the financial system. By ensuring that firms have sufficient quantity and quality of loss-absorbing capital to cover the risks that they are taking, the stress tests ensure the resilience and stability of the banking sector even in circumstances when stresses take unexpected forms.

The balance of those advantages and disadvantages of scenario severity can change over time. Losses at financial institutions are more likely to arise when the economy slows. Profits are more robust during periods of economic growth, in turn increasing resources available to cover future losses. In other words, capital is naturally procyclical, having an underlying tendency towards a positive correlation with financial conditions. Moreover, when underlying conditions are favorable and firm losses are low, firms sometimes project forward an expectation for low losses, paving the way to take more risk.[106] Conversely, when conditions are bad, firms may overcompensate and restrict credit even to otherwise creditworthy borrowers, exacerbating the downturn. Thus, firms' behavior may amplify underlying procyclicality.

Stress tests could, through different designs, either amplify or mitigate this procyclicality. If stress tests are always more severe in bad times, despite an expectation that conditions could soon improve, then this severity would add undue stress to the financial system, reducing financial intermediation with negative implications for the macroeconomy. That said, the purpose of the stress test scenarios is not to serve as an explicit countercyclical offset to the financial system, but rather to ensure that the firms are properly capitalized to withstand severe economic and financial conditions. Hence, the Board adopts a middle path, seeking to specify the severely adverse scenario to avoid adding sources of procyclicality to the financial system, neither explicitly mitigating any existing procyclical tendencies nor magnifying them. Indeed, Kohn and Liang (2019) argue that the ability to adjust elements that potentially add procyclicality can be a major benefit of stress tests as ''banks with forward-looking, less-procyclical capital buffers will not pull back as much when a downturn occurs.'' [107]

[96] Some of the well-known contributions are T. Schuermann, *Stress Testing Banks,* International Journal of Forecasting 30 (2014), 717–28; and N. Liang, *Well-Designed Stress Test Scenarios Are Important for Financial Stability,* Brookings Institution Paper (2018), *https://www.brookings.edu/articles/well-designed-stress-test-scenarios-are-important-for-financial-stability.*

[97] *See* 12 CFR 252, Appendix B.

[98] *Id.*

[99] *See* Schuermann (2014), *supra* note 95.

[100] *See* 90 FR 51856, 51880–51881 (Nov. 18, 2025).

[101] *See* Schuermann (2014), *supra* note 95.

[102] V. Acharya, A. Berger, and R. Roman, *Lending implications of U.S. bank stress tests: Costs or benefits?* Journal of Financial Intermediation 34 (2018), 58–90.

[103] *See* S. Doerr, *Stress Tests, Entrepreneurship, and Innovation,* Review of Finance 25, 1609–1637 (2021).

[104] *See* K.R. Cortés, Y. Demyanyk, L. Lei, E. Loutskina, and P. Strahan, *Stress tests and small business lending,* Journal of Financial Economics 136 (2021), 260–279.

[105] *See* J. Berrospide and R. Edge, *Bank capital buffers and lending, firm financing and spending: What can be learned from five years of stress test results?* Journal Financial Intermediation 47 (2024), 1010–61; T. Davydiuk, T. Marchuk, and S. Rosen, *Direct lenders in the U.S. middle market,* Journal of Financial Economics 162 (2024), 103946.

[106] *See* A. Berger and G. Udell, *The institutional memory hypothesis and the procyclicality of bank lending behavior,* Journal of Financial Intermediation 13 (2004), 458–495; A. Greenspan, ''Challenges facing community banks,'' Remarks before the Independent Community Bankers of America (Mar. 8, 2000), *https://www.federalreserve.gov/boarddocs/speeches/2000/20000308.htm.*

[107] D. Kohn and N. Liang, *Understanding the Effects of the U.S. Stress Tests,* Brookings Institution (Jul. 2019), *https://www.brookings.edu/*

When considering these principles in light of the recession approach and the scenario narrative, the Board also identified the importance of maintaining flexibility in the Board's scenario design framework and in establishing guides for certain values. As explained in the proposal, the flexibility principle helps ensure that the Board's efforts to increase the transparency, public accountability, and predictability of stress tests do not come at the expense of the overall effectiveness of the Board's stress testing program.

For instance, predictability and transparency could be achieved with a completely specified, entirely formulaic scenario that leaves no flexibility. However, simple, fixed guides may not achieve at least one of the goals of severity, credibility, or not adding to procyclicality. Similarly, more sophisticated formulations might improve on simple rules by accounting for the factors affecting firms' balance sheets and overall economic and financial conditions. For many types of economic indicators used in the Board's scenario framework, however, a fixed rule for the design of a scenario variable that satisfied the principles related to procyclicality and severity laid out above could require a complex structure that would conflict with the Board's principle of simplicity.[108]

A lack of simplicity is not, however, the only concern with a framework that eliminates flexibility. Unexpected shocks occur, like oil embargoes, national house price collapses, and pandemics. Moreover, the implications of these shocks are often not readily captured in concurrent data: especially their future effects on the economy and financial stability in the United States, and so on firms' future financial condition. Maintaining a degree of flexibility would allow the scenarios to adapt to evolving conditions while adhering to the principles outlined above.

In specifying the guides in this framework, the Board seeks to maintain flexibility by specifying ranges for the peak or trough value, the timing of that value, or the speed of adjustment for many of the variables. The amount of flexibility in the guides, as measured by the size of ranges specified, is calibrated to be as narrow as possible while adhering to the principles laid out above and is based on research and analysis of the behavior of those variables during past recessions, consistent with the recession approach, or periods of stress in financial markets. In addition to suggesting typical ranges within which scenarios will vary, the Board seeks to provide explanations of how the guide flexibility would be applied in different economic and financial conditions.

Generally speaking, the Board would design a more severe path for the scenario variables when it judged the level of systemic risks to be high, and a less severe path for the scenario variables when it judged systemic risks to be low. In some cases, the level of systemic risk can be tied to the level of specific indicators. For instance, when the unemployment rate is very high, the level of risk aversion also tends to be high, and that causes firms to reduce risk across their various business lines. In other cases, the Board would consider overall assessments by economists, supervisors, and financial market experts to assess the level of systemic risks, which typically incorporate many of the specific indicators mentioned in the discussions of individual guides below, when it is difficult to do so using individual or small sets of scenario variables.[109]

Therefore, the Board expects that, in an annual scenario, it may choose to have similar severities for variable values for those variables where the Board retains discretion within established ranges of the proposed guides. This expectation reflects the Board's consistent view that annual scenarios are not forecasts of potential future outcomes in the baseline or in a hypothetical stress environment. Establishing variable values with similar severity levels enhances the transparency and predictability of the annual scenarios, and reflects an expectation that these variables are likely to experience stress concurrently in a hypothetical stress scenario. As discussed below, if the Board were to determine that a specific salient risk should be addressed in a particular annual stress test, it would provide a specific assessment of that risk and the rationale for an alternative calibration of the variable's severity in the scenario disclosure for comment.

While flexibility allows scenarios to adapt to fast-evolving conditions, the guides in this framework are based on observed structural features of the economy. Macroeconomic history, however, features many examples where new data have contradicted long-held beliefs about underlying structural relationships. Also, the financial system is constantly evolving, presenting new risks and vulnerabilities. The relatively narrow ranges in the guides may not always allow for a fulsome response by the scenarios to significant developments. Therefore, the Board also sets out expectations for circumstances that could require additional flexibility in setting the specifications of the variables in the stress tests, so that the public can anticipate where the Board could adopt a specification that differs from those identified in the guides in this proposal. For instance, if events occur that alter the historical severity of a given variable, the Board could incorporate that data in its evaluation of the appropriate path for a given variable in annual scenarios that occur following such an event. The Board continuously monitors the macroeconomy and the financial system. If ongoing developments warrant, the Board may revisit this framework and adjust guides.

Finally, the increased predictability and transparency of the scenario as specified in this framework may allow firms to adjust their portfolios to reduce capital requirements, perhaps without a commensurate reduction in risk. While the Board acknowledged this possibility in the proposal and reiterates recognition of this risk, the Board expects that adherence to the principle of severity embraced in this framework will produce scenarios that adequately test such risks. At the same time, flexibility is maintained to allow scenarios to adapt to evolving conditions, not to reduce predictability and transparency. Overall, the Board finds that the degree of flexibility and the goals of transparency and predictability are well balanced as proposed, given the other requirements for designing effective and credible stress tests, and is adopting these principles without material changes.

### *G. Description of Variable Guides in the Severely Adverse Scenario*

#### 1. Unemployment Rate

The Board proposed to retain the guide established in the 2019 Scenario Design Policy Statement, with some additional explanation that would set out the following trajectories:

*articles/understanding-the-effects-of-the-u-s-stress-tests/.*

[108] Alongside conservatism, simplicity is one of the Board's principles for supervisory stress testing. *See* 12 CFR 252, Appendix B.

[109] For examples of relevant statistical analyses, *see, e.g.,* V. Acharya, L.H. Pedersen, T. Philippon, and M. Richardson. *Measuring Systemic Risk,* Review of Financial Studies 30 (2017), 2–47; T. Adrian and M. Brunnermeier, *CoVaR,* American Economic Review 106 (2016), 1705–41.

**Table 7:** Summary of Unemployment Rate Guide

| Component | Proposed Guide |
|---|---|
| Peak Value | The greater of (i) 3 to 5 percentage points above the jump-off value, or (ii) 10 percent. |
| Peak Value Timing | 6 to 8 quarters after jump-off. |
| Trajectory to Peak Value | High initial changes with smaller subsequent changes. |

The most common features of recessions are increases in the unemployment rate and contractions in aggregate incomes and economic activity.[110] For this and the following reasons, the Board intended to use the unemployment rate as the primary basis for specifying the severely adverse scenario. First, the unemployment rate is likely the most representative single summary indicator of adverse economic conditions. Second, in comparison to GDP, labor market data have traditionally featured more prominently in the set of indicators that the National Bureau of Economic Research (NBER) reviews to inform its recession dates.[111] Third and finally, the growth rate of potential output can cause the size of the decline in GDP to vary between recessions. While changes in the unemployment rate can also vary over time due to demographic factors, this seems to have more limited implications over time relative to changes in potential output growth. The unemployment rate used in the severely adverse scenario will reflect an unemployment rate that has been observed in severe post-war U.S. recessions, measuring severity by changes in the unemployment rate and GDP.[112] In the proposal, the Board described historical data that informed the Board's proposed guide specifications.[113]

The Board did not receive comment on this aspect of the proposal and has determined to finalize, as proposed, the guide for unemployment rate in the severely adverse scenario.

2. House Prices

The Board proposed to retain the guide established in the previous Scenario Design Policy Statement, with some additional information, including the timing of the trough value and the trajectory to the trough value.[114]

**Table 8:** Summary of House Price Guide

| Component | Proposed Guide |
|---|---|
| Trough Value | HPI-DPI falls by at least 25 percent or enough to bring the ratio down to the trough following the 2007–2009 financial crisis. |
| Trough Value timing | 8 to 10 quarters after jump-off. |
| Trajectory to Trough Value | Twenty percent of the decline realized in Quarter 1 and another 20 percent of the decline in Quarter 2. Thereafter, a linear decline to the trough. |

Firms subject to the supervisory stress test have a substantial exposure to the residential real estate market.[115] Given firms' direct exposures, and the broader impact of the housing sector on household balance sheets and the macroeconomy, the Board's methodology for supervisory stress tests incorporates house prices into a number of models.[116] Moreover, house price build-ups sometimes precede episodes of banking stress, with a notable example being the 2007–2009 financial crisis. By incorporating house prices into macroeconomic scenarios, supervisory stress tests help ensure that firms subject to the stress test are prepared for a range of market outcomes, including periods of large declines in house prices directly affecting loan performance and firms' balance sheets. This helps maintain the overall stability and resilience of the financial system. In the proposal, the

[110] To define the unemployment rate, the Board uses the quarterly average of seasonally adjusted monthly unemployment rates for the civilian, non-institutional population aged 16 years and older series from the Bureau of Labor Statistics (series LNS14000000).

[111] More recently, a monthly measure of GDP has been added to the list of indicators.

[112] Even though all recessions feature increases in the unemployment rate and contractions in incomes and economic activity, the size of this change has varied over post-war U.S. recessions. Table 5 documents the variability in the depth of post-war U.S. recessions. There is no universal agreement on how to categorize recession severity. For the purposes of this guide, the following categorization is employed: Recessions where the decline in real GDP and the increase in the unemployment rate are less than 1.5 percent or 1.5 percentage points, respectively, are considered mild; recessions where the decline in real GDP is 2.5 percent or more, or the increase in the unemployment rate is 3 percentage points or more, are considered severe; all other recessions are considered moderate.

[113] *See* 90 FR 51856, 51886–88 (Nov. 18, 2025).

[114] Trough value represents the minimum value achieved during the scenario.

[115] Regarding the importance of house prices to insured depository institutions generally, in 2025:Q1, mortgages and mortgage-backed securities comprised more than 20 percent of FDIC insured firms' assets (based on the ratio of Loans Secured by Real Estate, 1–4 Family Residential Mortgages, plus Mortgage-backed Securities, divided by Total Assets from Table II–A: Aggregate Condition and Income Data, All FDIC-Insured Institutions, FDIC Quarterly 2025, 19(2), 7, *https://www.fdic.gov/quarterly-banking-profile/fdic-quarterly-2025-volume-19-number-2.pdf*).

[116] *See* Board, 2025 Supervisory Stress Test Methodology (Jun. 2025), *https://www.federalreserve.gov/publications/files/2025-june-supervisory-stress-test-methodology.pdf*.

Board described historical data that informed the Board's proposed guide specifications.[117]

The Board did not receive comment on this aspect of the proposal and has determined to finalize, as proposed, the guide for house prices in the severely adverse scenario.

3. Commercial Real Estate Prices

The Board proposed a guide that would set out the following trajectories for commercial real estate prices as reported in the Board's Z.1 statistical release:[118]

**Table 9:** Summary of Commercial Real Estate Price Guide

| Component | Proposed Guide |
|---|---|
| Trough value | Falls between 30 and 45 percent from jump-off value. |
| Trough value timing | 8 to 10 quarters after jump-off. |
| Trajectory to trough value | Roughly linear. |

The Commercial Real Estate Price Index aggregates price indices across office, retail, industrial and other types of properties. In the supervisory stress test, commercial real estate prices capture a key part of the risks to firms from their commercial real estate exposures, which are reported by firms on FR Y–14Q, Schedule H.2 (Commercial Real Estate). Most firms subject to the supervisory stress test have a substantial exposure to the commercial real estate market. Moreover, commercial real estate price build-ups often precede episodes of market stress. By incorporating commercial real estate prices into macroeconomic scenarios, supervisory stress tests help ensure that firms subject to the stress test are prepared for a range of market conditions, including periods involving a large decline in commercial real estate prices directly affecting the firms' balance sheets. This helps maintain the overall stability and resilience of the financial system. In the proposal, the Board described historical data that informed the Board's proposed guide specifications.[119]

The Board did not receive comment on this aspect of the proposal and has determined to finalize, as proposed, the guide for commercial real estate prices in the severely adverse scenario.

4. Equity Prices

The Board proposed a guide that would set out the following trajectories for equity prices, as proxied by the U.S. Dow Jones Total Stock Market Index (DWCF):[120]

**Table 10:** Summary of Equity Price Guide

| Component | Proposed Guide |
|---|---|
| Trough value | Falls by $\begin{cases} 50\% + \min(10\%, \lvert\Delta(prior\ year)\rvert/2)\,, if\ \Delta(prior\ year) \geq 0 \\ 50\% - \min(10\%, \lvert\Delta(prior\ year)\rvert/2)\,, if\ \Delta(prior\ year) < 0. \end{cases}$ |
| Trough value timing | 3 to 4 quarters after jump-off. |
| Trajectory to trough value | 60 to 70 percent of the decline is realized in Quarter 1; 10 to 20 percent of the decline in Quarter 2; the rest of the decline is realized about equally in the remaining quarter(s) to trough. |

Notes: $\Delta(prior\ year)$ denotes the percentage change in the DWCF in the previous year.

[117] *See* 90 FR 51856, at 5188993.

[118] The source for the data is the Commercial Real Estate Price Index, Z.1 Release (Financial Accounts of the United States), Federal Reserve Board. This index is based on quarterly change of the Value Weighted Costar U.S. Composite Index Excluding Multifamily.

[119] *See* 90 FR 51856, at 51893–96 (Nov. 18, 2025).

[120] Specifically, the Board uses the U.S. Dow Jones Total Stock Market (Float Cap) Index (DWCF): End-of-quarter value via Bloomberg Finance L.P.; this index encompasses a wider universe of stocks than the S&P 500 Composite.

Along with commercial real estate prices, housing prices, and the VIX, equity prices are an essential gauge for asset prices that affect the U.S. economy and the financial conditions of financial and nonfinancial firms. Equity prices are generally recognized as a leading indicator of future economic conditions broadly, including economic growth and inflation.[121] Therefore, testing the ability of a firm to withstand a steep decline in equity prices helps ensure that these firms are properly capitalized to withstand severe economic and financial conditions. In the proposal, the Board described historical data that informed the Board's proposed guide specifications.[122]

One commenter criticized the equity prices guide, stating that the proposed guide for equity prices permits a maximal decline in equity prices that exceeds the decline observed during the 2007–2009 financial crisis, and that the paths for equity prices in the proposed 2026 scenario included a trough and pace of the decline in equity prices that considerably exceeds that observed historically.

The Board has considered comments submitted on the proposal and has determined to finalize, as proposed, the guide for equity prices in the severely adverse scenario.

While the Scenario Design Policy Statement establishes that the Board's scenario design process is informed by historical experience, the Board's scenario design process recognizes that ''historical relationships between macroeconomic variables could change over time'' [123] and that scenarios should be forward-looking, ''introduce[ing] elements outside of the realm of historical experience into the supervisory stress test.'' [124] Further, declines in equity prices greater than those experienced in the 2007–2009 financial crisis could reasonably occur in the future; and unprecedented policy interventions helped stabilize the economy and financial markets during the 2007–2009 financial crisis, which the stress test does not assume to occur during the hypothetical stress test scenarios.[125] Consistent with existing stress testing principles, the stress test assumes that, although permanent government stabilization programs (*e.g.,* unemployment insurance) and monetary policy in the United States and elsewhere would function normally, there would be no extraordinary measures taken by fiscal or financial authorities to support the economy or financial markets during the scenarios.

The Board addressed aspects of this comment that relate to the specification of the equity prices path for the final 2026 scenario in the 2026 Scenarios Review of Comments.[126]

5. VIX

The Board proposed a guide that would set out the following trajectories for the Chicago Board Options Exchange's CBOE Volatility Index (''VIX''):

**Table 11:** Summary of the VIX Guide

| Component | Proposed Guide |
|---|---|
| Peak value | VIX increases to the higher of a level between 65 percent and 75 percent, or by at least 10 percentage points from the jump-off value. |
| Peak value timing | 2 quarters after jump-off. |
| Trajectory to peak value | Largest share, 60 to 80 percent, of increase realized in Quarter 1. |

In the supervisory stress test models that use the macroeconomic scenario, the VIX can act as an indicator of stress for a wide range of important assets and income streams even if those business lines are not specifically linked to the VIX index. By incorporating the VIX into scenarios, stress tests help ensure that firms are prepared for a wide range of market conditions, including periods of extreme volatility and uncertainty and any associated economic downturn.[127] This helps maintain the overall stability and resilience of the financial system. In the proposal, the Board described historical data that informed the Board's proposed guide specifications.[128]

One commenter stated that the proposed VIX level remains at or close to its peak for a longer period over the course of the proposed 2026 scenario than has been observed historically. The commenter explained that this difference was likely due to the linear reversion approach the Board used to determine the peak-to-endpoint path and suggested that an exponential decay approach would be more appropriate.

The Board has considered comments submitted on the proposed 2026 scenario, for purposes of this proposal, and has determined to finalize, as proposed, the guide for the VIX in the severely adverse scenario.

The trajectory from peak or trough to end value for variables in the severely adverse scenario each year is expected to generally be determined by a roughly

[121] In the academic literature, stock prices are well-known to be fast-moving or forward-looking variables that react to shocks quickly. One prominent example is the study by B. Bernanke, J. Boivin, and P. Eliasz, *Measuring the Effects of Monetary Policy: A Factor-Augmented Vector Autoregressive (FAVAR) Approach,* Quarterly Journal of Economics 120 (2005), 387–422 (classifying stock market prices as fast-moving variables that respond to shocks on impact).

[122] *See* 90 FR 51856, at 51897–51900 (Nov. 18, 2025).

[123] 12 CFR 252, Appendix A, section 3.1(d).

[124] 12 CFR 252, Appendix B, section 1.2(b). *See also* section 2.4(a): ''The supervisory scenarios may potentially incorporate events that have not occurred historically. It is not necessarily consistent with the purpose of a stress testing exercise to assume that the future will be like the past.'' These design principles are also consistent with those more detailed expectations described in this final Scenario Design Policy Statement.

[125] *See* F. Mishkin, *Over the Cliff: From the Subprime to the Global Financial Crisis,* Journal of Economic Perspectives 25 (2011), 49–70.

[126] *See* Board, Review of Comments and Summary of Changes to the Proposed 2026 Stress Test Scenarios, at 20, available at *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2026.htm.*

[127] *See, e.g.,* N. Bloom, *The Impact of Uncertainty Shocks,* Econometrica 77 (2009), 623–85; S. Baker, N. Bloom, and S. Davis, *Measuring Economic Policy Uncertainty,* Quarterly Journal of Economics 131 (2016), 1593–1636.

[128] *See* 90 FR 51856, at 51900–4 (Nov. 18, 2025).

linear interpolation, and generally will be smooth for variables determined by guides and follow the model path for modeled variables;[129] however, the final variable guides, including the guide for the VIX, do not provide a specific guide for the trajectory of the peak-to-endpoint path. As discussed in the Board's Review of Comments and Summary of Changes to the Proposed 2026 Stress Test Scenarios, in evaluating whether an exponential decay approach would be more appropriate, the Board considered that this approach may have a strong historical fit to the data.[130] However, the Board's selection of a linear peak-to-endpoint path in the 2026 severely adverse scenario and in the guide is consistent with the convergence properties of the other variables in the final 2026 scenario. Additionally, the recovery of the VIX level was consistent with the broader 2026 scenario narrative, which featured GDP continuing to fall and the unemployment rate continuing to rise through later quarters of the scenario. The Board also considered academic research finding evidence that indicates that the VIX level would remain elevated when economic activity is weak.[131]

6. 5-Year Treasury Yield

The Board proposed a guide that would set out the following trajectories for the 5-year Treasury yield, which is measured using the quarterly average of the yield on 5-year U.S. Treasury notes:[132]

**Table 12:** Summary of 5-year Treasury Yield Guide

| Component | Proposed Guide |
|---|---|
| Trough value | The 5-year yield will fall between 1.5 and 3.5 percentage points, subject to a lower bound of 0.3 percent or a decline of 0.3 percentage points from the jump-off level, whichever is lower. |
| Trough value timing | 1 to 4 quarters after jump-off |
| Trajectory to trough value | The largest share of the decline is realized in Quarter 1. The approximate share is given by the following formula:<br>*100% – 15% * (Trough value timing – 1).*<br>Thereafter, the yield declines to its trough level at smoothly decreasing percent reductions. |

Because banks generally engage in maturity transformation by borrowing short-term (*i.e.,* deposits) to fund longer-term assets, fluctuations in interest rates can affect their financial health in various ways.[133] The 5-year Treasury yield is an important benchmark rate for credit markets and is, thus, directly related to the profitability of banks' investments in loans and securities as well as their trading activities. For example, a decline in longer-term Treasury yields that exceeds the decline in short-term yields (known as a flattening of the yield curve) tends to compress firms' net interest margins and can therefore reduce their profitability. At the same time, the decline in such yields tends to increase the market value of firms' investments in long-term fixed-rate bonds, some which is reflected in various measures of capital at firms.[134] Incorporating the 5-year Treasury yield into the supervisory stress test helps to ensure that firms are prepared for a wide range of market conditions, including periods with a sudden decline in a credit market benchmark rate. This helps maintain the overall stability and resilience of the financial system. In the proposal, the Board described historical data that informed the Board's proposed guide specifications.[135]

The Board did not receive comment on this aspect of the proposal and has determined to finalize, as proposed, the guide for the 5-year Treasury yield in the severely adverse scenario.

7. 10-Year Treasury Yield

The Board proposed a guide that would set out the following trajectories for the 10-year Treasury yield, which is measured using the quarterly average of

[129] *See* 12 CFR 252, Appendix A, section 4.2.2(h).

[130] *See* Board, Review of Comments and Summary of Changes to the Proposed 2026 Stress Test Scenarios, at 22–23, available at *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2026.htm.*

[131] This approach is also described in the Board's proposed 2025 Scenario Design Policy Statement. *See* 90 FR 51856, at 51900 (Nov. 18, 2025), note 174, citing N. Bloom, Fluctuations in Uncertainty, Journal of Economic Perspectives 28(2) (2014), 153–76.

[132] This series is constructed by Federal Reserve staff based on the Svensson smoothed term structure model. L. Svensson, *Estimating Forward Interest Rates with the Extended Nelson-Siegel Method,* Sveriges Riksbank Quarterly Review 3 (1995), 13–26.

[133] *See* W. English, S. Van den Heuvel, and E. Zakrajsek, *Interest Rate Risk and Bank Equity Valuations,* Journal of Monetary Economics 98 (2018), 80–97.

[134] The change in the fair value of securities held for sale is reflected in common equity for all firms and in common equity tier 1 for firms subject to Category I and Category II standards, as well as firms that opt into that treatment. *See* 12 CFR part 252.

[135] *See* 90 FR 51856, 51904–9 (Nov. 18, 2025).

the yield on 10-year U.S. Treasury notes: [136]

**Table 13:** Summary of 10-year Treasury Yield Guide

| **Component** | **Proposed Guide** |
|---|---|
| Trough value | The 10-year yield will fall between 1.0 and 3.0 percentage points, subject to a lower bound of 0.5 percent or a decline of 0.3 percentage points from the jump-off level, whichever is lower. |
| Trough value timing | 1 to 4 quarters after jump-off |
| Trajectory to trough value | The largest share of the decline is realized in Quarter 1. The approximate share is given by the following formula:<br><br>*100% – 15% * (Trough value timing – 1)*<br><br>Thereafter, the yield declines to its trough level at smoothly decreasing percent reductions. |

As noted above, because banks generally engage in maturity transformation by borrowing short-term (*i.e.,* deposits) to fund longer-term assets, fluctuations in interest rates can affect their financial health in various ways. Like the 5-year Treasury yield, the 10-year Treasury yield is an important benchmark rate for credit markets and is, thus, directly related to the profitability of firms' investments in loans and securities as well as their trading activities. For example, a decline in longer-term Treasury yields that exceeds the decline in short-term yields (known as a flattening of the yield curve) tends to compress firms' net interest margins and can therefore reduce their profitability. At the same time, the decline in such yields tends to increase the value of firms' investments in long-term fixed-rate bonds, some of which is reflected in various measures of capital at firms.[137] Incorporating the 10-year Treasury yield into the supervisory stress test helps to ensure that firms are prepared for a wide range of market conditions, including periods with a sudden decline in a credit market benchmark rate. This helps maintain the overall stability and resilience of the financial system. In the proposal, the Board described historical data that informed the Board's proposed guide specifications.[138]

The Board did not receive comment on this aspect of the proposal and has determined to finalize, as proposed, the guide for the 10-year Treasury yield in the severely adverse scenario.

8. BBB Yield

The Board proposed a guide that would set out the following trajectories for the BBB corporate spread, which is measured by the quarterly average of ICE BofA U.S. Corporate 7–10 Year Yield-to-Maturity Index relative to the 10-year Treasury yield: [139]

[136] This series is constructed by Federal Reserve staff based on the Svensson smoothed term structure model. Svensson (1995), *supra* note 131.

[137] The change in the fair value of securities held for sale is reflected in common equity for all firms and in common equity tier 1 for firms subject to Category I and Category II standards, as well as firms that opt into that treatment. *See* 12 CFR part 252.

[138] *See* 90 FR 51856, 51909–13 (Nov. 18, 2025).

[139] The source for the BBB corporate spread series is ICE BofAML U.S. Corporate 7–10 Year Yield-to-Maturity Index, ICE Data Indices, LLC, (C4A4 series). The 10-year yield is computed as the quarterly average of the yield on 10-year U.S. Treasury notes, constructed by Federal Reserve staff based on the Svensson smoothed term structure model. *See* Svensson (1995), *supra* note 131.

**Table 14:** Summary of BBB Spread Guide

| Component | Proposed Guide |
|---|---|
| Peak value | The spread will increase to between 500 and 600 basis points or by at least 100 basis points, whichever results in a higher peak level. |
| Peak value timing | 3 to 4 quarters after jump-off. |
| Trajectory to peak value | Highest share of increase realized in Quarters 1 and 2, between 60 to 80 percent of the increase in Quarter 1, smooth trajectory to peak thereafter. |

Although firms subject to the supervisory stress test do not hold substantial volumes of BBB corporate bonds on their balance sheets, they make business loans to large- and middle-market firms and hold other types of business debt on their balance sheets, *e.g.,* commercial and industrial (C&I) loans and collateralized loan obligations (CLOs). Corporate bond spreads and CLO spreads tend to move together in times of financial stress and high uncertainty. C&I loans to large- and middle-market firms, some of whom are also issuers of corporate bonds, account for 65 percent of total C&I loans. Because of these similarities with bond-issuing firms, changes in business conditions that underlie changes in spreads on BBB corporate bonds would affect these borrowers as well (and hence the balance sheets of the stress tested firms). In fact, empirical research finds that bank borrowers are more sensitive to macroeconomic and financial shocks than publicly-traded borrowers due to their relatively more-restricted access to funding sources. Hence, in the context of the severely adverse scenario, the Board views BBB corporate bond spreads as a measure representing conditions in the business sector more generally. In the proposal, the Board described historical data that informed the Board's proposed guide specifications.[140]

The Board did not receive comment on this aspect of the proposal and has determined to finalize, as proposed, the guide for the BBB yield in the severely adverse scenario.

9. Mortgage Spreads

The Board proposed a guide that would set out the following trajectories for the mortgage spread, as proxied by the quarterly average of weekly series for the interest rate of a conventional, conforming, 30-year fixed-rate mortgage, obtained from the Freddie Mac Primary Mortgage Market Survey relative to the 10-year Treasury yield.[141]

**Table 15:** Summary of Mortgage Spread Guide

| Component | Proposed Guide |
|---|---|
| Peak value | Increase to a range of peak values given by the jump-off value plus 70 to 160 basis points, with a minimum of 300 basis points |
| Peak value timing | 3 to 4 quarters after jump-off |
| Trajectory to peak value | 50 to 70 percent of increase realized in quarter 1, smooth trajectory to peak thereafter |

Note: The guide describes values of the mortgage rate relative to the 10-year Treasury yield.

In the supervisory stress test, the mortgage spread can act as both (i) an indicator of stress for certain important assets under the scenarios and (ii) a source of stress for firms subject to the supervisory stress test with substantial exposure to assets that are tied to mortgage spreads, such as mortgage loan portfolio or mortgage-backed securities, which are reported by firms on FR Y–14M, Schedule A (First Lien) and FR Y–14Q, Schedule B (Securities). Firms subject to the supervisory stress test typically have substantial exposure to the assets referenced in the mortgage

[140] *See* 90 FR 51856, 51913–17 (Nov. 18, 2025).

[141] The 10-year Treasury yield is calculated using the quarterly average of the yield on 10-year Treasury notes by the Federal Reserve Board based on the Svensson smoothed term structure model. *See* Svensson (1995), *supra* note 131.

spread, and as a result, by incorporating the mortgage spread into scenarios, stress tests help ensure that firms are prepared for a wide range of market conditions, including periods of elevated mortgage spreads, in part reflecting financial shocks and any associated economic downturn. This helps maintain the overall stability and resilience of the financial system. In the proposal, the Board described historical data that informed the Board's proposed guide specifications.[142]

The Board did not receive comment on this aspect of the proposal and has determined to finalize, as proposed, the guide for the mortgage spread in the severely adverse scenario.

10. International Variables

The Board proposed a guide that would set out the following trajectories for the international variables in the severely adverse scenario, including the path for real GDP, consumer price inflation, and the nominal exchange rate for four country blocs: the euro area, the U.K., Japan, and Developing Asia:[143]

**Table 16:** Summary of Guides for International Variables

| | **GDP (percent deviation from baseline)** | **Inflation (percentage point deviation from baseline)** | **Exchange Rate (percent deviation from jump-off)** |
|---|---|---|---|
| **Euro Area** | Trough: -7.5<br>End value: -7.5<br>Range: [-10, -5] | Trough: -3<br>End value: 0<br>Range: [-4, -2] | EUR/ USD Peak: 15<br>End value: 0<br>Range: [5, 25] |
| **United Kingdom** | Trough: -7.5<br>End value: -7.5<br>Range: [-10, -5] | Trough: -3<br>End value: 0<br>Range: [-4, -2] | GBP/ USD Peak: 15<br>End value: 0<br>Range: [5, 25] |
| **Japan** | Trough: -7.5<br>End value: -7.5<br>Range: [-10, -5] | Trough: -3<br>End value: 0<br>Range: [-4, -2] | YEN/ USD Trough: -1<br>End value: 0<br>Range: [-11, 9] |
| **Developing Asia** | Trough: -3<br>End value: 0<br>Range: [-5.5, -0.5] | Trough: -5<br>End value: 0<br>Range: [-9, -0.8] | Dev Asia USD Peak: 15<br>End value: 0<br>Range: [5, 25] |
| **Trajectory from jump-off to peak/trough*** | Exponential interpolation | Linear Interpolation | Exponential interpolation |

Note: Range refers to the value used for the trough. If the peak/trough is adjusted, the end value is modified to keep the ratio with the peak/trough value constant.

*This row was not included in the proposal. This addition is intended to clarify the Board's process of estimating values between data points for these variables and does not indicate a change in the Board's approach.

In conjunction with these guides, the Board proposed an approach that relies on both judgment and insights from economic models that informs the path of international variables.[144] As described in the Scenario Design Policy Statement, a scenario that targets all specific risk factor groups includes judgement on the projected paths of selected international variables. Recessions that occur simultaneously across countries are an important source of stress to the balance sheets of firms with notable international exposures but are not a typical feature of the international economy even when the United States is in recession. As a result, simply adopting the typical path of international variables in a severe U.S. recession would likely underestimate the risks stemming from the international economy. Consequently, an approach that relies on both judgment and insights from

[142] *See* 90 FR 51856, 51917–22 (Nov. 18, 2025).

[143] For the purpose of the supervisory stress tests, the Board defines Developing Asia as China, India, Hong Kong, South Korea, and Taiwan. Aggregate variables for this bloc (GDP, inflation, and the nominal exchange rate) are obtained by weighting country-specific variables by their relative share of the total nominal GDP (expressed in U.S. dollars). These economies capture the majority of the foreign exposure of U.S. banks.

[144] *See* Board, February 2026 Macroeconomic Model Guide (Feb. 2026), *https://www.federalreserve.gov/supervisionreg/files/2026-final-macroeconomic-model-guide.pdf.*

economic models informs the path of international variables. In the proposal, the Board described historical data that informed the Board's proposed guide specifications.[145]

One commenter stated that the use of identical trough values and ranges of GDP and inflation for the euro area, the United Kingdom, and Japan, would not be conceptually sound given that each of these three jurisdictions has operated on different economic trajectories since the 2007–2009 financial crisis. The commenter recommended that the Board incorporate jurisdiction-specific factors in determining the guides for these countries/regions, rather than applying a common shock across multiple jurisdictions, and explain how trough values within the prescribed range are chosen and the variables analyzed in making that choice when scenarios are released for comment.

The Board has considered the comments submitted and has determined to finalize, as proposed, the guides for international variables in the severely adverse scenario.

Differences in the economic trajectories of a given country bloc are reflected in the international variables in the baseline scenario—since variable specifications are expressed as deviations relative to the baseline scenario. Furthermore, the guides are expressed as ranges, so further differences could be imposed by selecting different values for different countries. Therefore, the Board determined that the proposed guides are appropriately formulated to set the paths of the international variables in the severely adverse scenario in a simple and reasonable manner. Other comments related to the Board's macroeconomic model for stress testing are addressed in 2027 Model Review of Comments and Summary of Changes.

*H. Global Market Shock*

The global market shock component is applied to market risk positions held by the firms on a given as-of date. Under the Board's regulations, the global market shock can apply to both the supervisory stress test and the company-run stress test for applicable firms. This section describes the Board's proposal related to the global market shock component in the Scenario Design Policy Statement, and comments received on that proposal. A discussion of adjustments to the global market shock component of the supervisory stress test, including the as-of date window, use of two scenarios on a single date, notification, and applicability, are discussed above in Section II.E. of this **SUPPLEMENTARY INFORMATION**.

1. Design of the Global Market Shock

In the proposal, the Board explained that the global market shock component comprises a large set of financial risk factors and associated hypothetical shocks to those risk factors. The Board considers emerging and ongoing areas of financial market vulnerabilities in the development of the global market shock component, informed by financial stability reports, supervisory information, and internal and external assessments of potential sources of distress such as geopolitical, economic, and financial market events. Financial risk factor shocks are calibrated based on assumed time horizons that reflect several scenario design considerations. The Board also considers liquidity characteristics of the different asset classes that constitute certain risk factors. These liquidity horizons approximate the variation in speed at which banks could reasonably close out, or effectively hedge, the associated risk exposures in the event of market stress. The Board has also published a summary of the models and processes of the global market shock component for the 2026 stress test on the Board's website.[146]

The Board considered enhancements to the design of the global market shock in the annual stress test to improve the stress test's ability to capture the impact of severe economic stress in financial markets. The Board also considered alternative approaches to the global market shock, including employing instantaneous shock events across multiple as-of dates, rather than the current approach of selecting a single date for an instantaneous shock event; and an annual stress test that features multiple global market shock components on a single as-of date, which would allow the Board to compare a given firm's losses across a variety of types of shocks for a given set of trading position, which could be aggregated using a simple average, an average of the two worst outcomes, or another technique.

2. Additional Guardrails

One commenter stated that the current methodology provides significant discretion in specifying primary risk factor shocks. The commenter stated that this discretion can lead to year-over-year volatility in capital requirements and suggested that the Board should establish, disclose, and publish guardrails for selecting and adjusting global market shock scenarios. Another commenter stated that the Board should not implement guardrails for the global market shock component, stating that advance disclosure of these parameters would allow large trading firms to optimize their portfolios around known stress test scenarios.

In consideration of these comments, the Board has determined to revise the range of ''severe'' shocks of the primary risk factors. The Board has revised the upper bound of the ''severe'' shock from the historical maximum to the 99.9th percentile (and the lower bound from the historical minimum to the 0.1th percentile). The Board will disclose the upper and the lower bound values associated with the revised range of ''severe'' shocks for each of the primary risk factors in the Fall2026 Global Market Shock Component Documentation. On an exceptional basis, the Board may consider shocks outside the range of ''severe'' shocks if a given scenario narrative includes forward-looking emerging risks, heightened vulnerabilities in particular asset classes, or stressed current financial market conditions.

The Board recognizes the existing judgment-based element of the global market shock scenario design framework. The February 2026 Global Market Shock Component Documentation specifies the percentile ranges for shock values within the given severity category. For example, as described in the February 2026 Global Market Shock Component Documentation, a ''severe'' shock can fall between the 99th percentile and the historical maximum. Selecting primary risk factor shock values from the extreme observations (such as the historical maximum or beyond the historical maximum) on a regular basis may, in some cases, contribute to volatility in year-to-year capital requirement.

The revised range of the ''severe'' shock category limits the discretion in the primary shock severity selection by limiting application of the extreme observations in the historical distributions. The Board will disclose the upper bound and lower bound values of ''severe'' shock in the Fall2026 Global Market Shock Component Documentation to provide additional transparency and predictability. The Board also clarifies that the Board may consider shocks outside the revised range of ''severe'' category only on an exceptional basis. The Board describes

[145] *See* 90 FR 51856, at 51922–27 (Nov. 18, 2025).

[146] *See* Board, Final 2026 Global Market Shock Component (Feb. 2026), *https://www.federalreserve.gov/supervisionreg/files/gms-model.pdf* (the ''February 2026 GMS Component Model Documentation'').

the basis for such exceptions in the Fall2026 Global Market Shock Component Documentation. This further promotes accountability of the shock severity selection process and is expected to improve the year-to-year stability of the stress test results, because it would likely reduce the application of historical minimum and maximum shock values, or exceeding these values, in the global market shock component.

The Board expects to continue to derive secondary and other remaining GMS shocks via models as described in the model documentation without defining ranges for these shocks. Restricting these model-based shocks to pre-determined ranges could result in less-coherent or less-plausible global market shock scenarios. The Board also expects to continue to seek public comment on the global market shock component each year, including on shock severities. This approach can continue to allow the Board to specify shock severities that are consistent with scenario narratives and sufficiently severe, while improving the transparency of the framework.

The Board considers that the current scenario design framework, including the revised percentile ranges, will help ensure the internal consistency of the market shocks in the global market shock component. As described in the 2019 Scenario Design Policy Statement and the February2026 Global Market Shock Component Documentation, the Board considers multiple sources of information specifying scenario narratives, which informs the shock size for primary risk factors. This includes supervisory experience and forward-looking expert judgment, as well as statistical analysis of historical and recent financial data, and consideration of historical shocks in combination with past firm risk exposures.[147] The percentile ranges allow the Board to specify shocks that are consistent with both the severity dictated by the narrative and current market conditions, and to adjust the shocks within the range as needed when conditions change during the comment period. In comparison, applying fixed percentile points (*e.g.,* using the same standardized percentile such as 99th or 95th percentiles for key shocks) mechanically without taking the scenario narratives and the current market conditions into consideration can lead to shocks that are not internally consistent with the narrative or not reflecting salient risks, if present.

Compared with fixed percentiles, percentile ranges provide flexibility that can, in some cases, promote the stability of the global market shock component year to year. While the scenario narrative determines the severity category and associated relevant percentile range, nuances in a given narrative may necessitate the selection of shocks from different points within the range. In addition, changes in market conditions and firms' trading positions impact the severity of shocks. For example, a shock that is considered severe in one environment may not be considered severe in others. Finally, the percentile ranges allow the Board to select primary risk factor shock values that are coherent and internally consistent, which may not be achievable if the severity category is mapped to fixed percentiles.

For the reasons described above, the Board believes that the approach adopted in this final Scenario Design Policy Statement, including the revised percentile ranges, is appropriate.

3. Global Market Shock Overlap With Risk-Based Capital Requirements

Several commenters recommended that the Board resolve overlaps between risk-based capital requirements, including in the credit valuation adjustment (CVA) and fundamental review of the trading book (FRTB) frameworks in the large bank capital proposal and the GMS component of the stress test, in order to prevent excessive capital requirements for firms' capital markets activities, to ensure that requirements are aligned with actual risks.

The Board has considered comments submitted on the proposal and has determined to finalize, with the revisions described above, the framework for the global market shock component.

The Board is mindful of potential overlaps between the capital and stress testing frameworks. The Board's supervisory stress test complements the risk-based framework by adding forward-looking granularity and risk sensitivity to ensure that firms subject to the stress test are sufficiently capitalized to absorb losses during a stress event. In contrast, the Board's 2026 Capital Proposals establish minimum capital requirements, which are designed to promote the safety and soundness of firms subject to those requirements.[148] As noted in the Board's recent proposals to modernize the regulatory capital framework, the Board considered the combined calibration of these frameworks and determined that they would be appropriate. The Board will further consider comments on the 2026 Capital Proposals, and the interaction of that proposal with this final action, in any final capital rulemakings.

4. Digital Assets

One commenter suggested that the Board should include certain digital asset market shocks to the global market shock component of the stress test scenario, while another commenter suggested that the Board clarify how exposures to crypto-related assets are treated.

The Board has considered the comments submitted and has determined to finalize, as proposed, the global market shock component described in the proposal without adding additional digital asset-based shocks.

The Board considered the commenter's suggestion of adding certain digital asset market shocks to the global market shock component of the stress test scenario and has determined not to add digital asset market shocks. Developing digital asset market shocks would require detailed data regarding firms' digital asset market exposures that are not sufficiently captured at the level of granularity necessary to develop market shocks in the FR Y–14Q and are not otherwise available. Capturing such data would increase reporting burden for firms. While the Board is finalizing this aspect of the proposal as-proposed, the Board regularly assesses the performance of the supervisory stress test, and may consider changes, as well as revisions to regulatory reports to assess potential changes, in the future.

5. Multiple Market Shocks—Two Global Market Shock Scenarios

A discussion of adjustments to the global market shock component of the supervisory stress test, including the use of two scenarios on a single date, are discussed above in Section II.E of this **SUPPLEMENTARY INFORMATION.**

6. Shock Values

The Board proposed the following shock definitions by asset class; shock values are generated for all exposures in the global market shock template:[149]

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[147] *See* 12 CFR 252, Appendix A, section 5; February 2026 GMS Component Model Documentation, *supra* note 145, at 12–14.

[148] *See* the 2026 Capital Proposals, *supra* note 37.

[149] Shock values represent the magnitudes of changes to the financial risk factors and reflect the severity of market stress that these risk factors experience in the scenario.

**Table 17:** Overview of Shock as Generated by the Global Market Shock in the Scenario Design Framework

| Asset class | Spot/futures curve shocks | Option-implied volatility shocks |
|---|---|---|
| Agencies | Option adjusted spread changes to U.S. residential agency products, U.S. commercial agency products, and non-U.S. agency products across various ratings. | N/A |
| Commodities | Arithmetic returns to spot prices and futures contract prices across maturities for commodities. | Changes to implied volatilities of commodities. |
| Foreign exchange rates | Arithmetic returns to spot exchange rates of various currencies against the U.S. dollar. Cross-currency spot exchange rates. | Changes in implied volatility of foreign exchange options across various maturities. |
| Interest rates | Absolute changes to term structures of government bond yields and swap rates for various countries. Absolute changes in inflation, cross-currency versus the U.S. dollar basis, and euro tenor basis risk. | Changes to interest rate implied volatilities across various swaption maturities. |
| Public equity | Arithmetic returns to public equity across regions (markets). | Changes in implied volatilities of public equity options across various maturities. |
| Public equity dividends | Relative yield shocks on dividend derivatives (e.g., dividend swaps and dividend futures) across various regions (markets) and tenors. | N/A |
| Sovereign credit | Changes to five-year credit default swap (CDS) spreads for various countries. | N/A |
| Corporate credit | Spread changes to corporate bonds, covered bonds, indices, index tranches, and index options across credit ratings. | N/A |
| Municipal credit | Spread changes to municipal bond indices and other municipal credit products across credit ratings. | N/A |
| Other fair value assets | Arithmetic returns to other securities held under fair value accounting rules. Examples include illiquid fair value securities, which cannot be grouped into another asset class, such as public | N/A |

| Asset class | Spot/futures curve shocks | Option-implied volatility shocks |
|---|---|---|
| | welfare investments covering housing credit, tax credit, and energy investments. | |
| Securitized products | Market value haircuts (price declines), expressed in percentage terms, to value-weighted portfolios of mortgage-backed securities and other asset-backed securities. | N/A |

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The Board has considered comments submitted on the proposal and has determined to finalize, as proposed, the shock values in the global market shock component.

7. Liquidity Horizons

For the global market shock component, the Board proposed to amend the Scenario Design Policy Statement to make the following changes to the liquidity horizons, which are broadly consistent with the standards in the Basel Committee on Banking Supervision's FRTB.[150] The proposed liquidity horizons were selected, in part referencing the FRTB, because those horizons represent a general consensus of a broad range of regulation authorities and the industry. Therefore, they can be considered to be a reasonable benchmark for defining the shock horizons that would be used in the global market shock component. The horizons in the proposal departed from the FRTB slightly by specifying the same liquidity horizon to all risk factors in the same asset class. This choice was consistent with the Board's stress test principle of simplicity and facilitated a more straightforward modeling framework for the global market shock. Additionally, these shortened horizons were proposed because they better align with the projection horizon in the stress test, and help avoid outlier outcomes that would both increase and decrease losses related to trading.

**Table 18:** Prior and Final Liquidity Horizons

| Asset class | Prior liquidity horizon | Final liquidity horizon |
|---|---|---|
| Agencies | 3 months | 1 month |
| Commodities | 3 months | 1 month |
| Foreign exchange rates | 3 months | 1 month |
| Interest rates | 3 months | 1 month |
| Public equity | 3 months | 1 month |
| Public equity dividends | 3 months | 1 month |
| Sovereign credit | 6 months | 1 month |
| Corporate credit | 6 months | 3 months |
| Municipal credit | 6 months | 3 months |
| Other fair value assets | 12 months | 3 months |
| Securitized products | 12 months | 3 months |

[150] *See* Basel Committee on Banking Supervision, ''Calculation of RWA for market risk,'' *The Basel Framework*, 675–970, *https://www.bis.org/committees/bcbs/basel-framework/basel-framework.pdf*. *See also* 88 FR 64028, 64138 (Sep. 18, 2023).

One commenter supported the revised liquidity horizon assumptions, including using the same liquidity horizons for all risk factors within the same asset class. The commenter also stated that the current instantaneous shock approach is preferable to the alternative dynamic approach. Another commenter also supported the revised liquidity horizon assumptions, and stated that this revision should lead to less year-over-year volatility in global market shock results and less atypical trading outcomes.

Consistent with these commenters, and for the reasons discussed in the proposal, for future scenarios, the Board is adopting the revised liquidity horizon assumptions as proposed and maintaining the current instantaneous shock approach.

8. Global Market Shock Simplification

The Board proposed to substantially reduce the number of disclosed risk factors from over 20,000 to approximately 2,300 shocks, determined based on their relevance for developing a global market shock scenario narrative, the materiality of the risk factor, data quality, and consistency across asset classes. Under this approach, the Board would also review consistency across asset classes. In this regard, where possible, the Board would generate shocks to the same set of countries, regions, and tenor points across different asset classes. Such consistency would simplify shock comparison across different asset classes and improve public understanding of the global market shock component. Additionally, the Board proposed to remove the inclusion of shocks to the values of private equity positions in section 3.2(b)(viii) of the Scenario Design Policy Statement, because private equity exposures are now stressed using the severely adverse macroeconomic scenario.

One commenter supported retaining the current level of risk factor granularity, as, in their view, it is essential to generating a scenario that accurately captures risk to financial market activities. The commenter suggested that, if the Board does reduce the number of disclosed risk factors, as proposed, then the Board should publish mapping methods for public review and perform the mapping itself to maintain consistency across firms.

The Board has considered the comments submitted and has determined to finalize, as proposed, the simplification of disclosed risk factors in the global market shock component.

In the proposal, the Board proposed to reduce the number of disclosed risk factors in the global market shock component from more than 20,000 to approximately 2,300 shocks in order to simplify the global market shock component, and help focus the disclosure on the most material shocks, as many of the 20,000 risk factors are often not material (for example, certain commodity shocks) and do not necessarily enhance the risk capture of the global market shock component.[151] The Board determined the shocks that would continue to be disclosed by assessing their relevance for developing a global market shock scenario narrative, the materiality of the risk factor, data quality, and consistency across asset classes.

To provide the ability to map from the simplified shocks to the full list of shocks in future scenarios, the Board has published detailed instructions for relative shock conversions and instructions on how to map from the simplified template to the original full template for public comment. These instructions include (1) the mapping between the simplified shock template and the original full shock template, (2) instructions on how to calculate foreign exchange crosses for non-U.S. dollar-denominated pairs, (3) descriptions of risk factors to use for conversions of absolute shocks to relative shocks on the as-of date, and (4) descriptions of any interpolation and extrapolation methods involved in the relative shock conversions.

For future scenarios, the Board expects to use the simplified shock template in substantially the same form as was disclosed in the 2026 scenarios without continuing to publish the full shock template at the same time; the full shock template, with the values of the over 20,000 shocks, can be determined, as desired, by using the mapping instructions published alongside the proposed and final scenarios.

## VII. Economic Analysis

As discussed above in Sections I.E and I.G of this **SUPPLEMENTARY INFORMATION**, this final rule's goal is generally to increase transparency and public accountability while improving the risk capture of the supervisory stress test and ensuring the test's ability to capture changes in the risks in the financial industry over time. These changes, which also involve adjustments to the stress test calendar, are expected to provide meaningful benefits to the public, as discussed below. This section provides economic analysis of the adopted enhanced disclosure of the supervisory stress test framework.

The Board's supervisory stress test has historically operated with some disclosure regarding the stress test models and scenarios used, with an increase in information shared with the public beginning in 2019, as discussed in Section I.B of this **SUPPLEMENTARY INFORMATION**. The enhanced disclosure, including the publication of comprehensive model documentation and the new disclosure process for the models and scenarios, provides several benefits. These benefits include improved credibility of the stress test, improved feedback regarding the modeling process, better informed investors, and improved market discipline. However, the enhanced disclosure comes with costs as well, including reduced model dynamism and increased systemic reliance on a single model, or ''model monoculture.'' These benefits and costs were described in the October 2025 proposal.[152]

The Board received several comments on the benefits and costs of the proposal. As described above in Section I.F of this **SUPPLEMENTARY INFORMATION**, most commenters were supportive of the proposal's objective to provide the public with more information about the stress test models and scenarios and to improve the transparency, public accountability, and predictability of the supervisory scenarios. However, some commenters objected to the increased transparency of the stress test, stating that it would undermine the effectiveness and dynamism of the stress test.

### *A. Baseline*

The economic analysis uses the stress testing framework in effect prior to the proposal, including the current disclosure regime, as the baseline. Throughout the analysis, the Board assesses the economic impact of the final rule by comparing outcomes under the final rule to the outcomes estimated under the baseline.

### *B. Final Policy Changes*

With this final rule, the Board is publishing final, comprehensive descriptions of the modeling framework used to conduct the supervisory stress test after reviewing public input. These descriptions include the equations, variables, and parameters of each model used to estimate the projections that, when aggregated, produce the results of the supervisory stress test. This final rule also codifies an enhanced disclosure process under which the

[151] 90 FR 51856, 51930 (Nov. 18, 2025).

[152] *See* 90 FR 51762 (Nov. 18, 2025).

Board will annually publish the stress test models, invite public input on any material model changes prior to implementing them in the stress test, and seek public input on the annual stress test scenarios prior to their finalization. This represents a significant increase in disclosure relative to the baseline, as prior stress test disclosures were relatively more limited. For example, prior disclosures were limited to the structure of the stress testing model framework and certain key variables.

In addition, this final rule will adjust several dates in the stress test calendar, including the GMS as-of date window, as described in Sections III.E of this **SUPPLEMENTARY INFORMATION**. Other changes to the calendar, such as the shift in the capital plan submission date, adjust the stress testing schedule to accommodate the public input process and mitigate risks that the enhanced disclosure provided under the final rule would undermine the goals of supervisory stress testing.

Section VI.A of this **SUPPLEMENTARY INFORMATION** summarizes the changes made to the stress testing models from the 2025 to the 2027 supervisory stress test, which will inform the Board's determination of firms' stress capital buffer requirements.[153] Section VI.B provides an analysis of the potential effects of these model changes.

Finally, Sections IV and VII of this **SUPPLEMENTARY INFORMATION** describe changes to the Board's Stress Testing Policy Statement and Scenario Design Policy Statement, respectively. The changes to the Board's Stress Testing Policy Statement and Scenario Design Policy Statement express the Board's expectations for how the Board will conduct the annual supervisory stress test and design annual scenarios for the supervisory stress test. These changes will provide additional transparency, public accountability, and predictability without creating binding legal obligations or economic impact. As described in Section I.H of this **SUPPLEMENTARY INFORMATION**, comments and interactions with other proposals that are not described in this notice will be addressed in any final actions associated with those proposals.

[153] For a more detailed discussion of the proposed model changes, *see* Board, Review of Comments and Summary of Changes to the Proposed 2026 Stress Test Scenarios, at 22–23, available at *https://www.federalreserve.gov/supervisionreg/dfa-stress-tests-2026.htm.*

*C. Analysis of Benefits and Costs of Enhanced Model Disclosure*

1. Benefits

Drawing from available literature, the proposal described several expected benefits: improved credibility of the stress test; improved model feedback from the public; improved ability for firms to evaluate business plans; and better informed investors and improved market discipline.

The Board received several comments on the benefits of the proposal. These commenters stated that improved transparency would support the predictability of the stress test for firms subject to the test; this predictability would improve capital allocation and planning. Commenters also suggested that the proposal would reduce the volatility of stress capital buffer requirements, which would support effective capital planning and the deployment of capital and liquidity into the broader economy and, in turn, improve the availability and cost of credit for businesses and households. One commenter further stated that reducing volatility would help limit risk migration out of the banking system.

One commenter supported the proposal because it would increase the predictability of the stress test, stating that predictable stress tests would improve market discipline by helping investors, counterparties, and analysts better understand stress test results. The commenter also noted that predictability would also improve the public's confidence in the stress test.

Commenters also suggested that the public input process would improve model quality by enabling feedback from the public to identify weaknesses or challenge assumptions in the models. One commenter stated that improving the risk capture of the stress test models through the public input process would lower risk in the financial system.

Other commenters stated that the proposal risked the credibility of the stress test, as described below in the Board's assessment of the costs of the final rule, because a less severe or dynamic annual stress test could lead to stress test results that offer false comfort that the banking system is safe. The Board considered these comments on the benefits of the proposal and assessed them below relative to the components of this final notice.

a. Improved Credibility of the Stress Test

As described in the proposal and above in Section II of this **SUPPLEMENTARY INFORMATION**, the supervisory stress test provides material safety and soundness benefits, and these benefits are expected to be more sustainable when the Board's stress testing program operates with high levels of accountability and credibility. The disclosure of comprehensive model documentation to the public, and the commitment to continue this disclosure, will help ensure that all institutions and stakeholders have equal access to the Board's supervisory stress test methodology. This access will strengthen accountability in supervisory decisions and promote fairness. Publicly disclosing the stress test models and scenarios also enhances trust in the stress testing process,[154] as stakeholders may be able to better assess the soundness of models and their alignment with best practices.[155] As a result, firms may better understand where there are discrepancies between their own internal stress testing models and the supervisory stress testing models, and consequently they may be better positioned to communicate specific concerns with supervisors. With greater transparency and public accountability, stakeholders may be more confident that the supervisory stress test results do not reflect the desires of firms or supervisors to obtain a specific outcome.[156] While the Board has previously released enhanced disclosures of the stress test models, such as portfolio-level average loss rates, risk drivers, and connections between hypothetical scenario values and losses, the comprehensive model documentation disclosed in connection with this proposal better illustrates how supervisors incorporate model refinements and emerging risks, which could further improve credibility of the supervisory stress test over time.

In addition, as described in Section II.E of this **SUPPLEMENTARY INFORMATION**, this final rule extends the date selection range of the GMS component as-of date from five months (between October 1 of

[154] For an overview of studies on the impact of government transparency, which generally suggest a mixed-to-positive impact on trust, *see* M. Cucciniello, G.A. Porumbescu, and S. Grimmelikhuijsen, *25 Years of Transparency Research: Evidence and Future Directions,* Public Administration Review 77 (2017), 32–44.

[155] *See* Goldstein and Leitner (2022), *supra* note 35.

[156] *See* I. Goldstein and H. Sapra, *Should Banks' Stress Test Results Be Disclosed? An Analysis of the Costs and Benefits,* Foundations and Trends in Finance 8 (2013), 1–54 (2013); F. Niepmann and V. Stebunovs, *Modeling our stress away,* Journal of Banking & Finance 158 (2024), 107042. When regulators are more constrained in their ability to make the models more or less severe, this could alleviate inefficient strategic interactions between supervisors and banks, referred to as ''policy traps.'' J. Shapiro and J. Zeng, *Stress Testing and Bank Lending,* Review of Financial Studies 37 (2024), 1265–1314.

the previous year and March 1 of a given year) to nine months (between April 1 and December 31 of the calendar year prior to the year the stress test is administered). Thus, the GMS component could be applied to market risk positions held by the firms on any selected date within a wider, nine-month period, instead of the current five-month period. This change could reduce the risk of gaming activities, such as ''window dressing,'' whereby firms subject to the GMS component could temporarily adjust their balance sheets to reduce losses without reducing actual risk. Additionally, revisions to the Scenario Design Policy Statement specify that the Board expects to subject firms to two GMS scenarios on a single as-of date for a single stress test. The Board expects to use the maximum loss of the combined trading and counterparty results across both GMS scenarios to determine a firm's stress test results. A second GMS scenario is expected to improve the risk capture and identification of the stress test by allowing the Board to capture a wider range of firms' vulnerabilities with opposite directions of shocks, and it is expected to reduce year-over-year volatility in trading and counterparty losses.

While the Board acknowledges comments that stated that the proposal, and therefore this final rule, would reduce the credibility of the stress test, the Board expects that the improved risk capture and identification, as well as reduced volatility in stress test results, will instead enhance the credibility of the stress test results.

b. Improved Model Feedback

The Board's supervisory stress test models consist of equations, parameters, and assumptions that translate hypothetical macroeconomic shocks under designed stress scenarios into loss estimates across asset classes, income streams, and capital ratios. Despite their complexity, the supervisory stress test models and stress scenarios, like all theoretical models, remain simplified representations of reality. As such, they benefit from feedback and refinement. Disclosure of models and scenarios is expected to enable academics, industry professionals, and the broader public to provide more effective feedback.[157] For example, the Board received significant feedback on the models disclosed with this proposal, and adopted several changes to the models incorporating that feedback, as described above in Section V of this **SUPPLEMENTARY INFORMATION**. This feedback also helped inform additional changes to the models that the Board is separately proposing for the 2027 stress test.

As demonstrated by this initial public input process, such feedback can be reasonably expected to help to refine and improve the models and scenarios as, over time, they could be updated to mitigate concerns and adopt improved modeling approaches where appropriate. In this sense, the final rule's enhanced disclosure enables stakeholders' feedback, which could ultimately lead to better model performance and further enhance the credibility of the supervisory stress testing process.[158]

c. Improved Ability To Evaluate Business Plans

Comprehensive disclosure of the stress test models is expected to help firms better understand how supervisors assess losses under severely stressed hypothetical scenarios. This may allow firms to more accurately predict their required capital ratios, reducing capital planning uncertainty[159] and possibly increasing firms' willingness to lend.[160] As described in the proposal and noted by certain commenters, reduced capital requirement uncertainty could help firms plan more effectively for future business decisions, as firms would better understand the impact of these decisions as it relates to stress test results and related capital requirements.

d. Better Informed Investors and Improved Market Discipline

Research suggests that investors use stress test results to assess firms' resilience. Indeed, disclosures of results from the stress test tend to affect firms' stock prices and CDS spreads.[161] Through such financial market signals, investors may help discipline firms' risk taking[162] behavior and incentivize firms to strengthen capital positions.[163] As described in the proposal and noted by certain commenters, the comprehensive disclosure of the supervisory stress testing models and scenarios may allow investors to make better informed decisions, potentially improving the effectiveness of market discipline.

2. Costs

The Board also received several comments on the costs of the proposal. Some commenters argued that the proposal would increase the predictability of the stress test, thereby reducing its dynamism. This would limit the stress test's ability to capture salient and unseen or under-appreciated risks by making the annual test more repetitive. These commenters generally expressed concern that model and scenario disclosure would enable or incentivize firms to limit their stress test losses under the test by adjusting their balance sheets. These commenters argued that firms would be able to optimize their balance sheets for the stress test, which would enable firms to lower their stress capital buffer requirements without necessarily reducing the riskiness of their portfolios.

One commenter stated that the proposal, together with other proposed and implemented changes to the supervisory stress test, would undermine the value of the stress test

[157] *See* Goldstein and Leitner (2022), *supra* note 35; B. Hirtle, ''Structural and Cyclical Macroprudential Objectives in Supervisory Stress Testing,'' Remarks at The Effects of Post-Crisis Banking Reforms Conference (Jun. 22, 2018), *https://www.newyorkfed.org/newsevents/speeches/2018/hir180622.*

[158] As an example of feedback on the Pre-provision Net Revenue Model under the current disclosure regime, *see* M. Xiao, ''What Goldman's appeal victory means for Fed stress tests,'' Risk.net (Oct. 30, 2024), *https://www.risk.net/risk-management/7960102/what-goldmans-appeal-victory-means-for-fed-stress-tests.*

[159] *See* G. Gallardo, T. Scheurmann, and M. Duane, *Stress testing convergence,* Journal of Risk Management in Financial Institutions 9 (2016), 32–45; Hirtle (2018), *supra* note 156.

[160] For evidence on the impact of regulatory uncertainty on lending, *see* S. Gissler, J. Oldfather, and D. Ruffino, *Lending on hold: regulatory uncertainty and bank lending standards,* Journal of Monetary Economics 81(2016), 89–101 (2016).

[161] *See* C. Sahin, J. de Haan, and E. Neretina, *Banking stress test effects on returns and risks,* Journal of Banking & Finance 117 (2020), 105843; L. Guerrieri and M. Modugno, *The information content of stress test announcements,* Journal of Banking & Finance 160 (2024), 107087; M. Flannery, B. Hirtle, and A. Kovner, *Evaluating the information in the federal reserve stress tests,* Journal of Financial Intermediation 29 (2017), 1–18; G. Petrella and A. Resti, *Supervisors as information producers: Do stress tests reduce bank opaqueness?* Journal of Banking & Finance 37 (2013), 5406–20; D. P. Morgan, S. Peristiani, and V. Savino, *The Information Value of the Stress Test,* Journal of Money, Credit & Banking 46 (2014), 1479–1500 (2014); C. Alves, V. Mendes, and P. Silva, *Do stress tests matter? A study on the impact of the disclosure of stress test results on European financial stocks and CDS markets,* Applied Economics 47 (2015), 1213–29; O. Georgescu, M. Gross, D. Kapp, and C. Kok, *Do stress tests matter?* European Central Bank Working Paper 2054 (2017), *https://www.ecb.europa.eu/pub/pdf/scpwps/ecb.wp2054.sv.pdf;* L. Ahnert, P. Vogt, V. Vonhoff, and F. Weigert, *Regulatory stress testing and bank performance,* European Financial Management 26 (2020), 1449–88; L. Gu, K. Wang, and J. Wu, ''The asset market effects of bank stress-test disclosures,'' *Stress Testing (2nd Edition): Approaches, Methods and Applications* (2019).

[162] *Id.*

[163] For evidence on the impact of stress test disclosure on bank risk-taking, *see supra* note 160. However, the impact on risk-taking is attributed more to supervisory scrutiny than disclosure in other research. *See* C. Kok, C. Müller, S. Ongena, and C. Pancaro, *The disciplining effect of supervisory scrutiny in the EU-wide stress test,* Journal of Financial Intermediation 53 (2023), 101015.

and make the largest banks, the financial system, and the economy more vulnerable. Commenters also stated that the proposal would have the effect of reducing capital requirements for firms subject to the supervisory stress test, which would reduce the resilience of such firms during periods of economic stress.

Commenters also stated that the public input process could slow the development of models over time, causing them to be outdated by the time any model changes are implemented. Additionally, some commenters expressed concern that model disclosure would lead to ''model monoculture,'' whereby firms adjust their internal models to adopt the Board's stress test models, and ultimately omit specific risks in these models that would be relevant to an applicable firm or set of firms. Other commenters disagreed, stating that concerns about ''model monoculture'' and balance sheet optimization are misplaced, and that supervisory attention and firm incentives eliminate any realistic possibility of such balance sheet optimization based on the disclosed models.

The Board considered these comments on the costs of the proposal and assessed them relative to the components of this final notice.

a. Reduced Dynamism

As discussed above, models are necessarily a simplified version of reality. As forecasting methodologies evolve or conditions in the economy and the financial system change, the existing models may no longer adequately capture risks. For this reason, an effective stress test must be able to adapt. Under this final rule, future material changes to the stress testing models would be published for public input, and the Board would be required to respond to such comments before implementing the material model changes in the supervisory stress test. This process will increase the resources needed to propose, develop, and implement material model changes, particularly to the extent that any changes are complex, present many alternatives, or affect firms' ability to distribute capital. As a result, according to certain academic literature and as described in the October 2025 proposal, the use of new models or model changes that explore less established risks may pose a high resource burden under the enhanced disclosure regime. This burden could limit the supervisory stress test to simpler, less controversial, and more familiar modeling approaches.[164] Tests of new risk dimensions or emerging threats may take significantly more time to implement. With less dynamism, the supervisory stress test may fail to capture new risk and could produce an increasingly stale view of how firms would likely perform under stressed conditions, according to certain academic literature.[165]

In consideration of the comments and the available literature described in the proposal and in this section, the Board recognizes several features that mitigate potential reduced dynamism in the final rule. First, firms subject to the stress test will not have the precise specifications of the proposed or final scenarios, or the final models to be used in the stress test, until after the stress test jump-off date or GMS as-of date for a given year. Additionally, the Board is implementing changes to the GMS component that expand the as-of date window and set the expectation that there will be two GMS scenarios for a given stress test. These process and substantive changes help mitigate the risk that firms could optimize their balance sheets for the stress test, which could in turn enable firms to lower their stress capital buffer requirements without necessarily reducing the riskiness of their portfolios. Additionally, the Board expects that the enhanced disclosure process for the scenarios and models will help the Board, firms, and the public better identify any impacts to the stress test results that could weaken the credibility of the supervisory stress test over time or in a given year.

The Board also considered comments related to slower model development. As explained above, the Board will continue to develop and enhance its models year-to-year, though certain model changes that meet the Board's definition of material model changes will be subject to public input prior to implementation in the annual stress test. This approach is similar to the Board's previous policy, which involved phasing in highly material changes to the models over a two-year period.[166] The enhanced disclosure process will also mitigate concerns about slower model development, as the public will be better able to review the Board's models and suggest enhancements that reflect the most up-to-date data and modeling techniques.

b. Reduced Risk Sensitivity and Overreliance on a Single Model Framework

Supervisory stress test results are important inputs to the capital requirements associated with firms' banking activities. With comprehensive model disclosure likely reducing the uncertainty of supervisory stress test results, firms' estimates of future regulatory capital requirements could rely more on the Board's stress test models and less on their own internal stress testing models or internal risk management tools, both of which may be less useful than before the introduction of enhanced disclosure for managing regulatory capital.[167] To the extent that firms' own internal stress testing models or risk management tools provide additional information about risk, the *expected* capital requirements could become less risk-sensitive as a result, which could reduce firms' incentives to independently measure and manage their vulnerabilities.

Disclosure could also enable firms to more easily optimize their exposures to minimize capital requirements in the supervisory stress test, which could allow vulnerabilities to build up where risks are not well or fully represented by standardized supervisory models.

Reliance on the supervisory stress testing models could extend further if enhanced disclosure results in firms increasing the similarity of their own stress models to the stress test models.[168] Increased reliance of all stress-tested firms on a single model, known as ''model monoculture,'' combined with a delay in material model changes, could cause risks to build in areas that are treated benignly in the stress test. Firms may face a greater incentive to shift business activities towards these areas to reduce their capital requirements.[169] The

[164] *See* M. Flannery, *Transparency and model evolution in stress testing,* SSRN Working Paper (2019), *http://dx.doi.org/10.2139/ssrn.3431679.* Even the current approach to stress testing may not allow for the optimal level of dynamism or macroprudential considerations. *See* D. Tarullo, *Reconsidering the regulatory uses of stress testing,* Hutchins Center Working Paper 92 (2024), *https://www.brookings.edu/wp-content/uploads/2024/05/WP92_Tarullo-stress-testing.pdf;* W. Bassett and D. Rappoport, ''Enhancing stress tests by adding macroprudential elements,'' *Handbook of Financial Stress Testing,* 455–83 (2022).

[165] For an example of the reduced utility of a stale stress model, *see* W.S. Frame, K. Gerardi, and P.S. Willen, *The failure of supervisory stress testing: Fannie Mae, Freddie Mac, and OFHEO,* Federal Reserve Bank of Boston Working Paper 15–4 (2015), *https://www.bostonfed.org/-/media/Documents/Workingpapers/PDF/wp1504.pdf.*

[166] *See* 12 CFR 252, Appendix B, section 2.3.

[167] *See, e.g.,* T. Schuermann, ''The Fed's Stress Tests Add Risk to the Financial System,'' Wall Street Journal (Mar. 19, 2013).

[168] Of course, as noted above, there is benefit to these changes to the extent that they are adopted to improve the ability of firms' models to capture risk.

[169] Relatedly, banks may have a stronger incentive to temporarily curtail those risk exposures treated

resulting convergence of risk taking could increase the vulnerability of the banking system, particularly to those risks that are under-reflected by the supervisory stress testing models.[170]

In addition to the comments considered above, the Board considered comments stating that the proposal would encourage overreliance on a single model framework. The Board expects that significant differences in the purposes of the Board's supervisory stress test models compared to firms' own risk management models are likely to discourage firms from supplanting their models with the Board's stress test models. For example, the Board uses models that assess risk on an industry-wide basis and at the level of detail reported in the FR Y–14 reporting forms. These models are applied to all firms subject to the stress test. By contrast, firms have more granular data related to their own positions and risks, which better enables firms to assess their own risks internally according to their own models. In the event that a firm adopts the Board's models in place of the firm's own models, supervisors retain appropriate tools to assess the firm's models and model development practices.

*D. Conclusion*

As discussed above, comprehensive model documentation published in connection with this final rule, as well as the finalized enhanced disclosure process, provide several benefits that outweigh the costs of the final notice.

Taken together, the Board assessed that the benefits of the changes described in this final notice justify the costs.

adversely by the stress testing models, *i.e.,* to ''window dress.'' *See* P. Alexander, ''How banks game stress tests: the 'shocking' truth,'' Risk.net (Sep. 30, 2019), *https://www.risk.net/regulation/6989811/how-banks-game-stress-tests-the-shocking-truth;* M.M. Cornett, K. Minnick, P. Schorno, and H. Tehranian, *An Examination of Bank Behavior around Federal Reserve Stress Tests,* Journal of Financial Intermediation 41 (2020), 100789.

[170] *See* Y. Leitner and B. Williams, *Model Secrecy and Stress Tests,* Journal of Finance 78 (2023), 1055–95; K. Rhee and K. Dogra, *Stress Tests and Model Monoculture,* Journal of Financial Economics 152 (2024), 103760; B. Hirtle (2018), *supra* note 156; M.J. Flannery, *Transparency and Model Evolution in Stress Testing,* SSRN, Working Paper (2019), *http://dx.doi.org/10.2139/ssrn.3431679;* B. Bernanke, ''Stress testing banks: what have we learned?'' Remarks at Maintaining Financial Stability: Holding a Tiger by the Tail Conference (Apr. 8, 2013), *https://www.bis.org/review/r130409c.pdf;* Goldstein and Leitner (2022), *supra* note 35; F. Bräuning and J. Fillat, *Stress Testing Effects on Portfolio Similarities Among Large US Banks,* Federal Reserve Bank of Boston Policy Perspectives Paper 19–1 (2019), *https://www.bostonfed.org/-/media/Documents/Workingpapers/PDF/2019/cpp1901.pdf.*

## VIII. Administrative Law Matters

*A. Paperwork Reduction Act Analysis*

In accordance with the requirements of the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), the Board 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 Board reviewed the information collections related to the proposed rule under the authority delegated to the Board by OMB.

The proposed rule would not have created any information collections subject to the PRA; however, the proposal would have revised the FR Y–14A/Q/M to reduce regulatory reporting burden by retiring items and removing supporting documentation requirements that are no longer needed to conduct the supervisory stress test. Additionally, the proposal would have collected additional information to support the proposed supervisory stress test models.

Final Approval Under OMB Delegated Authority To Extend for Three Years, With Revision, the Following Information Collection

*Collection Title:* Capital Assessments and Stress Testing Reports.

*Collection Identifier:* FR Y–14A/Q/M.

*OMB Control Number:* 7100–0341.

*General Description of Collection:* The FR Y–14 reports collect stress test and capital plan data from the largest holding companies, which are those with $100 billion or more in total consolidated assets. The data collected through the FR Y–14 reports provide the Board with the information needed to help ensure that large holding companies have strong, firm-wide risk measurement and management processes supporting their internal assessments of capital adequacy and that their capital resources are sufficient given their business focus, activities, and resulting risk exposures. Information gathered in this data collection is also used in the supervision and regulation of these financial institutions.

*Current Actions:* The final rule adopts the proposed revisions to the FR Y–14A/Q/M, with modifications as discussed below, to remove supporting documentation requirements, schedules, and data items that are no longer needed to conduct the supervisory stress test. The final rule also makes other revisions necessary to facilitate the stress test modeling decisions. Except as discussed below, all revisions to the FR Y–14Q and FR Y–14M are effective for the June 30, 2027, report date, and revisions to the FR Y–14A for the December 31, 2027, report date.

Supporting Documentation

As discussed in Section IV.A of this **SUPPLEMENTARY INFORMATION**, the Board is removing the FR Y–14A supporting documentation requirement as it is no longer necessary to assess firms' company-run stress test results and capital plans. This revision is effective for the December 31, 2026, report date.

Additionally, as previously described in Section IV.A of this **SUPPLEMENTARY INFORMATION**, the Board is not adopting a FR Y–14Q, Schedule F (Trading) supporting documentation requirement. However, the Board is adopting a supporting documentation requirement for FR Y–14Q, Schedule L (Counterparty) with a limited set of requests related to firms' submissions of counterparty data. This revisions is effective for the December 31, 2026, report date.

Revisions To Support Modeling Decisions

As outlined in Section IV of this , the Board is adopting several FR Y–14 revisions to support the final stress test models. For example, private equity exposures are modeled under the macroeconomic scenario, so the Board is revising FR Y–14Q, Schedule F to capture private equity data in a manner that better aligns with this treatment. This revision is effective for the June 30, 2027, report date.

Additionally, to more comprehensively incorporate hedges into the stress test models, the final notice revises FR Y–14Q, Schedule B (Securities) and FR Y–14Q, Schedule F to capture data on additional types of hedges and hedging relationships, as well as from a broader set of firms. Similarly, the Board is adopting revisions to FR Y–14M, Schedule D (Credit Card) and FR Y–14Q, Schedule G (PPNR) to capture data on credit card revenue and loss sharing agreements (RLSAs). The hedge revisions are effective for the June 30, 2027, report date and the RLSA revisions are effective for the December 31, 2027, report date.

Other Changes From the Initial Notice

GMS

To align with the changes to the stress test calendar discussed in Section II.E of this **SUPPLEMENTARY INFORMATION**, the jump-off date for the supervisory stress test will remain December 31 and the as-of date range for the GMS will be between April 1 and December 31 of the year preceding the stress test. Therefore,

the Board is adopting revisions to conform the FR Y–14A and FR Y–14Q to this GMS as-of date window while retaining a December 31 jump-off date for the FR Y–14A. Additionally, as discussed in Section II.E of this **SUPPLEMENTARY INFORMATION**, the Board is adopting a two GMS scenario per stress test approach. To align the FR Y–14 with this change, the Board is revising FR Y–14Q, Schedule L (Counterparty) such that applicable firms must report this schedule under both GMS scenarios. On the FR Y–14A, the Board is revising the instructions to instruct firms to report internal projections under the GMS scenario that results in the larger projected CET1 capital decline. However, to enable the Board's calculation of GMS losses under both scenarios, the Board is revising FR Y–14A, Schedule A.1.d (Capital) to collect adjusted starting values under both GMS scenarios. The revisions to collect the data necessary to conduct both GMS scenarios are effective for the December 31, 2026, report date.

Address Matching and Pre-Payment

The Board is also retiring several items from FR Y–14M, Schedule C (Address Matching) that are no longer necessary as discussed in Section IV.B of this **SUPPLEMENTARY INFORMATION**. Similarly, the Board proposed to retire several items from FR Y–14M, Schedule B (Home Equity). One commenter noted that since item 51 (''Pre-payment Penalty Term'') was proposed to be retired, item 50 (''Pre-payment Penalty Flag'') should also be retired. The Board agrees item 50 is no longer necessary. Therefore, the Board is adopting the removal of the items from Schedule B, including item 50. These revisions are effective for the December 31, 2026, report date.

Exchange Traded Funds

As discussed in Section IV.E of this **SUPPLEMENTARY INFORMATION**, the Board is revising the instructions for FR Y–14Q, Schedule F to clarify how firms should decompose exposures in exchange traded funds. This revision is effective for the June 30, 2027, report date.

Sovereign Counterparties

As discussed in Section V, the Board is adopting final models for the 2027 stress test. In support of these models, the Board is also revising certain aspects of the FR Y–14A/Q/M reports. As discussed in the final Market Risk Model Documentation, the Board excludes sovereign counterparties from the largest counterparty default (''LCPD'') component that are rated AA- or higher based on external ratings. To support this exclusion methodology, the Board is revising Schedule L to capture country codes for sovereign counterparties. This revision is effective for the June 30, 2027, report date.

Client-Cleared Derivatives

The Schedule L instructions for certain items that collect netting set characteristics allow for them to be left blank when the agreements in those netting sets are not legally enforceable. Specifically, the ''agreement role'' item on Schedule L.5.1 provides for this option. However, this item is used to identify client-cleared derivatives (''CCDs''), which are excluded from the LCPD model. To allow for better identification of CCDs, the Board is revising the instructions for this item such that it must be populated for CCDs. This revision is effective for the June 30, 2027, report date.

Credit Spreads

Additionally, the instructions for FR Y–14Q, Schedule F.18, Schedule F.19, and Schedule F.20 encourage firms to report relative changes in credit spreads. This instruction is no longer applicable as the GMS component shocks are now prescribed in absolute terms. Therefore, to align reporting practices with this approach, the Board is removing the language that instructs firms to report profit/(loss) for relative changes in credit spreads on Schedule F.18, Schedule F.19, and Schedule F.20. This revision is effective for the June 30, 2027, report date.

Other Revisions

The Board requested comment on FR Y–14M, Schedule D, item 86 (Cycles Past Due at Cycle Date) as it is currently inconsistently reported. To address ambiguity in the instructions, the Board is revising item 86, as well as items 53 (Days Past Due) and 87 (Cycles Past Due at Month-End), to clarify that firms should consider a missed payment to be a cycle past due. This revision is effective for the June 30, 2027, report date.

Other Comments

The Board also received comments on other areas of the FR Y–14 where it did not propose changes.

Further Item Removals

Commenters asked that the Board to conduct a line-by-line inventory of all FR Y–14 items and explain which are used in the supervisory models or are necessary for supervision and regulation, or to otherwise justify collecting that data. If an item does not fall into one of these buckets, the commenters suggested that it be retired. The Board has already undertaken significant steps to reduce reporting burden by proposing to retire the supporting documentation, removing line items no longer necessary, and proposing to reduce the historical data reporting requirements. Additionally, while many items may not currently be used as inputs to the stress test models, they are important for model development or other supervisory activities. Therefore, the Board is not proposing additional changes to the FR Y–14 at this time. As has been the Board's practice, it will continue to evaluate the usefulness of FR Y–14 line items.

FR Y–14M Reporting Frequency

The FR Y–14M collects data on firms' first lien, home equity, and credit card portfolios on a monthly cadence. Commenters recommended that the FR Y–14M instead be reported quarterly to reduce reporting burden. Data on firms' large retail portfolios is critical for monitoring purposes, especially during a period of economic stress, and used for monitoring purposes other than the supervisory stress test. To ensure that the Board continue to receive this data in a timely fashion, the Board is declining to adjust the cadence of FR Y–14M reporting.

Materiality Frameworks

One commenter recommended that the Board consider developing materiality frameworks for firms to consider for reporting the FR Y–14Q and FR Y–14M. The commenter suggested that collecting data on only material items would reduce burden on firms. Alternatively, the commenter suggested that the Board identify critical data elements and make the non-critical elements optional or best efforts. However, implementing a materiality threshold could result in crucial data not being reported and reflected in the stress test. Additionally, the FR Y–14 instructions allow for items to be reported as N/A if the data is not relevant or available. Therefore, the Board does not intend to implement materiality thresholds at this time.

Business Plan Changes Schedule

One commenter stated that the Board should remove FR Y–14A, Schedule F (Business Plan Changes) as they appear to not have any supervisory use. However, FR Y–14A, Schedule F contains information that is useful for analysis associated with capital plan resubmissions due to observed or expected changes to firms' risk profile,

financial condition, or corporate structure since the last capital plan submission. Therefore, the Board is retaining FR Y–14A, Schedule F.

Alignment With U.S. GAAP

One commenter recommended that the Board align the FR Y–14 with U.S. GAAP to mitigate operational burdens and reduce the risk of potential reporting errors. The commenter noted that the FR Y–14Q instructions include different criteria to classify a loan as modified, as compared to U.S. GAAP. The Board recently published in the **Federal Register** revisions to the FR Y–14 that introduces fields to capture loan modifications to borrowers experiencing financial difficulty, consistent with ASU 2022–02.[171] The Board aims to align the FR Y–14 with U.S. GAAP where appropriate; however divergences may exist in situations where information is needed to support the supervisory stress test or broader supervision of large firms.

*Respondents:* Holding companies with $100 billion or more in total consolidated assets, as based on (1) the average of the firm's total consolidated assets in the four most recent quarters as reported quarterly on the firm's Consolidated Financial Statements for Holding Companies (FR Y–9C; OMB No. 7100–0128) or (2) the average of the firm's total consolidated assets in the most recent consecutive quarters as reported quarterly on the firm's FR Y–9Cs, if the firm has not filed an FR Y–9C for each of the most recent four quarters.

*Total estimated number of respondents:* 35.

*Estimated change in burden:*

- *FR Y–14A: −3,605 hours.*
- *FR Y–14Q: −420 hours.*
- *FR Y–14M: −1,584 hours.*
- *Total estimated change in burden:* −5,609.

*Total estimated annual burden hours:* 754,819.

*B. Regulatory Flexibility Act Analysis*

The Regulatory Flexibility Act (''RFA'') generally requires that, in connection with a final rulemaking, an agency prepare and make available a final regulatory flexibility analysis describing the impact of the final rule on small entities.[172] However, a final regulatory flexibility analysis is not required if the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Under regulations issued by the U.S. Small Business Administration (''SBA''), a small entity includes a depository institution, bank holding company, or savings and loan holding company with total assets of $850 million or less.[173] Consistent with the SBA's General Principles of Affiliation, the Board includes the assets of all domestic and foreign affiliates toward the applicable size threshold when determining whether to classify a particular entity as a small entity.[174] For the reasons stated below and under section 605(b), the Board certifies that the rule will not have a significant economic impact on a substantial number of small entities.[175]

In connection with the proposed rule, the Board stated that it believed that the proposal would not have a significant economic impact on a substantial number of small entities. Nevertheless, the Board published and invited comments on an initial regulatory flexibility analysis of the proposal. No comments were received on the initial regulatory flexibility analysis.

As discussed in this **SUPPLEMENTAL INFORMATION**, the Board's final rule establishes a process to enhance the transparency and public accountability of the Board's stress testing framework. The rule amends the Policy Statement on the Scenario Design Framework for Stress Testing, including to implement guides for additional scenario variables, and the Stress Testing Policy Statement. The final rule codifies an enhanced disclosure process under which the Board would annually publish comprehensive documentation on the stress test models, invite public comment on any material changes that the Board seeks to make to those models, and annually publish the stress test scenarios for comment. Lastly, the final rule makes changes to the FR Y–14A/Q/M to remove items that are no longer needed to conduct the supervisory stress test and to collect additional data to support the stress test models and improve risk capture.

The Board has considered whether to conduct a final regulatory flexibility analysis in connection with the final rule. However, the final rule applies to bank holding companies, U.S. intermediate holding companies of foreign banking organizations, and savings and loan holding companies, each with at least $100 billion in total consolidated assets, as well as state member banks with more than $250 billion in total consolidated assets, certain nonbank financial companies supervised by the Board, and any other bank holding company or covered savings and loan holding company domiciled in the United States that is made subject to the capital plan rule by order of the Board.[176] Companies that would be impacted by the final rule therefore substantially exceed the $850 million asset threshold at which a banking entity is considered a ''small entity'' under SBA regulations. Further, although the Board does not project there to be a direct impact to reporting, recordkeeping, or other compliance requirements as a result of the rule, the Board also is proposing to revise the FR Y–14A/Q/M (Capital Assessments and Stress Testing) reports to remove items that are no longer needed to conduct the supervisory stress test and to collect data that would improve the calculation of the stress capital buffer requirement. These reports are submitted by firms subject to the Board's capital plan rule requirements; thus, the changes would not impact small entities. Because the final rule does not apply to any company with total assets of $850 million or less, it is not expected to apply to any small entity for purposes of the RFA. In light of the foregoing, the Board certifies that the final rule does not have a significant economic impact on a substantial number of small entities.

*C. Plain Language*

Section 722(a) of the Gram-Leach-Bliley Act (12 U.S.C. 4809(a)) requires the Board to use plain language in its proposed and final rulemakings. In the proposal, the Board invited but did not receive comments on its use of plain language. In the final rule, the Board uses plain language.

**List of Subjects**

*12 CFR Part 225*

Administrative practice and procedure, Banks, Banking, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Securities.

*12 CFR Part 238*

Administrative practice and procedure, Banks, Banking, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Securities.

*12 CFR Part 252*

Administrative practice and procedure, Banks, Banking, Capital planning, Federal Reserve System, Holding companies, Reporting and

[171] See 91 FR 29485.

[172] 5 U.S.C. 601 *et seq.*

[173] 13 CFR 121.201 (sectors 522110–522180).

[174] 13 CFR 121.103.

[175] 5 U.S.C. 605(b).

[176] There currently are no entities with less than $100 billion in total consolidated assets subject to the capital plan rule or to the stress test rules.

recordkeeping requirements, Securities, Stress testing.

**Authority and Issuance**

For the reasons stated in the preamble, the Board of Governors of the Federal Reserve System amends 12 CFR chapter II as follows:

## PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL (REGULATION Y)

■ 1. The authority citation for part 225 continues to read as follows:

**Authority:** 12 U.S.C. 1817(j)(13), 1818, 1828(o), 1831i, 1831p–1, 1843(c)(8), 1844(b), 1972(1), 3106, 3108, 3310, 3331–3351, 3354, 3906, 3907, and 3909; 15 U.S.C. 1681s, 1681w, 6801 and 6805.

### Subpart A—General Provisions

#### § 225.8 [Amended]

■ 2. In § 225.8:
■ a. In paragraph (e)(1)(ii), remove the text ''April 5'' and add in its place the text ''April 30''.
■ b. In paragraph (h)(4)(i), remove the text ''August 31'' and add in its place the text ''September 30''.
■ c. In paragraph (i)(2), remove the text ''15 calendar days'' and add in its place the text ''15 business days''.

## PART 238—SAVINGS AND LOAN HOLDING COMPANIES (REGULATION LL)

■ 3. The authority citation for part 238 continues to read as follows:

**Authority:** 5 U.S.C. 552, 559; 12 U.S.C. 1462, 1462a, 1463, 1464, 1467, 1467a, 1468, 5365; 1813, 1817, 1829e, 1831i, 1972, 15 U.S.C. 78 *l.*

### Subpart O—Supervisory Stress Test Requirements for Covered Savings and Loan Holding Companies

■ 4. In § 238.130, add definitions of *Material model change, Materiality determination company, Model change,* and *Model or models* in alphabetical order to read as follows:

#### § 238.130 Definitions.

* * * * *

*Material model change* means a model change that, based on the prior year's severely adverse scenario and the prior year's input data, could have, in the Board's estimation, an impact equal to:

(1) A change of 20 basis points or more in any materiality determination company's projected post-stress common equity tier 1 capital ratio, as defined in 12 CFR part 217; or

(2) A change of 10 basis points or more in the average of all materiality determination companies' absolute value of the change in projected post-stress common equity tier 1 capital ratios, as defined in 12 CFR part 217.

*Materiality determination company* means a company that:

(1) In at least one of the past two stress test cycles, has been subject to a supervisory stress test;

(2) In both the year prior to the year in which the stress test is performed and in the year the stress test is performed, is subject to the requirements of either this subpart, pursuant to § 238.131, or 12 CFR part 252, subpart E, pursuant to § 252.43; and

(3) Has average total consolidated assets of $100 billion or more, as of the date of disclosure of material model changes pursuant to § 238.132(e)(2).

*Model change* means the introduction of a new model or a conceptual change to an existing model.

*Model or models* means the analytical techniques that the Board determines are appropriate for use in the supervisory stress test.

* * * * *

■ 5. In § 238.132:
■ a. Revise paragraph (b).
■ b. In paragraph (c)(2)(ii), remove the text ''January 15'' and add in its place the text ''January 5''.
■ c. Add paragraph (e).

The revision and addition read as follows:

#### § 238.132 Analysis conducted by the Board.

* * * * *

(b) *Economic and financial scenarios related to the Board's analysis.* The Board will conduct its analysis using a minimum of two different scenarios, including a baseline scenario and a severely adverse scenario. The Board will disclose proposed scenarios by January 10 of the calendar year in which the stress test is performed, and will provide for at least a 30-day period for public input. The Board will disclose the final scenarios by no later than February 28 of that year in which the stress test is performed, except with respect to trading and counterparty or any other components of the scenarios and any additional scenarios that the Board will apply to conduct the analysis, which will be communicated by no later than March 1 of that year. The data used in any trading and counterparty component of the scenarios must be as of a date selected by the Board that is no earlier than April 1 of the calendar year one year prior to the year in which the stress test is performed and that precedes January 1 of the year in which the stress test is performed. Unless otherwise determined by the Board, the as-of date for any trading and counterparty component of the scenarios will be communicated by the Board to any applicable covered companies by no later than two weeks following the occurrence of the as-of date selected by the Board.

* * * * *

(e) *Disclosure of models and material model changes*—(1) *Annual disclosure.* The Board will publicly disclose the models that the Board used to conduct the analysis for the stress test by May 15 of the calendar year in which the stress test is performed pursuant to this section, with any additional adjustments to the models used to conduct the analysis for the stress test published no later than June 30 of the calendar year in which such stress test is performed. Additional adjustments would be limited to fixing clear errors, making technical changes, and addressing circumstances where the Board determines that a change in the models is necessary to accurately determine covered companies' projected post-stress common equity tier 1 capital ratio, as defined in 12 CFR part 217.

(2) *Material model changes from previous stress test cycle.* The Board will invite public input on any material model changes before implementing them. Beginning with the 2028 stress test cycle, the Board will invite public input, for a period of no less than 30 days, on any material model changes, by August 31 of the year prior to the year in which the stress test is performed, before implementing such material model changes in the stress test.

(3) *Response to public input on material model changes.* The Board will consider and respond to substantive public input on any material model changes before implementing such material model changes in the stress test.

### Subpart P—Company-Run Stress Test Requirements for Savings and Loan Holding Companies

■ 6. In § 238.143:
■ a. In table 1 to paragraph (a)(2)(i), remove the text ''April 5'' wherever it appears and add in its place the text ''April 30''.
■ b. In paragraph (b)(1), remove the text ''February 15'' and add in its place the text ''February 28''.
■ c. Revise paragraph (b)(2)(i).

The revision reads as follows:

#### § 238.143 Stress test.

* * * * *

(b) * * *

(2) * * *

(i) The Board may require a covered company with significant trading activity, as determined by the Board and specified in the Capital Assessments and Stress Testing report (FR Y–14), to include a trading and counterparty component in its severely adverse scenario in the stress test required by this section. The data used in this component must be as of a date selected by the Board that is no earlier than April 1 of the calendar year one year prior to the year in which the stress test is performed and that precedes January 1 of the year in which the stress test is performed pursuant to this section. Unless otherwise determined by the Board, the as-of date of such component will be communicated to the company by no later than two weeks following the occurrence of the as-of date selected by the Board and a final description of the component will be communicated to the company by no later than March 1 of the calendar year in which the stress test is performed pursuant to this section.

* * * * *

■ 7. In § 238.145, revise paragraph (a) to read as follows:

**§ 238.145 Reports of stress test results.**

(a) *Reports to the Board of stress test results.* A covered company must report the results of the stress test required under § 238.143 to the Board in the manner and form prescribed by the Board. Except as required by the relevant reporting forms and the instructions thereto, such results must be submitted by April 30 of the calendar year in which the stress test is performed pursuant to § 238.143, unless that time is extended by the Board in writing.

* * * * *

## Subpart S—Capital Planning and Stress Capital Buffer Requirement

**§ 238.170 [Amended]**

■ 8. In § 238.170:

■ a. In paragraph (e)(1)(ii), remove the text ''April 5'' and add in its place the text ''April 30''.

■ b. In paragraph (h)(4)(i), remove the text ''August 31'' and add in its place the text ''September 30''.

■ c. In paragraph (i)(2), remove the text ''15 calendar days'' and add in its place the text ''15 business days''.

# PART 252—ENHANCED PRUDENTIAL STANDARDS (REGULATION YY)

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

**Authority:** 12 U.S.C. 321–338a, 481–486, 1467a, 1818, 1828, 1831n, 1831o, 1831p–1, 1831w, 1835, 1844(b), 1844(c), 3101 *et seq.,* 3101 note, 3904, 3906–3909, 4808, 5361, 5362, 5365, 5366, 5367, 5368, 5371.

## Subpart B—Company-Run Stress Test Requirements for State Member Banks With Total Consolidated Assets Over $250 Billion

■ 10. In § 252.14:

■ a. In table 1 to paragraph (a)(2)(i), remove the text ''April 5'' wherever it appears and add in its place the text ''April 30''.

■ b. In paragraph (b)(1), remove the text ''February 15'' and add in its place the text ''February 28''.

■ c. Revise paragraph (b)(2)(i).

The revision reads as follows:

**§ 252.14 Stress test.**

* * * * *

(b) * * *

(2) * * *

(i) The Board may require a state member bank with significant trading activity, as determined by the Board and specified in the Capital Assessments and Stress Testing report (FR Y–14), to include a trading and counterparty component in its severely adverse scenario in the stress test required by this section. The Board may also require a state member bank that is subject to 12 CFR part 217, subpart F, or that is a subsidiary of a bank holding company that is subject to section § 252.54(b)(2)(i) to include a trading and counterparty component in the state member bank's severely adverse scenario in the stress test required by this section. The data used in this component must be as of a date selected by the Board that is no earlier than April 1 of the calendar year one year prior to the year in which the stress test is performed and that precedes January 1 of the year in which the stress test is performed pursuant to this section. Unless otherwise determined by the Board, the as-of date of such component will be communicated to the company by no later than two weeks following the occurrence of the as-of date selected by the Board and a final description of the component will be communicated to the company by no later than March 1 of the calendar year in which the stress test is performed pursuant to this section.

* * * * *

■ 11. In § 252.16, revise paragraph (a)(2)(i) to read as follows:

**§ 252.16 Reports of stress test results.**

(a) * * *

(2) * * *

(i) Except as required by the relevant reporting forms and the instructions thereto, a state member bank that is a covered company subsidiary must report the results of the stress test to the Board by April 30, unless that time is extended by the Board in writing; and

* * * * *

## Subpart E—Supervisory Stress Test Requirements for Certain U.S. Banking Organizations With $100 Billion or More in Total Consolidated Assets and Nonbank Financial Companies Supervised by the Board

■ 12. In § 252.42, add definitions of *Material model change, Materiality determination company, Model change,* and *Model or models* in alphabetical order to read as follows:

**§ 252.42 Definitions.**

* * * * *

*Material model change* means a model change that, based on the prior year's severely adverse scenario and the prior year's input data, could have, in the Board's estimation, an impact equal to:

(1) A change of 20 basis points or more in any materiality determination company's projected post-stress common equity tier 1 capital ratio, as defined in 12 CFR part 217; or

(2) A change of 10 basis points or more in the average of all materiality determination companies' absolute value of the change in projected post-stress common equity tier 1 capital ratios, as defined in 12 CFR part 217.

*Materiality determination company* means a company that:

(1) In at least one of the past two stress test cycles, has been subject to a supervisory stress test;

(2) In both the year prior to the year in which the stress test is performed and in the year the stress test is performed, is subject to the requirements of either this subpart, pursuant to § 252.43, or 12 CFR part 238, subpart O, pursuant to § 238.131; and

(3) Has average total consolidated assets of $100 billion or more, as of the date of disclosure of material model changes pursuant to § 252.44(e)(2).

*Model change* means the introduction of a new model or a conceptual change to an existing model.

*Model or models* means the analytical techniques that the Board determines are appropriate for use in the supervisory stress test.

* * * * *

■ 13. In § 252.44:

■ a. Revise paragraph (b).

■ b. In paragraph (d)(2)(ii), remove the text ''January 15'' and add in its place the text ''January 5''.

■ c. Add paragraph (e).

The revision and addition read as follows:

**§ 252.44 Analysis conducted by the Board.**

* * * * *

(b) *Economic and financial scenarios related to the Board's analysis.* The Board will conduct its analysis using a minimum of two different scenarios, including a baseline scenario and a severely adverse scenario. The Board will disclose proposed scenarios by January 10 of the calendar year in which the stress test is performed, and will provide for at least a 30-day period for public input. The Board will disclose the final scenarios by no later than February 28 of that year in which the stress test is performed, except with respect to trading and counterparty or any other components of the scenarios and any additional scenarios that the Board will apply to conduct the analysis, which will be communicated by no later than March 1 of that year. The data used in any trading and counterparty component of the scenarios must be as of a date selected by the Board that is no earlier than April 1 of the calendar year one year prior to the year in which the stress test is performed and that precedes January 1 of the year in which the stress test is performed. Unless otherwise determined by the Board, the as-of date for any trading and counterparty component of the scenarios will be communicated by the Board to any applicable covered companies by no later than two weeks following the occurrence of the as-of date selected by the Board.

* * * * *

(e) *Disclosure of models and material model changes*—(1) *Annual disclosure.* The Board will publicly disclose the models that the Board used to conduct the analysis for the stress test by May 15 of the calendar year in which the stress test is conducted pursuant to this section, with any additional adjustments to the models used to conduct the analysis for the stress test published no later than June 30 of the calendar year in which such stress test is performed. Additional adjustments would be limited to fixing clear errors, making technical changes, and addressing circumstances where the Board determines that a change in the models is necessary to accurately determine covered companies' projected post-stress common equity tier 1 capital ratio, as defined in 12 CFR part 217.

(2) *Material model changes from previous stress test cycle.* The Board will invite public input on any material model changes before implementing them. Beginning with the 2028 stress test cycle, the Board will invite public input, for a period of no less than 30 days, on any material model changes, by August 31 of the year prior to the year in which the stress test is performed, before implementing such material model changes in the stress test.

(3) *Response to public input on material model changes.* The Board will consider and respond to substantive public input on any material model changes before implementing such material model changes in the stress test.

## Subpart F—Company-Run Stress Test Requirements for Certain U.S. Bank Holding Companies and Nonbank Financial Companies Supervised by the Board

■ 14. In § 252.54:

■ a. In table 1 to paragraph (a)(2)(i), remove the text ''April 5'' wherever it appears and add in its place the text ''April 30''.

■ b. In paragraph (b)(1), remove the text ''February 15'' and add in its place the text ''February 28''.

■ c. Revise paragraph (b)(2)(i).

The revision reads as follows:

**§ 252.54 Stress test.**

* * * * *

(b) * * *

(2) * * *

(i) The Board may require a covered company with significant trading activity to include a trading and counterparty component in its severely adverse scenario in the stress test required by this section. The data used in this component must be as of a date selected by the Board that is no earlier than April 1 of the calendar year one year prior to the year in which the stress test is performed and that precedes January 1 of the year in which the stress test is performed pursuant to this section. Unless otherwise determined by the Board, the as-of date of such component will be communicated to the company by no later than two weeks following the occurrence of the as-of date selected by the Board and a final description of the component will be communicated to the company by no later than March 1 of the calendar year in which the stress test is performed pursuant to this section. A covered company has significant trading activity if it has:

(A) Aggregate trading assets and liabilities of $50 billion or more, or aggregate trading assets and liabilities equal to 10 percent or more of total consolidated assets; and

(B) Is not a Category IV bank holding company.

* * * * *

■ 15. In § 252.57, revise paragraph (a) to read as follows:

**§ 252.57 Reports of stress test results.**

(a) *Reports to the Board of stress test results.* A covered company must report the results of the stress test required under § 252.54 to the Board in the manner and form prescribed by the Board. Except as required by the relevant reporting forms and the instructions thereto, such results must be submitted by April 30 of the calendar year in which the stress test is conducted pursuant to § 252.54, unless that time is extended by the Board in writing.

* * * * *

■ 16. Appendix A to part 252 is revised to read as follows:

## Appendix A to Part 252—Policy Statement on the Scenario Design Framework for Stress Testing

**1. Background**

(a) The Board has imposed stress testing requirements through its regulations (stress test rules) implementing section 165(i) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act or Act), section 10(g) of the Home Owners' Loan Act, and section 401(e) of the Economic Growth, Regulatory Relief, and Consumer Protection Act, and through its capital plan rule (§ 225.8). Under the stress test rules, the Board conducts a supervisory stress test of each bank holding company with total consolidated assets of $100 billion or more, intermediate holding company of a foreign banking organization with total consolidated assets of $100 billion or more, and nonbank financial company that the Financial Stability Oversight Council has designated for supervision by the Board (together, covered companies).[1] In addition, under the stress test rules, certain firms are also subject to company-run stress test requirements.[2] The Board will provide two different sets of conditions (each set, a scenario), including baseline and severely adverse scenario for both supervisory and company-run stress tests (macroeconomic scenarios).[3]

(b) The stress test rules provide that the Board will notify covered companies, by no

[1] 12 U.S.C. 5365(i)(1); subpart E of this part.

[2] 12 U.S.C. 5365(i)(2); subparts B and F of this part.

[3] The stress test rules define scenarios as those sets of conditions that affect the United States economy or the financial condition of a company that the Board determines are appropriate for use in stress tests, including, but not limited to, baseline and severely adverse scenarios. The stress test rules define baseline scenario as a set of conditions that affect the United States economy or the financial condition of a company and that reflect the consensus views of the economic and financial outlook. The stress test rules define severely adverse scenario as a set of conditions that affect the U.S. economy or the financial condition of a company and that overall are significantly more severe than those associated with the baseline scenario and may include trading or other additional components.

later than February 28 of each year, of the scenarios it will use to conduct its supervisory stress tests and provide, also by no later than February 28, covered companies and other financial companies subject to the final rules, the set of scenarios they must use to conduct their company-run stress tests. Under the stress test rules, the Board may require certain companies to use additional components in the severely adverse scenario or additional scenarios. For example, the Board expects to require large banking organizations with significant trading activities to include a trading and counterparty component (market shock, described in the following sections) in their severely adverse scenario. The Board will provide any additional components or scenarios by no later than March 1 of each year.[4] The Board expects that the scenarios it will require the companies to use will be the same as those the Board will use to conduct its supervisory stress tests (together, stress test scenarios).

(c) In addition, § 225.8 (capital plan rule) requires covered companies to submit annual capital plans, including stress test results, to the Board in order to allow the Board to assess whether they have robust, forward-looking capital planning processes and have sufficient capital to continue operations throughout times of economic and financial stress.[5]

(d) Stress tests required under the stress test rules and under the capital plan rule require the Board and financial companies to calculate pro-forma capital levels—rather than ''current'' or actual levels—over a specified planning horizon under baseline and stressful scenarios. This approach integrates key lessons of the 2007–2009 financial crisis and subsequent stress events into the Board's supervisory framework. During the financial crisis, investor and counterparty confidence in the capitalization of financial companies eroded rapidly in the face of changes in the current and expected economic and financial conditions, and this loss in market confidence imperiled companies' ability to access funding, continue operations, serve as a credit intermediary, and meet obligations to creditors and counterparties. Importantly, such a loss in confidence occurred even when a financial institution's capital ratios were in excess of regulatory minimums. This is because the institution's capital ratios were perceived as lagging indicators of its financial condition, particularly when conditions were changing.

(e) The stress tests required under the stress test rules and capital plan rule are a valuable supervisory tool that provide a forward-looking assessment of large financial companies' capital adequacy under hypothetical economic and financial market conditions. Currently, these stress tests primarily focus on credit risk, operational risk, and market risk—that is, risk of mark-to-market losses associated with companies' trading and counterparty positions—and not on other types of risk, such as liquidity risk. Pressures stemming from these sources are considered in separate supervisory exercises. No single supervisory tool, including the stress tests, can provide an assessment of a company's ability to withstand every potential source of risk.

(f) Selecting appropriate scenarios is an especially significant consideration for stress tests required under the capital plan rule, which ties the review of a company's performance under stress scenarios to its ability to make capital distributions. More severe scenarios, all other things being equal, generally translate into larger projected declines in banks' capital. Thus, a company would need more capital today to meet its minimum capital requirements in more stressful scenarios and have the ability to continue making capital distributions, such as common dividend payments. This translation is far from mechanical, however; it will depend on factors that are specific to a given company, such as underwriting standards and the company's business model, which would also greatly affect projected revenue, losses, and capital.

**2. Overview and Scope**

(a) This policy statement provides more detail on the characteristics of the stress test scenarios and explains the considerations and procedures that underlie the approach for formulating these scenarios. The considerations and procedures described in this policy statement apply to the Board's stress testing framework, including to the stress tests required under subparts B, E, and F of this part as well as the Board's capital plan rule (§ 225.8).[6]

(b) Although the Board does not envision that the broad approach used to develop scenarios will change from year to year, the stress test scenarios will reflect changes in the outlook for economic and financial conditions and changes to specific risks or vulnerabilities that the Board, in consultation with the other federal banking agencies, determines should be considered in the annual stress tests. The stress test scenarios should not be regarded as forecasts; rather, they are hypothetical paths of economic variables that will be used to assess the strength and resilience of the companies' capital in various economic and financial environments.

(c) The remainder of this policy statement is organized as follows. Section 3 provides a broad description of the baseline and severely adverse scenarios and describes the relationship between the macroeconomic scenario and the market shock component of the severely adverse scenario applicable to companies with significant trading activity. This section also describes the types of variables that the Board expects to include in the macroeconomic scenarios and the market shock component. Section 4 describes the Board's approach for developing the macroeconomic scenarios, and section 5 describes the approach for the market shocks. Section 6 provides a timeline for the formulation and publication of the macroeconomic assumptions and market shocks.

**3. Content of the Stress Test Scenarios**

(a) The Board will publish two different scenarios, including baseline and severely adverse conditions, for use in stress tests required in the stress test rules.[7] In general, the Board anticipates that it will not issue additional scenarios. Specific circumstances or vulnerabilities that in any given year the Board may determine require particular vigilance to help ensure the resilience of the banking sector may be captured in the severely adverse scenario. The Board would expect to explain such a determination through the comment process in those stress test cycles.

(b) While the Board generally expects to use the same scenarios for all companies subject to the final rule, it may require a subset of companies—depending on a company's financial condition, size, complexity, risk profile, scope of operations, or activities, or risks to the U.S. economy—to include additional scenario components or additional scenarios that are designed to capture different effects of adverse events on revenue, losses, and capital. One example of such components is the market shock that applies only to companies with significant trading activity. Additional components or scenarios may also include other stress factors that may not necessarily be directly correlated to macroeconomic or financial assumptions but nevertheless can materially affect companies' risks, such as the unexpected default of a major counterparty.

(c) Early in each stress testing cycle, the Board plans to publish the macroeconomic scenarios along with a brief narrative summary that provides a description of the economic situation underlying the scenario and explains how the scenarios have changed relative to the previous year. In addition, to assist companies in projecting the paths of additional variables in a manner consistent with the scenario, the narrative will provide descriptions of the general path of some additional variables. These descriptions will be general—that is, they will describe developments for broad classes of variables rather than for specific variables—and will specify the intensity and direction of variable changes but not numeric magnitudes. These descriptions should provide guidance that will be useful to companies in specifying the paths of the additional variables for their company-run stress tests. Note that in practice it will not be possible for the narrative to include descriptions of all the additional variables that companies may need for their company-run stress tests. In cases where scenarios are designed to reflect particular risks and vulnerabilities, the narrative will also explain the underlying motivation for these features of the scenario. The Board also plans to release a description of the market shock components.

*3.1 Macroeconomic Scenarios*

(a) The macroeconomic scenarios will consist of the future paths of a set of economic and financial variables.[8] The

[4] Sections 252.14(b); 252.44(b); 252.54(b).

[5] *See* § 225.8.

[6] Sections 252.14(a); 252.44(a); 252.54(a).

[7] Sections 252.14(b); 252.44(b); 252.54(b).

[8] The future path of a variable refers to its specification over a given time period. For example,

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economic and financial variables included in the scenarios will likely comprise those included in the ''2014 Supervisory Scenarios for Annual Stress Tests Required under the Dodd-Frank Act Stress Testing Rules and the Capital Plan Rule'' (2013 supervisory scenarios). The domestic U.S. variables provided for in the 2013 supervisory scenarios included:

(1) Six measures of economic activity and prices: Real and nominal gross domestic product (GDP) growth, the unemployment rate of the civilian non-institutional population aged 16 and over, real and nominal disposable personal income growth, and the Consumer Price Index (CPI) inflation rate;

(2) Four measures of developments in equity and property markets: The Core Logic National House Price Index, the National Council for Real Estate Investment Fiduciaries Commercial Real Estate Price Index, the Dow Jones Total Stock Market Index, and the Chicago Board Options Exchange Market Volatility Index; and

(3) Six measures of interest rates: The rate on the 3-month Treasury bill, the yield on the 5-year Treasury bond, the yield on the 10-year Treasury bond, the yield on a 10-year BBB corporate security, the prime rate, and the interest rate associated with a conforming, conventional, fixed-rate, 30-year mortgage.

(b) The international variables provided for in the 2014 supervisory scenarios included, for the euro area, the United Kingdom, developing Asia, and Japan:

(1) Percent change in real GDP;

(2) Percent change in the CPI or local equivalent; and

(3) The U.S./foreign currency exchange rate.[9]

(c) The economic variables included in the scenarios influence key items affecting financial companies' net income, including pre-provision net revenue and credit losses on loans and securities. Moreover, these variables exhibit fairly typical trends in adverse economic climates that can have unfavorable implications for companies' net income and, thus, capital positions.

(d) The economic variables included in the scenario may change over time. For example, the Board may add variables to a scenario if the international footprint of companies that are subject to the stress testing rules changed notably over time such that the variables already included in the scenario no longer sufficiently capture the material risks of these companies. Alternatively, historical relationships between macroeconomic variables could change over time such that one variable (*e.g.,* disposable personal income growth) that previously provided a good proxy for another (*e.g.,* light vehicle sales) in modeling companies' pre-provision net revenue or credit losses ceases to do so, resulting in the need to create a separate path, or alternative proxy, for the other variable. However, recognizing the amount of work required for companies to incorporate the scenario variables into their stress testing models, the Board expects to eliminate variables from the scenarios only in rare instances.

(e) The Board expects that the company may not use all of the variables provided in the scenario, if those variables are not appropriate to the company's line of business, or may add additional variables, as appropriate. The Board expects the companies to ensure that the paths of such additional variables are consistent with the scenarios the Board provided. For example, the companies may use, as part of their internal stress test models, local-level variables, such as state-level unemployment rates or city-level house prices. While the Board does not plan to include local-level macro variables in the stress test scenarios it provides, it expects the companies to evaluate the paths of local-level macro variables as needed for their internal models, and ensure internal consistency between these variables and their aggregate, macro-economic counterparts. The Board will provide the macroeconomic scenario component of the stress test scenarios for a period that spans a minimum of 13 quarters. The scenario horizon reflects the supervisory stress test approach that the Board plans to use. Under the stress test rules, the Board will assess the effect of different scenarios on the consolidated capital of each company over a forward-looking planning horizon of at least nine quarters.

*3.2 Market Shock Component*

(a) The market shock component of the severely adverse scenario will only apply to companies with significant trading activity and their subsidiaries.[10] The component consists of large moves in market prices and rates that would be expected to generate losses. Market shocks differ from macroeconomic scenarios in several ways, both in their design and application. For instance, market shocks that might typically be observed over an extended period (*e.g.,* 3 months) are assumed to affect the market value of the companies' trading assets and liabilities immediately. In addition, under the stress test rules, the as-of date for market shocks will usually differ from the as-of date of the macroeconomic scenario, and the Board will provide the as-of date for market shocks within two weeks of the date occurring. Finally, as described in section 4, the market shock includes a much larger set of risk factors than the set of economic and financial variables included in macroeconomic scenarios. Broadly, these risk factors include shocks to financial market variables that affect asset prices, such as a credit spread or the yield on a bond, and, in some cases, the value of the position itself (*e.g.,* the market value of securitized positions).

(b) The Board envisions that the market shocks will include shocks to a broad range of risk factors that are similar in granularity to those risk factors that trading companies use internally to produce profit and loss estimates, under stressful market scenarios, for all asset classes that are considered trading assets, including public equities, credit, interest rates, foreign exchange rates, and commodities. Examples of risk factors include, but are not limited to:

(1) Public equity indices to which companies with significant trading activity may have exposure, along with term structures of implied volatilities;

(2) Cross-currency foreign exchange rates of selected currencies, along term structures of implied volatilities;

(3) Term structures of government rates (*e.g.,* U.S. Treasuries), interbank rates (*e.g.,* swap rates) and potentially other key rates (*e.g.,* commercial paper) for developed markets and for developing and emerging market nations to which companies may have exposure;

(4) Term structures of implied volatilities that are key inputs to the pricing of interest rate derivatives;

(5) Term structures of futures prices for energy products including crude oil (differentiated by country of origin), natural gas, and power;

(6) Term structures of futures prices for metals and agricultural commodities; and

(7) Credit spreads or instrument prices for credit-sensitive product segments including: corporate bonds, credit default swaps, and collateralized debt obligations by risk; non-agency residential mortgage-backed securities and commercial mortgage-backed securities by risk and vintage; sovereign debt; and, municipal bonds.

(c) The Board expects to structure the market shock component so that it reflects two separate market shock scenarios, which would occur on the same date within the stress test. To calculate trading and counterparty losses for a given stress test, the Board expects that the losses from whichever market shock scenario produces the largest dollar losses would be used to determine a firm's stress test results. This approach can help improve the risk capture of the stress test.

**4. Approach for Formulating the Macroeconomic Assumptions for Scenarios**

(a) This section describes the Board's approach for formulating macroeconomic assumptions for each scenario. The methodologies for formulating this part of each scenario differ by scenario, so these methodologies for the baseline and severely adverse scenarios are described separately in each of the following subsections.

(b) In general, the baseline scenario will reflect the most recently available consensus views of the macroeconomic outlook expressed by professional forecasters, government agencies, and other public-sector organizations as of the beginning of the stress-test cycle. The severely adverse

the path of unemployment can be described in percentage terms on a quarterly basis over the stress testing time horizon.

[9] The Board may increase the range of countries or regions included in future scenarios, as appropriate.

[10] Currently, companies with significant trading activity include any bank holding company or intermediate holding company that (1) has aggregate trading assets and liabilities of $50 billion or more, or aggregate trading assets and liabilities equal to 10 percent or more of total consolidated assets, and (2) is not a Category IV firm. The Board may also subject a state member bank subsidiary of any such bank holding company to the market shock component. The set of companies subject to the market shock component could change over time as the size, scope, and complexity of the covered company's trading activities evolve.

scenario will consist of a set of economic and financial conditions that reflect the conditions of post-war U.S. recessions.

(c) Each of these scenarios is described further in sections below as follows: Baseline (subsection 4.1) and severely adverse (subsection 4.2).

*4.1 Approach for Formulating Macroeconomic Assumptions in the Baseline Scenario*

(a) The stress test rules define the baseline scenario as a set of conditions that affect the U.S. economy or the financial condition of a banking organization, and that reflect the consensus views of the economic and financial outlook. Projections under a baseline scenario are used to evaluate how companies would perform in more likely economic and financial conditions. The baseline serves also as a point of comparison to the severely adverse scenario, giving some sense of how much of the company's capital decline could be ascribed to the scenario as opposed to the company's capital adequacy under expected conditions.

(b) The baseline scenario will be developed around a macroeconomic projection that captures the prevailing views of private-sector forecasters (*e.g.,* Blue Chip Consensus Forecasts and the Survey of Professional Forecasters), government agencies, and other public-sector organizations (*e.g.,* the International Monetary Fund and the Organization for Economic Co-operation and Development) near the beginning of the annual stress-test cycle. The baseline scenario is designed to represent a consensus expectation of certain economic variables over the time period of the tests and it is not the Board's internal forecast for those economic variables. For example, the baseline path of short-term interest rates is constructed from consensus forecasts and may differ from that implied by the Federal Open Market Committee's *Summary of Economic Projections.*

(c) For some scenario variables—such as U.S. real GDP growth, the unemployment rate, and the consumer price index—there will be many different forecasts available to project the paths of these variables in the baseline scenario. For others, a more limited number of forecasts will be available. If available forecasts diverge notably, the baseline scenario will reflect an assessment of the forecast that is deemed to be most plausible. The Board also considers the output of a macroeconomic model, for which the Board will maintain a description separately on the Board's website, developed by Board staff for use in constructing the values of some of the variables in the scenarios for the annual stress test. In setting the paths of variables in the baseline scenario, particular care will be taken to ensure that, together, the paths present a coherent and plausible outlook for the U.S. and global economy, given the economic climate in which they are formulated. However, the macroeconomic model was designed to meet the specific needs of the stress testing program, and the resulting baseline scenarios are not Federal Reserve forecasts.

*4.2 Approach for Formulating the Macroeconomic Assumptions in the Severely Adverse Scenario*

The stress test rules define a severely adverse scenario as a set of conditions that affect the U.S. economy or the financial condition of a covered company and that overall are significantly more severe than those associated with the baseline scenario. The covered company will be required to publicly disclose a summary of the results of its stress test under the severely adverse scenario, and the Board intends to publicly disclose the results of its analysis of the covered company under the severely adverse scenario.

4.2.1 General Approach: The Recession Approach

(a) The Board intends to use a recession approach to develop the severely adverse scenario. In the recession approach, the Board will specify the future paths of variables to reflect conditions that characterize post-war U.S. recessions, generating either a typical or specific recreation of a post-war U.S. recession. The Board chose this approach because it has observed that the conditions that typically occur in recessions—such as increasing unemployment, declining asset prices, and contracting loan demand—can put significant stress on companies' balance sheets. This stress can occur through a variety of channels, including higher loss provisions due to increased delinquencies and defaults; losses on trading positions through sharp moves in market prices; and lower bank income through reduced loan originations. For these reasons, the Board believes that the paths of economic and financial variables in the severely adverse scenario should, at a minimum, resemble the paths of those variables observed during a recession.

(b) This approach requires consideration of the type of recession to feature. All post-war U.S. recessions have not been identical: Some recessions have been associated with very elevated interest rates, some have been associated with sizable asset price declines, and some have been relatively more global. Recessions that are caused by or exacerbated by a financial crisis often are deeper and more protracted than other recessions. The Board therefore believes that the severely adverse scenario should be triggered by a sudden and substantial increase in risk aversion and uncertainty that causes sharp declines in risky financial asset prices, lower interest rates on safe assets, and a rise in volatility big enough to disrupt functioning in some markets. Although markets resume normal functioning within a few months, the rise in uncertainty and decline in wealth causes businesses to take nearly simultaneous steps to reduce employment and investment and households to reduce spending. Negative feedback effects between contracting economic activity and financial markets' response lead to a deep and prolonged decline in overall economic activity, inflation, and asset prices followed by a shallow recovery.

(c) Indeed, the most common features of recessions are increases in the unemployment rate and contractions in aggregate incomes and economic activity. For this and the following reasons, the Board intends to use a rise in the unemployment rate as the primary basis for calibrating the severity of the severely adverse scenario. First, the unemployment rate is likely the most representative single summary indicator of adverse economic conditions. Second, in comparison to GDP, labor market data have traditionally featured more prominently than GDP in the set of indicators that the National Bureau of Economic Research reviews to inform its recession dates.[11] Third and finally, the growth rate of potential output can cause the size of the decline in GDP to vary between recessions. While changes in the unemployment rate can also vary over time due to demographic factors, this seems to have more limited implications over time relative to changes in potential output growth. The unemployment rate used in the severely adverse scenario will reflect an unemployment rate that has been observed in severe post-war U.S. recessions, measuring severity by the absolute level of and relative increase in the unemployment rate.[12]

(d) The Board believes that the severely adverse scenario should also reflect a housing recession. The house prices path set in the severely adverse scenario will reflect developments that have been observed in post-war U.S. housing recessions, measuring severity by the absolute level of and relative decrease in the house prices.

(e) As described below, the Board has developed guides for several additional variables including equity prices; the Chicago Board Options Exchange's Volatility Index (VIX); BBB corporate spread (relative to the 10-year Treasury yield); conventional, conforming, 30-year fixed-rate mortgage spread (relative to the 10-year Treasury yield), commercial real estate prices, and 5-year and 10-year Treasury yields. The international variables (GDP, inflation, and exchange rates) are also subject to guides.

(f) The Board's specification of the paths of the macroeconomic and financial market variables listed in paragraph 4.2.1(e) will be informed by their behavior during previous recessions or other periods of financial stress, as well as informed assessments of how that behavior co-moved with the paths of unemployment, income, house prices, and activity during periods of macrofinancial stress. Some of these other variables, however, have taken divergent paths in previous recessions (*e.g.,* foreign GDP). The analysis that the Board conducted to develop the guides informed its judgment in selecting the appropriate ranges for the peak or trough, and the timing of that peak or trough. In

[11] More recently, a monthly measure of GDP has been added to the list of indicators.

[12] Even though all recessions feature increases in the unemployment rate and contractions in incomes and economic activity, the size of this change has varied over post-war U.S. recessions. Table 1 documents the variability in the depth of post-war U.S. recessions. Some recessions—labeled mild in Table 1—have been relatively modest, with GDP declining less than one percent and the unemployment rate moving up about a percentage point on average. Other recessions—labeled severe in Table 1—have been much harsher, with GDP dropping 3.75 percent and the unemployment rate moving up a total of about 4 percentage points.

general, the path for these variables also will be based on their underlying structure at the time that the scenario is designed (*e.g.,* economic or financial-system vulnerabilities in other countries).

(g) The Board considered alternative methods for scenario design of the severely adverse scenario, including a probabilistic approach. The probabilistic approach constructs a baseline forecast from a large-scale macroeconomic model and identifies a scenario that would have a specific probabilistic likelihood given the baseline forecast. The Board believes that, at this time, the recession approach is better suited for developing the severely adverse scenario than a probabilistic approach because it guarantees a recession of some specified severity. In contrast, the probabilistic approach requires the choice of an extreme tail outcome—relative to baseline—to characterize the severely adverse scenario (*e.g.,* a 5 percent or a 1 percent tail outcome). In practice, this choice is difficult as adverse economic outcomes are typically thought of in terms of how variables evolve in an absolute sense rather than how far they lie in the probability space away from the baseline. In this sense, a scenario featuring a recession may be somewhat clearer and more straightforward to communicate. Finally, the probabilistic approach relies on estimates of uncertainty around the baseline scenario and such estimates are in practice model-dependent.

4.2.2 Setting Variables in the Severely Adverse Scenario

(a) Generally, the variables in the severely adverse scenario will be specified to be consistent with their expected behavior in severe recessions or periods of market stress. The approach for specifying the paths of these variables in the scenario will reflect the Board's assessment of:

(1) how economic models suggest that these variables should evolve given the path of the unemployment rate,

(2) how these variables have typically evolved in past U.S. recessions or other relevant periods of significant stress in particular asset markets, and

(3) other relevant factors, including the current state of the economy; the level of vulnerabilities in the financial system; and consensus estimates of long-run equilibrium values of potential GDP, interest rates, and inflation expectations.

(b) For certain variables subject to guides that provide a range or potential values (BBB spread, VIX, commercial real estate prices, and mortgage rate spread), the Board expects that it could be appropriate to set the paths for these variables at similar levels of severity. In making this determination, the Board would consider the expected severity of the unemployment rate and house prices variables and the prevailing macroeconomic and financial conditions described in the baseline scenario.

(c) The expected trajectories for the variables related to unemployment, long-term bond yields and spreads, asset prices, and volatility will be informed by quantitative guides. These guides provide plausible ranges within which the Board expects to choose the level of the peak or trough that each of these variables will reach in the scenario, and the timing of that peak or trough. The Board's choices relative to those ranges will be informed by the factors listed in paragraph 4.2.2(a).

(d) Economic models—such as medium-scale macroeconomic models—should be able to generate plausible paths consistent with the unemployment rate for a number of scenario variables, such as real GDP growth, CPI inflation, and short-term interest rates, which have relatively stable (direct or indirect) relationships with the unemployment rate (*e.g.,* Okun's Law, the Phillips Curve, and interest rate feedback rules). The Board has developed a model specifically structured and calibrated to the needs of the stress testing program to inform the trajectories of these variables (as well as disposable personal income, or DPI), a description of which will be maintained on the Board's website. The output of this model is not a forecast of the Federal Reserve.

(e) In addition, judgment is necessary in projecting the path of a scenario's international variables. Recessions that occur simultaneously across countries are an important source of stress to the balance sheets of companies with notable international exposures but are not a typical feature of the international economy even when the U.S. is in recession. As a result, simply adopting the typical path of international variables in a severe U.S. recession would likely underestimate the risks stemming from the international economy. Consequently, an approach that uses the guides set out in section 4.2.2.10, and both judgment and economic models informs the path of international variables.

(f) The Board expects that the variables described in this section 4.2.2 will be specified in the annual scenarios in the severely adverse scenario to be consistent with certain scenario design principles and the guides for each variable below. In designing these guides and setting the values for the variables in the severely adverse scenario, the Board will consider the following scenario design principles:

(1) *Severity:* The scenarios should be sufficiently severe. Severity is an important component in ensuring that covered companies are adequately capitalized against a hypothetical severe recession and in maintaining the public credibility of stress tests. In determining the adequate level of severity for these guides, the principle of severity requires that, at times, variable paths may exceed levels observed in the historical data. Since no single scenario can account for all potential contingencies, the scenario must be sufficiently severe to ensure that banks will be resilient to a range of alternative and plausible scenarios that could generate net losses that are of similar magnitudes, even if such scenarios would have different characteristics from the single annual scenario. In establishing a sufficiently severe scenario, the Board considers the potential unintended effects of the scenario on the operations of firms subject to the stress tests.

(2) *Credibility:* The scenarios should be credible. Credible stress tests maintain the confidence of the public and financial markets that the stress tests are sufficiently severe to ensure that the firms are properly capitalized to withstand severe economic and financial conditions.

(3) *Avoiding adding procyclicality:* The scenarios should avoid adding sources of procyclicality. If stress tests are relatively more severe in already stressed conditions, then this severity could add undue stress to the financial system, reducing financial intermediation with negative implications for the macroeconomy. The stress tests should balance the need for an adequately severe scenario without unduly magnifying existing procyclical tendencies in the financial system.

(4) *Flexibility:* While the Board's scenario design framework promotes transparency and predictability, fixed paths often would fail to achieve at least one of the Board's goals of severity, credibility, and not adding to procyclicality, as well as the principles established in the Board's Stress Testing Policy Statement.[13] As a result, the Board has designed guides in this section that generally establish ranges of historically observed values that can be selected for a given severely adverse scenario. At the same time, the scenario design framework enables the Board to consider testing unexpected shocks that may have implications for the economy and the financial stability of the United States, and therefore, firms' future financial condition, even if these shocks could exceed historically observed values. Further, flexibility is important to enable the Board to implement reasonable technical adjustments to the values and trajectories of the variables, consistent with these scenario design principles.

(g) The guides described in this section set out paths for each variable until it reaches its peak/trough in the severely adverse scenario. The stress test requires projections of 13 quarters' worth of losses to determine capital ratios at the end of 9 quarters of the scenario, because loss provisions in quarter 9 are affected by bank performance in quarters 10 to 13. To describe these paths, most guides adopt a simple framework involving the following 4 parameters:

(1) *the jump-off value:* the value of the variable in the quarter preceding the scenario. The jump-off value will be set to reflect the conditions at the time that the scenario is designed.

(2) *the peak or trough value:* the paths in each guide specify that each variable in the scenario will either increase or decrease from its jump-off value. If the variable increases, it will reach a maximum or peak value during the scenario. If it decreases, it will reach a minimum or trough value during the scenario.

(3) *the timing of the peak or trough:* the quarter of the scenario in which the variable path reaches its peak or trough.

(4) *the trajectory from jump-off to peak or trough:* the values between the jump-off and peak or trough will be determined with a roughly linear interpolation, a nonlinear function, or by specifying the proportion of the change from jump-off to peak or trough that will obtain in each of the intervening quarters.

[13] Appendix B to this part.

(h) The severely adverse scenario will also set out end values and trajectories to end values. The end value is expected to generally be consistent with the historical values of a given variable within a 10 to 15 quarter window after the beginning of either a recession or other identified stress event. The trajectory from peak or trough to end value is expected to generally be determined by a roughly linear interpolation. The trajectory from the peak or trough to the end value generally will be smooth for variables determined by guides and follow the model path for modeled variables.

4.2.2.1 Setting the Unemployment Rate Under the Severely Adverse Scenario

(a) The Board anticipates that the severely adverse scenario will feature an unemployment rate peak value that increases between 3 to 5 percentage points from its jump-off value. However, if a 3 to 5 percentage point increase in the unemployment rate does not raise the level of the unemployment rate to at least 10 percent, the path of the unemployment rate in most cases will be specified so as to raise the unemployment rate to at least 10 percent.

(b) The Board anticipates that the unemployment rate peak value will occur between quarters 6 and 8 after the jump-off point for the scenario. The trajectory to peak value is expected to experience high initial changes with smaller subsequent changes quarter to quarter.

4.2.2.2 Setting House Prices in the Severely Adverse Scenario

(a) In specifying the path for nominal house prices, the Board will consider the ratio of the nominal house price index (HPI) to nominal per capita DPI. The Board anticipates that the severely adverse scenario will feature an HPI–DPI ratio that falls (1) by at least 25 percent, or (2) by enough to bring the ratio down to the trough reached in the first quarter of 2012 after the 2007–2009 financial crisis.

(b) The trough is expected to occur between quarter 8 and quarter 10 after the jump-off quarter. The trajectory to trough value is expected to experience 20 percent of the decline realized in quarter 1 and another 20 percent of the decline in quarter 2 (40 percent in total), with a roughly linear trajectory to trough thereafter.

4.2.2.3 Setting the BBB Spread for the Severely Adverse Scenario

(a) The Board anticipates that the severely adverse scenario will feature a BBB corporate spread value, defined as the difference between the yield on BBB corporate bonds and the 10-year Treasury yield, that increases to the higher of (1) between a spread level of 500 to 600 basis points, or (2) a total increase of about 100 basis points from the jump-off value.

(b) The Board anticipates that the BBB spread peak value will occur between quarters 3 and 4 after the jump-off point for the scenario. The trajectory to peak value is expected to experience the highest share of the increase in quarters 1 and 2, with between 60 and 80 percent of the increase in quarter 1, followed by a smooth trajectory to peak thereafter.

4.2.2.4 Setting the Mortgage Rate Spread for the Severely Adverse Scenario

(a) The Board anticipates that the severely adverse scenario will feature a mortgage rate spread value, relative to the 10-year Treasury yield, that will be set based on the conditions at the time that the scenario is designed. The Board anticipates that the severely adverse scenario will increase to the higher of (1) between a 70 to 160 basis point increase in the mortgage rate spread, or (2) increase to a level of at least 300 basis points.

(b) The Board anticipates that the mortgage rate spread peak value will occur between quarters 3 and 4 after the jump-off point for the scenario. The trajectory to peak value is expected to experience between 50 and 70 percent of the increase realized in quarter 1, with a smooth trajectory to peak thereafter.

4.2.2.5 Setting the VIX for the Severely Adverse Scenario

(a) The Board anticipates that the severely adverse scenario will feature a VIX peak value that will increase to the higher of (1) between 65 and 75 percent or (2) by at least 10 percentage points from the jump-off value.

(b) The Board anticipates that the VIX peak value will occur in quarter 2 after the jump-off point for the scenario. The trajectory to peak value is expected to experience the largest share of the increase, of 60 to 80 percent, in quarter 1.

4.2.2.6 Setting Equity Prices for the Severely Adverse Scenario

(a) The Board anticipates that the severely adverse scenario will feature an equity price value that falls by around 50 percent plus or minus up to 10 percent, depending on the performance of equity prices over the 12-month period prior to the jump-off value. When equity prices have risen over the past 12 months, equity prices will fall to a trough level below the jump-off value of 50 percent plus one half of the percentage increase in equity prices up to a maximum of 10 percent. When equity prices have decreased over the past 12 months, equity prices will fall to a trough level below the jump-off value of 50 percent minus one half of the percentage decrease in equity prices, up to a maximum of 10 percent. Thus, the equity prices reach a trough level of between 40 and 60 percent below the jump-off value.

(b) The Board anticipates that the equity price trough value will occur in quarter 3 or 4 after the jump-off point for the scenario. The trajectory to trough value is expected to experience the highest share of the decrease, 60 to 70 percent, in quarter 1, with 10 to 20 percent of the decline occurring in quarter 2 and the remaining decline realized about equally in the remaining quarter(s) to the trough value.

4.2.2.7 Setting CRE Prices for the Severely Adverse Scenario

(a) The Board anticipates that the severely adverse scenario will feature a CRE price value that falls between 30 and 45 percent from its jump-off value.

(b) The Board anticipates that the CRE trough value will occur between 8 and 10 quarters after the jump-off value for the scenario. The trajectory to trough value is expected to be roughly linear.

4.2.2.8 Setting the 5-Year Treasury Yield for the Severely Adverse Scenario

(a) The Board anticipates that the severely adverse scenario will feature a 5-year Treasury yield value that falls to the lower of (1) between 1.5 and 3.5 percentage points from its jump-off value, subject to a lower bound of 0.3 percent, or (2) a decline of 0.3 percent from the jump-off level.

(b) The Board anticipates that the 5-year Treasury yield trough value will occur between 1 and 4 quarters after the jump-off value for the scenario. The trajectory to trough value is expected to experience the highest share of the decrease in quarter 1, depending on the quarter that the trough value will occur, such that the share of the decrease in quarter 1 will be between 55 percent and 100 percent. If the trough value is set to occur in quarters 2, 3, or 4, the yield decline trajectory following quarter 1 will decrease smoothly to the trough quarter.

4.2.2.9 Setting the 10-Year Treasury Yield for the Severely Adverse Scenario

(a) The Board anticipates that the severely adverse scenario will feature a 10-year Treasury yield value that falls to the lower of (1) between 1 and 3 percentage points from its jump-off value, subject to a lower bound of 0.5 percent, or (2) a decline of 0.3 percent from the jump-off level.

(b) The Board anticipates that the 10-year Treasury yield trough value will occur between 1 and 4 quarters after the jump-off value for the scenario. The trajectory to trough value is expected to experience the highest share of the decrease in quarter 1, depending on the quarter that the trough value will occur, such that the share of the decrease in quarter 1 will be between 55 percent and 100 percent. If the trough value is set as quarters 2, 3, or 4, the yield decline trajectory following quarter 1 will decrease smoothly to the trough quarter.

4.2.2.10 Setting the Calibration of International Variables

(a) The Board expects to calibrate values for certain international variables in the euro area, the United Kingdom, Japan, and Developing Asia.

(b) For the euro area, the Board expects in general to specify that GDP will decline by 7.5 percent from the baseline value to its trough in the scenario, and reach an end value of 7.5 percent below the baseline value. However, the Board may choose a value for the decline in GDP between 5 and 10 percent. The Board expects to specify that euro area inflation will decline by 3 percentage points from the baseline scenario to its trough, and reach an end value of 0 percentage points below the baseline value. However, the Board may choose a value for the decline in inflation between 2 and 4 percentage points. The Board expects to specify that the U.S. dollar will appreciate against the euro by approximately 15 percent from its jump-off value at its peak and then revert back to the jump-off value by the end of the scenario. However, the Board may choose a value for U.S. dollar appreciation between 5 and 25 percent.

(c) For the United Kingdom, the Board expects in general to specify that GDP will decline by 7.5 percent from the baseline

value to its trough in the scenario, and reach an end value of 7.5 percent below the baseline value. However, the Board may choose a value for the decline in GDP between 5 and 10 percent. The Board expects to specify that inflation will decline by 3 percentage points from the baseline value to its trough, and reach an end value of 0 percentage points below the baseline value. However, the Board may choose a value for the decline in inflation between 2 and 4 percentage points. The Board expects to specify that the U.S. dollar will appreciate against the Great Britain Pound by 15 percent from its jump-off value at its peak and then revert back to the jump-off value by the end of the scenario. However, the Board may choose a value for U.S. dollar appreciation between 5 and 25 percent.

(d) For Japan, the Board expects in general to specify that GDP will decline by 7.5 percent from the baseline value to its trough in the scenario, and reach an end value of 7.5 percent below the baseline value. However, the Board may choose a value for the decline in GDP between 5 and 10 percent. The Board expects to specify that inflation will decline by 3 percentage points from the baseline value to its trough, and reach an end value of 0 percentage points below the baseline value. However, the Board may choose a value for the decline in inflation between 2 and 4 percentage points. The Board expects to specify that the U.S. dollar will depreciate against the Japanese yen by 1 percent from its jump-off value at its peak and then revert back to the jump-off value by the end of the scenario. However, the Board may choose a value for change in value of the U.S. dollar against the Japanese yen ranging from a 9 percent depreciation to an 11 percent appreciation.

(e) For Developing Asia, the Board expects in general to specify that GDP will decline by 3 percent from the baseline value to its trough, and reach an end value of 0 percent below the baseline value. However, the Board may choose a value for the decline in GDP between 0.5 and 5.5 percent. The Board expects to specify that inflation will decline by 5 percentage points from the baseline value to its trough, and reach an end value of 0 percentage points below the baseline value. However, the Board may choose a value for the decline in inflation between 0.8 and 9 percentage points. The Board expects to specify that the U.S. dollar will appreciate against the currencies in Developing Asia by 15 percent from its jump-off value at its peak and then revert back to the jump-off value by the end of the scenario. However, the Board may choose a value for the appreciation of the U.S. dollar between 5 and 25 percent.

4.2.3 Adding Salient Risks to the Severely Adverse Scenario

(a) The severely adverse scenario will be developed to reflect specific risks to the economic and financial outlook that are especially salient but that would feature minimally in the scenario if the Board were to use only approaches that looked to past recessions or relied on historical relationships between variables.

(b) There are some important instances in which it will be appropriate to augment the recession approach with salient risks. For example, if an asset price were especially elevated and thus potentially vulnerable to an abrupt and potentially destabilizing decline, it would be appropriate to include such a decline in the scenario even if such a large drop were not typical in a severe recession. Likewise, if economic developments abroad were particularly unfavorable, assuming a weakening in international conditions larger than what typically occurs in severe U.S. recessions would likely also be appropriate.

(c) While the recession component of the severely adverse scenario is within some predictable range, the salient risk aspect of the scenario is far less so, and therefore, needs an annual assessment. As appropriate, the Board will identify the risks to the financial system and the domestic and international economic outlooks that appear more elevated than usual, using its internal analysis and supervisory information and in consultation with the Federal Deposit Insurance Corporation (FDIC) and the Office of the Comptroller of the Currency (OCC). Using the same information, the Board will then calibrate the paths of the macroeconomic and financial variables in the scenario to reflect these risks.

(d) The Board will factor in particular risks to the domestic and international macroeconomic outlook identified by its economists, bank supervisors, and financial market experts and make appropriate adjustments to the paths of specific economic variables. These adjustments will not be reflected in the general severity of the recession and, thus, all macroeconomic variables; rather, the adjustments will apply to a subset of variables to reflect co-movements in these variables that are historically less typical. The Board plans to discuss the motivation for the adjustments that it makes to variables to highlight systemic risks in the narrative describing the scenarios, which will be released for public comment and subsequently adjusted, if necessary, in response to those comments.[14]

**5. Approach for Formulating the Market Shock Component**

(a) This section discusses the approach the Board proposes to adopt for developing the market shock component of the severely adverse scenario appropriate for companies with significant trading activities. The design and specification of the market shock component differs from that of the macroeconomic scenarios because profits and losses from trading are measured in mark-to-market terms, while revenues and losses from traditional banking are generally measured using the accrual method. As noted above, another critical difference is the time-evolution of the market shock component. The market shock component consists of a sudden ''shock'' to a large number of risk factors that determine the mark-to-market value of trading positions, while the macroeconomic scenarios supply a projected path of economic variables that affect traditional banking activities over the entire planning period.

(b) The development approaches for the market shock component that are detailed in this section are as follows: baseline (subsection 5.1) and severely adverse (subsection 5.2).

*5.1 Approach for Formulating the Market Shock Component Under the Baseline Scenario*

Market shocks are large, previously unanticipated moves in asset prices and rates. Under the baseline scenario, asset prices should, broadly speaking, reflect consensus opinions about the future evolution of the economy. Sudden price movements, as envisioned in the market shock, should not occur along the baseline path. As a result, the market shock will not be included in the baseline scenario.

*5.2 Approach for Formulating the Market Shock Component Under the Severely Adverse Scenario*

This section addresses possible approaches to designing the market shock component in the severely adverse scenario, including important considerations for scenario design, possible approaches to designing scenarios, and a development strategy for implementing the preferred approach.

5.2.1 Design Considerations for Market Shocks

(a) The general market practice for stressing a trading portfolio is to specify market shocks either in terms of changes to observable, broad financial market indicators and risk factors or directly as changes to the mark-to-market values of financial instruments.

(b) While the number of market shocks used in companies' pricing and stress-testing models typically exceeds that provided in the Board's scenarios, the number of market shocks in the Board's scenarios allows for the consistency and comparability of market losses across companies. However, the benefit from specifying a large set of market shocks is at least partly offset by the potential difficulty in creating shocks that are coherent and internally consistent, particularly as the framework for developing market shocks deviates from historical events. The Board's process for generating the scenario market shocks has developed over time to rely less on models and has expanded its use of simpler methods, such as multipliers and mappings to modeled risk factors.

(c) Also, importantly, the ultimate losses associated with a given market shock will depend on a company's trading positions, which can make it difficult to rank order, ex ante, the severity of the scenarios. In certain instances, market shocks that include large market moves may not be particularly

[14] The means of effecting an adjustment to the severely adverse scenario to address salient systemic risks differs from the means used to adjust variables within the ranges specified by the guides or the paths suggested by the macroeconomic model. For example, in adjusting the scenario for an increased unemployment rate, the Board would modify all variables such that the future paths of the variables would be similar to how these variables have moved historically in response to a change in the unemployment rate. In contrast, to address salient risks, the Board may only modify a small number of variables in the scenario and, as such, their future paths in the scenario would be somewhat more atypical, but not implausible, given existing risks.

stressful for a given company. Aligning the market shock with the macroeconomic scenario for consistency may result in certain companies actually benefiting from risk factor moves of larger magnitude in the market scenario if the companies are hedging against salient risks to other parts of their business. Thus, the severity of market shocks must be calibrated to take into account how a complex set of risks, such as directional risks and basis risks, interacts with each other, given the companies' trading positions at the time of stress. For instance, a large depreciation in a foreign currency would benefit companies with net short positions in the currency while hurting those with net long positions. In addition, longer maturity positions may move differently from shorter maturity positions, adding further complexity.

(d) The sudden nature of market shocks and the early recognition of mark-to-market losses add another element to the design of market shocks, and to determining the appropriate severity of shocks. The design of the market shocks must factor in appropriate assumptions around the period of time during which market events will unfold and any associated market responses.

(e) The design of market shocks includes calibration of shock magnitudes based on assumed time horizons that reflect several scenario design considerations. One consideration is the liquidity characteristics of different asset classes. More specifically, the calibration horizons reflect the variation in speed at which banks could reasonably close out, or effectively hedge, the associated risk exposures in the event of a market stress. The horizons are generally longer than the typical times needed to liquidate exposures under normal conditions because they are designed to capture the unpredictable liquidity conditions that prevail in times of stress. Another consideration is maintaining consistency between the assumed time horizons used to calibrate market shocks and the timeline for attributing the losses stemming from them. Specifically, losses associated with the global market shock component are attributed in one quarter of the stress test horizon, which implies an upper bound of three months for calibrating the shocks.

(f) Given these considerations, shock liquidity horizons are chosen to be broadly consistent with the standards in the Fundamental Review of the Trading Book (FRTB). The horizons in the FRTB are specified based on recommendations from consultations with the financial industry and its regulators. The horizons in the FRTB are therefore considered a reasonable benchmark for defining the shock horizons used in the global market shock. The liquidity horizons used in the market shock scenarios are not expected to be perfectly matched with the FRTB liquidity horizons due to granularity differences between the FRTB standards and the global market shock template. The FRTB specifies horizons at a more granular level, often using different horizons within each asset class, whereas the Board uses the same liquidity horizon for all market shocks within each asset class. Given these differences, the global market shock scenario aims to align with the horizons specified by the FRTB by using a weighted average of the FRTB horizons within each asset class. The weights are determined using aggregate firm exposures. For example, FRTB horizons for equity risk factors vary between 10 and 60 business days, and the global market shock horizon for this asset class is assumed to be 4 weeks. Because the Board imposes an upper bound on global market shock horizons of one quarter, there are cases where in which the range of FRTB horizons is longer than the global market shock horizon. For example, FRTB horizons for corporate credit market shocks vary between 60 and 120 business days, but the Board uses a horizon of 3 months for corporate credit.

5.2.2 Approaches to Market Shock Design

(a) As an additional component of the severely adverse scenario, the Board plans to use a standardized set of market shocks that apply to all companies with significant trading activity. The market shocks could be based on a single historical episode, hypothetical (but plausible) events, or some combination of historical episodes, with or without the addition of-hypothetical events (hybrid approach). Depending on the type of hypothetical events, a scenario based on such events may result in changes in risk factors that were not previously observed.

(b) For the market shock component in the severely adverse scenario, the Board plans to use the hybrid approach to develop shocks. The hybrid approach allows the Board to maintain certain core elements of consistency in market shocks each year while providing flexibility to add hypothetical elements based on market conditions at the time of the stress tests. In addition, this approach will help ensure internal consistency in the scenario because of its basis in historical episodes; however, combining the historical episode and hypothetical events may require some adjustments to ensure mutual consistency of the joint moves. In general, the hybrid approach provides considerable flexibility in developing scenarios that are relevant each year, and by introducing variations in the scenario, the approach will also reduce the ability of companies with significant trading activity to modify or shift their portfolios to minimize expected losses in the severely adverse market shock.

(c) The Board has considered a number of alternative approaches for the design of market shocks. For example, the Board explored an option of providing tailored market shocks for each trading company, using information on the companies' portfolios gathered through ongoing supervision, or other means. By specifically targeting known or potential vulnerabilities in a company's trading position, the tailored approach would be useful in assessing each company's capital adequacy as it relates to the company's idiosyncratic risk. However, the Board does not believe this approach to be well-suited for the stress tests required by regulation. Consistency and comparability are key features of annual supervisory stress tests and annual company-run stress tests required in the stress test rules. It would be difficult to use the information on the companies' portfolios to design a common set of shocks that are universally stressful for all covered companies. As a result, this approach would be better suited to more customized, tailored stress tests that are part of the company's internal capital planning process or to other supervisory efforts outside of the stress tests conducted under the capital rule and the stress test rules.

5.2.3 Development of the Market Shock

(a) Consistent with the approach described above, the market shock component for the severely adverse scenario will incorporate key elements of market developments during historical periods of stress, and may include other price and rate movements in certain markets that the Board deems to be plausible, though such movements may not have been observed historically.

(b) The Board will identify potential market stress scenarios, based on multiple sources of information, including financial stability reports, supervisory information, and internal and external assessments of market risks and potential flash points. The hypothetical elements could originate from major geopolitical, economic, or financial market events with potentially significant impacts on market risk factors. The severity of these hypothetical moves will likely be guided by similar historical events, assumptions embedded in the companies' internal stress tests or market participants, and other available information.

(c) Once broad market scenarios are agreed upon, the implications for key risk factor groups will be defined. For example, a scenario involving the failure of a large, interconnected globally active financial institution could begin with a sharp increase in credit default swap spreads and a precipitous decline in asset prices across multiple markets, as investors become more risk averse and market liquidity evaporates. These broad market movements will be extrapolated to the granular level for all risk factors by examining transmission channels and the historical relationships between variables, though in some cases, the movement in particular risk factors may be amplified based on theoretical relationships, market observations, or the saliency to company trading books. If there is a disagreement between the risk factor movements in the historical event used in the scenario and the hypothetical event, the Board will reconcile the differences by assessing a priori expectations based on financial and economic theory and the importance of the risk factors to the trading positions of the firms.

**6. Consistency Between the Macroeconomic Scenarios and the Market Shock**

(a) As discussed earlier, the market shock comprises a set of movements in a large number of risk factors that are realized in the first quarter of the stress test horizon. Among the risk factors specified in the market shock are several variables also specified in the macroeconomic scenarios, such as short- and long-maturity interest rates on Treasury and corporate debt, the level and volatility of U.S. stock prices, and exchange rates.

(b) The market shock component is an add-on to the macroeconomic scenarios that reflects abrupt market disruptions. As a result, the market shock component may not

always be directionally consistent with the macroeconomic scenario. Because the market shock is designed, in part, to mimic the effects of a sudden market dislocation, while the macroeconomic scenarios are designed to provide a description of the evolution of the real economy over two or more years, assumed economic conditions can move in significantly different ways. In effect, the market shock can simulate a market panic, during which financial asset prices move rapidly in unexpected directions, and the macroeconomic assumptions can simulate the severe recession that follows. Indeed, the pattern of a financial crisis, characterized by a short period of wild swings in asset prices followed by a prolonged period of moribund activity, and a subsequent severe recession is familiar and plausible.

(c) As discussed in section 4.2.3, the Board may feature a particularly salient risk in the macroeconomic assumptions for the severely adverse scenario, such as a fall in an elevated asset price. In such instances, the Board may also seek to reflect same risk in the market shock. For example, if the macroeconomic scenario were to feature a substantial decline in house prices, it may be plausible for the market shock to feature a significant decline in market values of any securities that are closely tied to the housing sector or residential mortgages.

**7. Timeline for Scenario Publication**

(a) The Board will provide a final description of the macroeconomic scenarios by no later than February 28. During the period immediately preceding the publication of the scenarios, the Board will collect and consider information from academics, professional forecasters, international organizations, domestic and foreign supervisors, and other private-sector analysts that regularly conduct stress tests based on U.S. and global economic and financial scenarios, including analysts at the firms. In addition, the Board will consult with the FDIC and the OCC on setting the guides in the scenarios. The Board expects to conduct this process each year and disclose the developed scenarios for public comment. The Board will update the scenarios, based on the public comments and incoming macroeconomic data releases and other information.

(b) The Board expects to provide a broad overview of the market shock component along with the macroeconomic scenarios. The Board will publish the market shock templates by no later than March 1 of each year.

TABLE 1—CLASSIFICATION OF U.S. RECESSIONS

| Peak (1) | Trough (2) | Severity (3) | Duration (quarters) (4) | Decline in real GDP (5) | Change in the unemployment rate during the recession (6) | Total change in the unemployment rate (incl. after the recession) (7) |
|---|---|---|---|---|---|---|
| 1957Q3 | 1958Q2 | Severe | 4 (Medium) | −3.0 | 3.2 | 3.2 |
| 1960Q2 | 1961Q1 | Moderate | 4 (Medium) | −0.1 | 1.6 | 1.8 |
| 1969Q4 | 1970Q4 | Moderate | 5 (Medium) | −0.2 | 2.2 | 2.4 |
| 1973Q4 | 1975Q1 | Severe | 6 (Long) | −3.1 | 3.5 | 4.1 |
| 1980Q1 | 1980Q3 | Moderate | 3 (Short) | −2.2 | 1.4 | 1.4 |
| 1981Q3 | 1982Q4 | Severe | 6 (Long) | −2.5 | 3.3 | 3.3 |
| 1990Q3 | 1991Q1 | Mild | 3 (Short) | −1.4 | 0.9 | 1.9 |
| 2001Q1 | 2001Q4 | Mild | 4 (Medium) | 0.5 | 1.3 | 1.9 |
| 2007Q4 | 2009Q2 | Severe | 7 (Long) | −3.8 | 4.5 | 5.1 |
| 2019Q4 | 2020Q2 | Severe | 2 (Short) | −9.2 | 9.4 | 9.4 |
| Average | | Severe | 5 | −4.3 | 4.8 | 5 |
| Average | | Moderate | 4 | −0.8 | 1.7 | 1.9 |
| Average | | Mild | 3 | −0.4 | 1.1 | 1.9 |

Source: Bureau of Economic Analysis, National Income and Product Accounts and Bureau of Labor Statistics.

**Notes:** (1) Peak refers to a peak quarter of the business cycle as defined by the NBER US Business Expansions and Contractions; (2) Trough refers to a trough quarter of the business cycle as defined by the NBER US Business Cycle Expansions and Contractions; (3) There is no universal agreement on how to categorize recession severity. For the purposes of this table, the following categorization is employed: Recessions where the decline in real GDP or the increase in the unemployment rate are less than 1.5 percent or 1.5 percentage points, respectively, are considered mild; recessions where the decline in real GSP is 2.5 percent or more, or the increase in the unemployment rate is 3 percentage points or more, are considered severe; all other recessions are considered moderate; (4) Recession duration is categorized as follows: <4 quarters, short; 4–5 quarters, medium; >5 quarters, long; (5) Real GDP is real GDP adjusted for inflation from the Bureau of Economic Analysis (National Income and Products Accounts table 1.1.6, line 1); (6) Unemployment rate is the quarterly average of seasonally adjusted monthly unemployment rates for the civilian, non-institutional population aged 16 years and older from Bureau of Labor Statistics (series LNS14000000); (7) Total change in the unemployment rate (incl. after the recession) calculates the difference between the maximum unemployment rate achieved during the NBER-defined recession period or the subsequent six quarters and the value of the unemployment rate during the peak quarter.

TABLE 2—HOUSE PRICES IN HOUSING RECESSIONS

| Peak | Trough | Severity | Duration (quarters) | %-Change in NHPI | %-Change in HPI–DPI | HPI–DPI trough level (2000:Q1 = 100) |
|---|---|---|---|---|---|---|
| 1980Q2 | 1985Q2 | Moderate | 19 (long) | 24.2 | −13.1 | 100.2 |
| 1989Q4 | 1997Q1 | Moderate | 30 (long) | 12.5 | −16.8 | 93.6 |
| 2005Q4 | 2012Q1 | Severe | 25 (long) | −28.7 | −40.4 | 89.5 |
| Average | | | 24.7 | 2.7 | −23.4 | 94.4 |

Source: CoreLogic, Bureau of Economic Analysis.

**Note:** The date ranges of housing recessions listed in Table 2 are based on the timing of house-price retrenchments.

■ 17. In appendix B to part 252:
■ a. Revise paragraph (a) of section 2.1.
■ b. Revise section 2.2.
■ c. Remove the text ''and non-public information about'' from paragraph (b) of section 3.1.
■ d. Revise paragraph (c) of section 3.2.

The revisions read as follows:

## Appendix B to Part 252—Stress Testing Policy Statement

* * * * *

*2.1 Soundness in Model Design*

(a) During development, the Federal Reserve

(i) subjects supervisory models to extensive review of model theory and logic and general conceptual soundness;

(ii) examines and evaluates justifications for modeling assumptions;

(iii) tests models to establish the accuracy and stability of the estimates and forecasts that they produce; and

(iv) invites, evaluates, and responds to substantive public input on material model changes.

* * * * *

*2.2. Disclosure of Information Related to the Supervisory Stress Test*

(a) In general, the Board does not disclose information related to the supervisory stress test to covered companies if that information is not also publicly disclosed. However, the Board will generally provide additional information directly to a covered company about such covered company's supervisory stress test results, provided that the Board will only do so if it provides the same type of information to all other covered companies participating in the same stress test cycle.

(b) The Board has increased the breadth of its public disclosure since the inception of the supervisory stress test to include comprehensive descriptions of the supervisory stress models, changes to those models, and, for each supervisory stress test cycle, more information about model changes and key risk drivers, in addition to more detail on different components of projected net revenues and losses. Increasing public disclosure can help the public understand and interpret the results of the supervisory stress test, particularly with respect to the condition and capital adequacy of participating firms. Providing additional information about the supervisory stress test allows the public to make an evaluation of the quality of the Board's assessment. This policy also promotes consistent and equitable treatment of covered companies by ensuring that institutions do not have access to information about the supervisory stress test that is not also accessible to other covered companies, corresponding to the principle of consistency and comparability.

* * * * *

*3.2. Technical Competence of Validation Staff*

* * * * *

(c) The model validation program covers three main areas of validation:

(1) Conceptual soundness;

(2) ongoing monitoring; and

(3) outcomes analysis. Validation staff evaluates all aspects of model development, implementation, and use, including but not limited to theory, design, methodology, input data, testing, performance, documentation standards, implementation controls (including access and change controls), and code verification.

* * * * *

## PART 265—RULES REGARDING DELEGATION OF AUTHORITY

■ 18. The authority citation for part 265 continues to read as follows:

**Authority:** 12 U.S.C. 248(i) and (k).

## Subpart B—Delegations of Authority

■ 19. In § 265.7, revise paragraph (c)(11)(i)(A) to read as follows:

**§ 265.7 Functions delegated to the Director of the Division of Supervision and Regulation.**

* * * * *

(c) * * *

(11) * * *

(i) * * *

(A) To develop proposed and final scenarios, respond to public input received on draft scenarios, and publish in the **Federal Register** notices of such scenarios, including, but not limited to, the baseline scenario and the severely adverse scenario, that the Board would use to conduct analyses under § 238.132 of Regulation LL (12 CFR 238.132) or § 252.44 of Regulation YY (12 CFR 252.44) and that a company would use to conduct its stress tests under § 238.143 of Regulation LL (12 CFR 238.143) or § 252.14 or § 252.54 of Regulation YY (12 CFR 252.14 or 252.54), as appropriate; and

* * * * *

■ 20. In § 265.13, revise paragraph (a)(1)(i)(A) to read as follows:

**§ 265.13 Functions delegated to the Director of the Division of Financial Stability.**

* * * * *

(a) * * *

(1) * * *

(i) * * *

(A) To develop proposed and final scenarios, respond to public input received on draft scenarios, and publish in the **Federal Register** notices of such scenarios, including, but not limited to, the baseline scenario and the severely adverse scenario, that the Board would use to conduct analyses under § 238.132 of Regulation LL (12 CFR 238.132) or § 252.44 of Regulation YY (12 CFR 252.44) and that a company would use to conduct its stress tests under § 238.143 of Regulation LL (12 CFR 238.143) or § 252.14 or § 252.54 of Regulation YY (12 CFR 252.14 or 252.54), as appropriate; and

* * * * *

By order of the Board of Governors of the Federal Reserve System.

**Michele Taylor Fennell,**

*Associate Secretary of the Board.*

[FR Doc. 2026–20247 Filed 10–1–26; 8:45 am]

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Part IV

## Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 513

Global Benchmark for Efficient Drug Pricing (GLOBE) Model; Interim Final Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 513**

**[CMS–5545–F]**

**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:** Final rule.

**SUMMARY:** This final rule implements the Global Benchmark for Efficient Drug Pricing Model (GLOBE Model), a new mandatory Medicare payment model under section 1115A of the Social Security Act. The GLOBE Model will test whether a payment model that uses an alternative method for calculating Medicare Part B drug inflation rebate amounts for certain separately payable Medicare Part B drugs and biological products reduces costs for Original Medicare (OM) beneficiaries and the Medicare program while preserving quality of care. The term OM has the same meaning as Medicare fee-for-service and the traditional Medicare program.

**DATES:** These regulations are effective on November 30, 2026.

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**SUPPLEMENTARY INFORMATION:**

### I. Executive Summary and Background

#### *A. Background Overview*

The high cost of healthcare continues to impact many Americans' lives. According to the West Health-Gallup Affordability Index, only 61 percent of adults over age 65 in the United States (U.S.) are considered ''Cost Secure,'' where a person has ''access to quality, affordable care and ha[s] been able to pay for visits and prescriptions in recent months.'' [1] Simultaneously, health insurance costs continue increasing. Challenges related to the affordability of prescription drugs adversely affect taxpayers by diverting funds that could be used to improve health.

Medicare Part B funding comes from two sources: beneficiary premiums and general Federal revenues. Total Medicare Part B beneficiary premium amounts increased by $39 billion, or 53 percent, from 2016 to 2021.[2] While this increase may be due to the total number of Medicare beneficiaries increasing from 52 million to 58 million in that period, the premium amount per enrollee also increased from $1,423 in 2016 to $1,942 in 2021.[3] Concurrently, the annual Federal revenue contribution has also increased from $235.6 billion in 2016 to $386.0 billion in 2024, illustrating increased burdens across all financing mechanisms in Medicare Part B.[4]

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.[5] [6] 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.[7] 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.[8] Financial toxicity, or the negative impact that the monetary burden of medical care can have on patients' well-being, fiscal security, and overall health,[9] can be most pronounced among the elderly population and among patients with low income and for whom the cost of treatment can be high. 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.[10] A separately conducted survey 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.[11] [12] 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).[13] [14] [15] One study has theorized Medicare beneficiaries without supplemental insurance are limited in accessing

[1] Ellyn Maese, Gallup. U.S. Adults' Ability to Afford Healthcare at a Five-Year Low, June 17, 2026. Available at: *https://news.gallup.com/poll/710942/adults-ability-afford-healthcare-five-year-low.aspx.*

[2] Centers for Medicare & Medicaid Services. CMS Program Statistics—Medicare Premiums, Table, MDCR Premiums 4. Available at: *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-premium-reports/cms-program-statistics-medicare-premiums.*

[3] These enrollment numbers include total Medicare Part B beneficiaries in OM Part B, Medicare Advantage plans, section 1876 cost plans, and section 1833 healthcare prepayment plans. OM Part B enrollment for 2016 and 2021 was 34 million and 31 million, respectively.

[4] Centers for Medicare & Medicaid Services, Office of the Actuary. 2025 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, June 2025. Available at: *https://www.cms.gov/oact/tr/2025.*

[5] Piette, J., Langa, K., Kabeto, M., Vijan, S., Rosen, A., Choi, H., & Heisler, M. (2010). Hospitalizations and Deaths Among Adults With Cardiovascular Disease Who Underuse Medications Because of Cost: A Longitudinal Analysis. *Medical Care, 48*(2), 87–94. *https://doi.org/10.1097/MLR.0b013e3181c12e53.*

[6] Blanchard J, Madden JM, Ross-Degnan D, Gresenz CR, Soumerai SB. The relationship between emergency department use and cost-related medication nonadherence among Medicare beneficiaries. Ann Emerg Med. 2013 Nov;62(5):475–485. doi: 10.1016/j.annemergmed.2013.04.013. Epub 2013 May 28. PMID: 23726522; PMCID: PMC3812390.

[7] 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.*

[8] 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/.*

[9] 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.

[10] 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/.*

[11] 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.*

[12] 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.*

[13] Nekhlyudov, L., Madden, J., Graves, A. J., Zhang, F., Soumerai, S. B., & Ross-degnan, D. (2011). Cost-related medication nonadherence and cost-saving strategies used by elderly Medicare cancer survivors. *Journal of Cancer Survivorship, 5*(4), 395–404. doi: 10.1007/s11764–011–0188–4

[14] 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.

[15] 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.

immune checkpoint inhibitors (ICIs) due to the high cost of coinsurance.[16]

Studies have also shown that the impact 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, finding 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.[17] 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.[18] Similarly, research has also found an increased risk of mortality among patients with certain types of cancer who filed for bankruptcy, compared with those who did not file.[19]

Research conducted by the Assistant Secretary for Planning and Evaluation (ASPE) and the RAND Corporation reveals a substantial and growing disparity between U.S. prescription drug prices and those of peer nations across the Organisation for Economic Co-operation and Development (OECD). An ASPE-funded study originally published in July 2022—using 2018 pricing data—found that U.S. drug prices with available pricing information exceeded the combined average of non-U.S. OECD countries by 256 percent.[20] A subsequent 2024 update incorporating 2022 pricing data demonstrated that this gap had widened further to 278 percent.[21] The disparity is most pronounced for originator (brand-name) drugs, where U.S. prices surpass the non-U.S. OECD average by 422 percent, with G7 country comparisons ranging from 324 percent above Canada to 464 percent above Japan.[22] A separate ASPE analysis focused on the top 50 Medicare Part B drugs—which collectively accounted for 80 percent of total 2018 Medicare Part B drug expenditures—found that U.S. prices were, on average, 211 percent higher than those in comparable OECD nations, with G7 country differentials ranging from 148 percent above Japan to 225 percent above France.[23]

*B. Purpose*

Prices for prescription drugs in the U.S.—including drugs covered under Medicare Part B—remain high, contributing to increased program expenditures. To address this challenge, this final rule implements a new mandatory payment model: the Global Benchmark for Efficient Drug Pricing (GLOBE) Model. The GLOBE Model is established under section 1115A of the Social Security Act (the Act), which authorizes CMS's Center for Medicare and Medicaid Innovation (hereinafter, ''the CMS Innovation Center'') to test innovative payment and service delivery models to evaluate whether they reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of care for beneficiaries of such programs. The Inflation Reduction Act of 2022 (Pub. L. 117–169, enacted August 16, 2022) (IRA) established the Medicare Part B Drug Inflation Rebate Program, which requires drug manufacturers to pay a rebate when they raise prices for certain drugs faster than the rate of inflation. CMS calculates and invoices these rebates, which are deposited into the Medicare Prescription Drug Account within the Federal Supplementary Medical Insurance Trust Fund. Building on this framework, the CMS Innovation Center is finalizing the GLOBE Model to test an alternative approach to calculating Medicare Part B drug inflation rebates for certain Part B drugs and biological products. The model's purpose is to evaluate whether this alternative approach will reduce program expenditures while maintaining or enhancing quality of care for beneficiaries. The GLOBE Model will begin on January 1, 2027 with the collection of voluntary manufacturer-submitted international drug net pricing data, and will be tested over 5 performance years, running from April 1, 2027 through March 31, 2032. The associated payment period will run from April 1, 2027 through March 31, 2034.

*C. Summary of Major Provisions*

The GLOBE Model will test changes to the Medicare Part B Drug Inflation Rebate Program, specifically testing whether an alternative calculation for the Medicare Part B drug inflation rebate for certain drugs and biological products will reduce program spending for Medicare and taxpayers while preserving or enhancing the quality of care furnished to Medicare beneficiaries. We are finalizing the GLOBE Model to include the following major provisions.

1. Model Performance and Test Period

The GLOBE Model will begin on January 1, 2027, with the collection of voluntary manufacturer-submitted international drug net pricing data. The model will include 5 performance years, which will begin on April 1, 2027 and will end on March 31, 2032, during which the GLOBE Model beneficiary coinsurance and adjusted payments to providers and suppliers would apply and monitoring activities will occur. The model will also include a 7-year payment period, which will begin on April 1, 2027 and will end on March 31, 2034, during which CMS will calculate, invoice, collect, and reconcile the GLOBE Model rebates for a performance year. The model evaluation will reflect the entire GLOBE Model test period—which includes the voluntary manufacturer submission period and the 7-year payment period.

2. GLOBE Model Drugs

The GLOBE Model will focus on a set of Part B rebatable drugs that are single source drugs and sole source biological products and that are furnished to a cohort of beneficiaries in the OM program. The set of included drugs, as described in section II.B. of this final

[16] Horn, D., Alpert, A., Duggan, M., Jacobson, M. The impact of immunotherapy on reductions in cancer mortality: Evidence from Medicare. *Journal of Health Economics,* 2026, 106. doi: 10.1016/j.jhealeco.2026.103115.

[17] 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.

[18] 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.*

[19] Ramsey, Scott D., et al. Financial Insolvency as a Risk Factor for Early Mortality Among Patients With Cancer. *Journal of Clinical Oncology,* 2016, 34(9): 980–986. doi: 10.1200/JCO.2015.64.6620.

[20] Ratios from this study are not adjusted for differences in purchasing power-adjusted GDP per capita. *See* Andrew W. Mulcahy, Christopher M. Whaley, Mahlet G. Tebeka, 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.*

[21] 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/.*

[22] The G7 countries are Canada, France, Germany, Italy, Japan, the United Kingdom, and the U.S.

[23] Office of the Assistant Secretary for Planning and Evaluation. Medicare FFS Part B and International Drug Prices: A Comparison of the Top 50 Drugs, 2020. Available at: *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//197401/Part-B%20Drugs-International-Issue-Brief.pdf.*

rule, will include certain Part B rebatable drugs as identified in 42 Code of Federal Regulations (CFR) 427.101 for the purpose of the Medicare Part B Drug Inflation Rebate Program and that meet the definition of GLOBE Model drugs in § 513.130. Specifically, the GLOBE Model will include a subset of Part B rebatable drugs that have the following United States Pharmacopeia (USP) Drug Classification (DC) categories: Antigout Agents, Antineoplastics, Blood Products and Modifiers, Central Nervous System Agents, Immunological Agents, Metabolic Bone Disease Agents, and Ophthalmic Agents. These drugs must have a Healthcare Common Procedure Coding System (HCPCS) Level II code with OM Part B spending greater than $100 million over a 12-month period ending 6 months prior to the start of the applicable calendar quarter (as further specified in § 513.130(b)(3) and § 513.130(d)) and must not be excluded from the GLOBE Model as set forth in § 513.130(c).

The following drugs and biological products are excluded from the GLOBE Model as set forth in § 513.130(c): (1) 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); (2) a Part B rebatable drug for which a maximum fair price under the Medicare Drug Price Negotiation Program is in effect; (3) a drug or biological product which is no longer a Part B rebatable drug; (4) a Part B rebatable drug that is designated as a drug for one or more rare diseases or conditions under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) and for which the only approved indication (or indications) is for one or more such rare disease or conditions; (5) a Part B rebatable drug that is a product listed on the FDA Approved Cellular and Gene Therapy Products website; and (6) a Part B rebatable drug that is a plasma-derived product as set forth in 42 CFR 427.400. Items (4), (5), and (6) were added to § 513.130(c) in response to public comments received during the comment period for the GLOBE Model proposed rule (90 FR 60244 through 60336). Drug selection (and removal, if applicable) for the model test will be determined by CMS based on the eligibility criteria and will not be subject to appeal, pursuant to section 1115A(d)(2) of the Act.

3. Defined Population and Intervention

The model cohort, as described in section II.C of this final rule, will be identified by CMS from approximately 25 percent of beneficiaries who are enrolled in OM Part B, have OM Part B as their primary payer (as defined by a beneficiary being enrolled in OM), and are not enrolled in a Medicare Advantage (MA) plan, section 1876 cost plan,[24] or section 1833 healthcare prepayment plan.[25] Beneficiaries must not have other group health coverage that is a primary payer (such as employer-sponsored health insurance). The GLOBE Model geographic areas will be determined through a random selection of ZIP Code Tabulation Areas (ZCTAs). Prior to the model performance period, and no more frequently than monthly thereafter, CMS will identify beneficiaries for inclusion in the model cohort by determining whether the beneficiary's address of record falls within the GLOBE Model geographic areas. To be eligible for inclusion in the model cohort, a beneficiary must not be identified by CMS for inclusion in the comparison group and must otherwise meet the eligibility criteria for inclusion. Medicare beneficiaries who are in the model cohort, or ''GLOBE Model beneficiaries,'' will not be model participants [26] but will benefit from reduced coinsurance, as applicable, when they receive a separately payable GLOBE Model drug as described in section II.G.7. of this final 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 GLOBE Model drug will be eligible for GLOBE Model reduced coinsurance and included in the calculation of GLOBE Model billing units, as applicable, as described in section II.G.4. of this final rule. To identify the GLOBE Model beneficiary coinsurance amount for GLOBE Model drugs and 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, CMS will compare the per unit GLOBE Model benchmark amount as set forth in § 513.400(c)(4) 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. Beneficiary selection for the model cohort and comparison group (and removal, if applicable) will be solely determined by CMS and will not be subject to appeal pursuant to section 1115A(d)(2) of the Act. Providers and suppliers who furnish GLOBE Model drugs to GLOBE Model beneficiaries who are in the model cohort will not be model participants and will 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, and other pharmacies (in certain situations). When the reduced beneficiary coinsurance applies to units of GLOBE Model drugs furnished to a GLOBE Model beneficiary, the provider or supplier will reduce the amount of coinsurance charged to the beneficiary and the portion of the Medicare Part B allowed amount that will be payable by Medicare Part B will be adjusted upwards, as applicable. For example, if the Medicare Part B allowed amount for a GLOBE Model drug 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 will be adjusted upward and will be $90 (instead of the usual $80) and the beneficiary coinsurance financial responsibility will be $10 (instead of the usual $20).

4. Manufacturer Participation

The GLOBE Model will require mandatory participation for all manufacturers (as defined in 42 CFR 427.20) of Part B rebatable drugs that are GLOBE Model drugs. When Part B rebatable drugs subject to the GLOBE Model are furnished to OM beneficiaries who are in the model cohort, manufacturers that are GLOBE Model participants will 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 will be based on available international drug pricing information (as described in section II.G. of this final rule). This amount will not be less than any rebates owed under the Medicare Part B Drug Inflation Rebate Program and will be invoiced using an incremental approach (as described in section II.G.8. of this final rule). The GLOBE Model rebate amount will only apply to certain units of the GLOBE Model drugs (as specified in § 513.520) and will be solely

[24] As established in section 1876 of the Act (42 U.S.C. 1395mm).

[25] As established in section 1833 of the Act (42 U.S.C. 1395l).

[26] As discussed in section II.E. of this final rule, manufacturers of GLOBE Model drugs will be model participants.

determined by CMS and will not be subject to appeal, pursuant to section 1115A(d)(2) of the Act. Manufacturers may submit a Suggestion of Error (SOE) if they believe that a mathematical error exists and requires a correction.

5. Model Alternative Rebate Amount Calculation and Rebate Payment

As described in section II.G.2. of this final rule, the GLOBE Model will incorporate two approaches for establishing a benchmark amount for the alternative rebate amount calculation, each using differently sourced international drug pricing information and distinct calculation methodologies. The model evaluation will assess the impact of testing these two approaches. The first approach, Method I, as described in section II.G.2.a. of this final rule, will use existing, commercially available international drug pricing information to establish a benchmark based on an estimate of the lowest country-level price among the set of reference countries, as set forth in § 513.310, at a baseline. This pricing data may represent drug-specific sales data, list prices, ex-manufacturer prices, retail prices, other prices, or a combination of such pricing information, as available to CMS in commercially available data sources.

The second approach, Method II, as described in section II.G.2.b. of this final rule, will use voluntary manufacturer-submitted international drug net pricing data to establish a benchmark based on an average international price among the set of countries. This benchmark will reflect net prices realized by a manufacturer. Manufacturer submission of international drug net pricing data is discussed in section II.G.6. of this final rule.

CMS is finalizing that the set of reference countries for Method I and Method II benchmarks, as set forth in § 513.310(b), will include Australia, Austria, Belgium, Canada, Czech Republic, Denmark, France, Germany, Ireland, Israel, Italy, Japan, Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom.

The GLOBE Model is designed to capture all applicable billing units for separately payable OM Part B claims for GLOBE Model drugs that are: (1) furnished to OM Part B beneficiaries in the model cohort on the date of service; (2) paid under the GLOBE Model for dates of service during a performance year; and (3) could be subject to the GLOBE Model beneficiary coinsurance and adjusted payments to providers and suppliers. For purposes of calculating the total and incremental GLOBE Model rebate amount for a GLOBE Model drug that a manufacturer would owe, CMS will identify applicable billing units several months after the end of a calendar quarter, as described in section II.G. of this final rule. Additional time is required for the calculation of these rebate amounts and the preparation of invoices. As a result, GLOBE Model operational processes—including claims processing, data collection, invoicing, payment of GLOBE Model rebates, and reconciliation—will occur concurrently with, and continue after the end of each performance year, including after the conclusion of the last performance year. In addition, CMS will use an incremental invoicing approach for these GLOBE Model operational processes which is described in section II.G.8. of this final rule.

6. Model Waivers

CMS has determined that it will 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, as described in 1115A(b) of the Act. Specifically, as further described in section II.O. of this final rule, pursuant to the CMS Innovation Center's waiver authority under section 1115A(d)(1) of the Act, CMS will waive provisions of sections 1847A(i), 1833(a), and 1833(t) of the Act, as well as associated regulatory provisions at 42 CFR 410.152(m), 419.41(e), 489.30(b)(1), and 489.30(b)(6), to the extent necessary to permit the testing of an alternative rebate amount calculation for certain units of GLOBE Model drugs, the collection of GLOBE Model rebate amounts, GLOBE Model reduced coinsurance, and adjusted Medicare payment.

In this final rule, CMS is codifying the requirements of the GLOBE Model at 42 CFR part 513. Section 513.1(d) provides that should any provision of part 513 be held invalid or unenforceable—whether by its terms, or as applied to any person or circumstance—such provision will be severable from the remainder of part 513, and the invalidity or unenforceability of that provision will not affect the remainder of the provisions of part 513.

7. Enforcement of Manufacturer Payment of Rebate

Consistent with the enforcement framework of the Medicare Part B Drug Inflation Rebate Program, manufacturers of a GLOBE Model drug that have failed to timely pay the incremental GLOBE Model rebate amount may be subject to a civil money penalty (CMP). Further details on the enforcement of manufacturer payment of rebates are provided in section II.H. of this final rule.

8. Quality and Monitoring Strategy

CMS has finalized a quality and monitoring strategy for the GLOBE Model. CMS will monitor and evaluate whether the alternative Medicare Part B drug inflation rebate calculation under the GLOBE Model reduces Medicare spending while preserving or enhancing the quality of care for beneficiaries. Consistent with section 1115A(b)(4) of the Act, CMS will conduct ongoing monitoring and evaluation activities throughout the model performance period to identify potential changes in beneficiary access to GLOBE Model drugs, utilization and prescribing patterns, beneficiary out-of-pocket costs, continuity and site of care, downstream healthcare utilization, drug availability and distribution patterns, and other unintended consequences. CMS will rely primarily on claims-based measures and existing data sources and may use targeted, voluntary surveys or other supplemental data collection, as appropriate, while seeking to minimize additional burden. Further details on the GLOBE Model quality, monitoring, and evaluation strategy are provided in sections II.J., II.L., and II.P. of this final rule.

9. Beneficiary Protections

CMS has finalized beneficiary protections activities for the GLOBE Model. CMS will not require direct beneficiary notification or establish a beneficiary opt-out because inclusion in the model does not require beneficiaries to enroll or take any action and does not change Medicare coverage or provider choice. CMS will coordinate, to the extent feasible, with 1–800–MEDICARE, the Medicare Ombudsman, and the CMS Office of Program Operations and Local Engagement (OPOLE) and will make a GLOBE Model helpdesk available so beneficiaries, providers, and other stakeholders can report model-related concerns. CMS will post accessible technical documentation, user-friendly fact sheets, FAQs, the GLOBE Model Drug HCPCS Level II Code List, and the model geographic areas on the GLOBE Model website to support beneficiary and provider awareness. Further details on beneficiary protections are provided in section II.K. of this final rule.

10. Interaction and Coordination With Other Models and Programs

CMS reviewed potential interactions between the GLOBE Model and other models and programs to ensure that the

evaluation of model impact is not compromised by issues of model overlap. The GLOBE Model has been designed to function alongside and in addition to the Medicare Part B Drug Inflation Rebate Program. Further details on CMS's approach to overlap of the GLOBE Model with other CMS Innovation Center Models and interaction with other Federal programs are provided in sections II.M. and II.N. of this final rule, respectively. Existing CMS Innovation Center Models may utilize waiver authority to waive the requirement of mandatory participation of manufacturers of GLOBE Model drugs is further discussed in section II.M. of this final rule.

11. Evaluation Methods

The GLOBE Model evaluation will employ a design to provide evidence that the proposed intervention would reduce Medicare expenditures and would preserve or enhance the quality of care for Medicare beneficiaries. 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. Consistent with the purpose of section 1115A of the Act, the collection and analysis of these data would also generate evidence on the effects of an international benchmark-based rebate methodology on Medicare expenditures, and quality of care that could inform future legislative action relating to such policies. Further details on the evaluation methodology, including data collection methods, key evaluation research questions, and the evaluation period and anticipated reports, are provided in section II.P. of this final rule.

*D. Summary of Costs and Benefits*

In section IV. of this final rule, we set forth a detailed analysis of the regulatory and Federalism impacts that the GLOBE Model may have on affected entities and beneficiaries. Tables 13, 14, and 15 in section IV.D. of this final rule display the estimated overall impact of the GLOBE Model on the Medicare and Medicaid programs.

We estimate that the GLOBE Model will result in overall savings of $440 million [27] in Medicare Part B net spending during the 7-year payment period, inclusive of $298 million in OM Part B benefit savings, $288 million in MA payment savings, and $147 million in premium offset impacts. In this estimate, we assume manufacturer behavioral changes and beneficiary utilization changes, as described in section IV. of this final rule. We estimate savings for the MA program of $288 million due to the way CMS calculates MA rates based on OM claims, which will include claims paid under the GLOBE Model beginning with rate setting for 2028. We also estimate savings for the Medicaid program of $39 million, of which roughly $17 million will be Federal premium savings, $6 million will be Federal cost sharing savings, $10 million will be state premium savings, and $5 million will be state cost sharing savings.[28] When annualized over the 7-year payment period, we estimate that the GLOBE Model will result in overall cost savings in Medicare Part B net spending of approximately $80 million at either the 3 percent or 7 percent rates of discount.

*E. Background*

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 U.S. and that most of these categories have shown notable growth between 2023 and 2024.[29] This trend is also observed in Part B rebatable drugs, where these five therapeutic classes represent at least $42 billion (or 60 percent) in OM Part B drug allowed charges in 2024.[30] [31]

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 IRA 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.

OM Part B drug spending [32] has also grown by 85.8 percent ($18.7 billion) [33] from 2014 to 2021 with the standard monthly Medicare Part B premium for beneficiaries increasing by 41.5 percent ($104.90 [34] to $148.50 [35]). Based on the increasing OM Part B and beneficiary drug spending, we proposed, and are finalizing, to test a model to reduce OM Part B drug spending and beneficiary coinsurance amounts using international drug pricing information as a benchmark for an alternative Medicare Part B inflation rebate amount calculation for certain single source drugs and sole source biological products while preserving or enhancing quality of care.

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 physicians' 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 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, and certain other outpatient settings, such as ambulatory

[27] Overall Medicare Part B net spending savings are calculated by adding OM Part B benefit savings and MA payment savings and then subtracting the premium offset. Totals do not add up due to rounding. See section IV. of this final rule for the Final Regulatory Impact Analysis.

[28] Note: Totals do not add up due to rounding. See section IV. of this final rule for the Final Regulatory Impact Analysis.

[29] HDA Research Foundation. HDA 96th Edition HDA Factbook. The Facts, Figures, and Trends in Healthcare (2025–2026). Available at: *https://www.hda.org/publications/.*

[30] Dickson, S.R., and James, K.E. Medicare Part B Spending on Macular Degeneration Treatments Associated with Manufacturer Payments to Ophthalmologists. *JAMA Health Forum,* 2023, 4 (9): e232951. doi:10.1001/jamahealthforum.2023.2951.

[31] 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 Epidemio,* 2024, 31(5): 468–477. doi: 10.1080/09286586.2024.2310854.

[32] Measured by drug allowed charges.

[33] Assistant Secretary for Planning and Evaluation. Medicare Part B Drug Pricing, June 9, 2023. Available at: *https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf.*

[34] Centers for Medicare & Medicaid Services. CMS announces major savings for Medicare beneficiaries. Available at: *https://www.cms.gov/newsroom/press-releases/cms-announces-major-savings-medicare-beneficiaries.*

[35] Centers for Medicare & Medicaid Services. 2021 Medicare Parts A & B Premiums and Deductibles. Available at: *https://www.cms.gov/newsroom/fact-sheets/2021-medicare-parts-b-premiums-and-deductibles.*

surgery centers. When Medicare allows separate payment for these drugs, the payment limit is typically based on the methodology described in section 1847A of the Act, with certain exceptions, such as the methodology described in section 1833(t)(14)(A)(iii) 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, the Hospital Outpatient Prospective Payment System, 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 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 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 IRA requires a temporary, 5-year increase for qualifying biosimilar biological products (as defined in section 1847A(b)(8)(B)(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)(B)(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 payment limit for a HCPCS Level II code is calculated quarterly by CMS using manufacturer-submitted ASP data on sales to all purchasers (with limited exceptions as articulated in section 1847A(c)(2) of the Act,[36] such as sales at nominal charge and sales exempt from Medicaid best price)[37] 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). As a general matter, the ASP-based payment limit that Medicare pays for a separately payable OM Part B 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 a MedPAC report,[38] 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-sharing[39] is generally 20 percent of the Medicare-allowed amount. The term ''Medicare-allowed amount'' means the maximum amount that a provider or supplier will be paid for a covered health care service or drug. However, for items and services paid under the OPPS, beneficiaries are only financially responsible for a copayment amount up to the amount of the inpatient hospital deductible.[40] Medicare pays for the remaining portion of the Medicare allowed amount.[41]

b. Medicare Part B Drug Inflation Rebate Program

Section 11101 of the IRA established requirements under which drug manufacturers must pay Medicare 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, which may change pursuant to changes in CFR 427.101,[42] include: (1) qualifying biosimilar biological products;[43] (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 per year per individual under the applicable threshold; (7) certain vaccines and other products;[44] and (8) generic drugs.[45] 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

[36] OMB Control Number 0938–0921, Centers for Medicare & Medicaid Services.

[37] Best price is defined in section 1927(c)(1)(C) of the Act.

[38] MedPAC. Medicare Part B Drug Payment Policy Issues, June 2017, Available at: *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun17_ch2.pdf.*

[39] Not including the annual deductible.

[40] 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.

[41] 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.*

[42] In the CY 2027 PFS Proposed Rule (91 FR 44006), CMS proposed that skin substitute products licensed as a drug or biological product under section 351 of the PHS Act would be rebatable.

[43] 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.

[44] This includes influenza, pneumococcal, hepatitis B, and COVID–19 vaccines, and monoclonal antibodies used for treatment or post-exposure prophylaxis of COVID–19.

[45] Drugs submitted in an Abbreviated New Drug Application (ANDA) and approved under section 505(j) of the FD&C Act.

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.[46]

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. To implement section 11101 of the IRA, in the CY 2025 PFS final rule (89 FR 98228 through 98313) [47] 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),[48] CMS adopted certain limited modifications to the policies for the Medicare Part B Drug Inflation Rebate Program set forth in part 427 under title 42, chapter IV of the CFR for Part B. For example, 42 CFR 427.302(c)(5) described how CMS identifies the payment amount benchmark quarter in certain instances and the calculation for the Medicare Part B drug inflation rebate amount in such instances. In the CY 2027 PFS proposed rule (91 FR 43842 through 44557),[49] CMS proposed additional limited modifications to the policies for the Medicare Part B Drug Inflation Rebate Program, including the treatment of skin substitutes approved as a drug or biological product under section 351 of the PHS Act as rebatable products, and identification of the CPI–U in the event CPI–U data are unavailable.

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) [50] 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 or renegotiation beginning with 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 OM drug allowed charges from 2014 to 2021.[51] OM Part B drug allowed charges increased from $21.8 billion in 2014 to $40.5 billion in 2021, an increase of $18.7 billion. While total spending and drug allowed charges have both increased significantly, OM Part B drug allowed charges have seen higher spending growth. In 2014, OM Part B drug allowed charges represented about 12.1 percent of OM Part B spending but grew to 20 percent in 2021.[52]

The same report also found that between 2014 and 2021, OM Part B 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). OM Part B 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-biological products, biological products accounted for 89 percent of the OM Part B drug spending growth between 2008 and 2021 and 79 percent of OM Part B drug spending in 2021. When reviewing OM Part B spending on multi-source drugs and biological products in 2021, generic drugs [53] accounted for only 2 percent of spending, and only 3 of the top 20 drugs by spend [54] (all biological products) were multi-source. Therefore, the majority of OM Part B drug expenditures in 2021 were attributable to single source drugs and sole source biological products.

An ASPE report evaluating OM Part B 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.[55] 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 OM Part B has decreased (8.8 percent) between 2016 to

[46] 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.

[47] ''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 through 98313 (December 9, 2024).

[48] ''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 through 50481 (November 5, 2025).

[49] ''Medicare and Medicaid Programs; CY 2027 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,'' 91 FR 43842 through 44557 (July 16, 2026).

[50] 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.

[51] Assistant Secretary for Planning and Evaluation. Medicare Part B Drug Pricing, June 9, 2023. Available at: *https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf*.

[52] Assistant Secretary for Planning and Evaluation. Medicare Part B Drug Pricing, Exhibit 3 Part B FFS drugs' share of Part B FFS spending, 2014 to 2021, June 9, 2023. Available at: *https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf*.

[53] 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.

[54] 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).

[55] Assistant Secretary for Planning and Evaluation. Medicare Part B Enrollee Use and Spending on Biosimilars, 2018–2023, January 2025. Available at: *https://aspe.hhs.gov/sites/default/files/documents/be065dbbd1f866c65cf627995bd2ea56/biosimilars-medicare-part-b.pdf*.

2021 (34 million to 31 million),[56] while OM Part B drug allowed charges has increased (47 percent) for the same time period.[57] Therefore, this increase in OM Part B spending for drugs during this period is likely explained more by increases in the prices of drugs, introduction of new drugs,[58] 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.[59]

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 billion.[60] While this increase in total Medicare Part B premiums is partially attributable to the increase in all Medicare beneficiaries from 52 million to 58 million,[61] 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 in OM and MA.[62] 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.[63] [64] [65]

In addition to a monthly premium, OM Part B beneficiaries typically need to cover 20 percent of the cost of a Medicare Part B drug once their Medicare Part B deductible is met. OM Part B 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 OM Part B spending has increased. As previously discussed, this increase is likely driven by high overall prices and the introduction of new drugs.[66] [67]

Further, as discussed earlier in section I.A., 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 32.4 percent ($136.2 billion) between 2019 to 2024.[68] 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 Medicare patients without low-income subsidies,[69] while another showed that 7 percent of adults 65 and older skipped or did not take their medications as prescribed because of cost.[70] [71] Research has also found multiple indications of worse health status were associated with a higher likelihood of cost-related nonadherence to medications.[72]

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.[73] 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.[74]

c. Relative High Price of Medicare Part B Drugs

Research from ASPE and RAND provides comparative data on U.S.

[56] 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.*

[57] Assistant Secretary for Planning and Evaluation. Medicare Part B Drug Pricing, Exhibit 3 Part B FFS drugs' share of Part B FFS spending, 2014 to 2021, June 9, 2023. Available at: *https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf.*

[58] 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.*

[59] 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.

[60] Centers for Medicare & Medicaid Services. CMS Program Statistics—Medicare Premiums, MDCR Premiums 4. Available at: *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-premium-reports/cms-program-statistics-medicare-premiums.*

[61] 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.

[62] 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/.*

[63] Centers for Medicare & Medicaid Services. 2025 Medicare Parts A & B Premiums and Deductibles, November 8, 2024. Available at: *https://www.cms.gov/newsroom/fact-sheets/2025-medicare-parts-b-premiums-and-deductibles.*

[64] 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/.*

[65] Congressional Research Service. Medicare Part B: Enrollment and Premiums, 2021. CRS Report R40082. Available at: *https://www.congress.gov/crs_external_products/R/PDF/R40082/R40082.48.pdf.*

[66] 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.

[67] Assistant Secretary for Planning and Evaluation. Changes in the List Prices of Prescription Drugs, 2017 to 2023, October 6, 2023. Available at: *https://aspe.hhs.gov/sites/default/files/documents/e24f630a33f0a0585337c65745904487/aspe-drug-price-tracking-brief.pdf.*

[68] The 32.4 percent and $136.2 billion was calculated using NHE Table 3: National Health Expenditures, by Source of Funds for out of pockets costs for years 2019 and 2024. Available at: *https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet.*

[69] Beneficiaries with a full low-income subsidy, which is applicable to the Part D program only, see a 95% reduction in out-of-pocket spending, compared to beneficiaries without low-income subsidies. Shoemaker JS, Davidoff AJ, Stuart B, Zuckerman IH, et al. *Eligibility and Take-up of the Medicare Part D Low-Income Subsidy.* Inquiry 49, no. 3 (2012): 214–230. *https://doi.org/10.5034/inquiryjrnl_49.03.04.*

[70] 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.*

[71] 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.*

[72] 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.*

[73] 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, January 2020. Available at: *https://www.gao.gov/assets/gao-20-156.pdf.*

[74] Centers for Medicare & Medicaid Services, Office of the Actuary. 2025 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, June 2025. Available at: *https://www.cms.gov/oact/tr/2025.*

prescription drug prices relative to 32 other OECD countries.[75] 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 drug prices exceeded those of non-U.S. OECD countries combined by 256 percent[76] using 2018 data.[77] In 2024, the 2022 ASPE funded 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.[78] When comparing the U.S. against individual G7 countries, 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 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.[79]

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 Medicare Part B drugs against non-U.S. OECD countries using 2018 drug spending data.[80] 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.[81] 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.[82]

The research findings indicate that U.S. prices used to calculate ASP rates for OM Part B 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.[83]

The data show that U.S. prescription drug prices, particularly for U.S. originator drugs,[84] 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 OM Part B and Medicare Part B beneficiaries on single source drugs and sole source biological products, in this final rule, we finalized the GLOBE Model to test the impact of using international drug pricing information as a benchmark for an alternative Medicare Part B inflation rebate amount calculation for a subset of Medicare Part B rebatable drugs (certain single source drugs and sole source biological products that meet the criteria defined in § 513.130) on Medicare program expenditures and quality of care.

### *F. Issuance of the Proposed Rule*

On December 23, 2025, CMS published in the **Federal Register** (90 FR 60244) a proposed rule titled ''Global Benchmark for Efficient Drug Pricing (GLOBE) Model'' (hereinafter referred to as the ''GLOBE Model proposed rule''). We solicited public comment on our proposals and on any alternatives considered (90 FR 60244). In response to the final rule, we received 20,168 pieces of correspondence, of which 157 were unique, timely correspondence from a variety of commenters, including, but not limited to, academia, consumer/patient advocacy organizations, consulting groups,

[75] 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.

[76] Mulcahey *et al.* calculated price indexes using U.S. volume weights to account for differences in volume and mix of drugs across countries.

[77] Ratios from this study are not adjusted for differences in purchasing power-adjusted GDP per capita. *See* Andrew W. Mulcahy, Christopher M. Whaley, Mahlet G. Tebeka, 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.*

[78] 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/.*

[79] 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(a) 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 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.

[80] Assistant Secretary for Planning and Evaluation. Medicare FFS Part B and International Drug Prices: A Comparison of the Top 50 Drugs, 2020. Available at: *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//197401/Part-B%20Drugs-International-Issue-Brief.pdf.*

[81] 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 was 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.

[82] 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.

[83] Young, C.L., Frank, R.G., & Sachs, R. Brookings Institution. International reference pricing for prescription drugs, 2025. Available at: *https://www.brookings.edu/articles/international-reference-pricing-for-prescription-drugs/.*

[84] U.S. originator drugs are the original biologics and drugs 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.

distributors, health plans, health care companies or providers, professional associations, pharmaceutical manufacturers, and individuals. The other 20,011 pieces of correspondence were duplicative correspondence submitted by the same entity.

In the sections of this final rule that follow, we present our proposals, summaries of the comments received, and responses to the comments within scope of the proposed rule. Some of the public comments received in response to the GLOBE Model proposed rule were outside of the scope of the proposed rule and are not addressed in this final rule.

## II. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

In this final rule, we summarize our proposals and final policies for the GLOBE Model, including the general framework for implementing and evaluating the GLOBE Model, model-specific parameters, requirements, and definitions. We note that section 1115A(b) of the Act gives the Secretary discretion in the design of models. Through the GLOBE Model proposed rule (90 FR 60244 through 60336), published on December 23, 2025, CMS sought input from interested parties and welcomed comments on the proposed GLOBE Model. The proposed model-specific parameters, requirements, and definitions are described in sections of the GLOBE Model proposed rule and this final rule. We proposed to codify them at 42 CFR part 513.

For purposes of the GLOBE Model, we proposed 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 (ASP), 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 also proposed 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.

We did not receive comments on these proposed definitions; therefore, CMS is finalizing these definitions as proposed with non-substantive technical corrections, except for severe supply chain disruption. To align with our proposed definitions, we have added the definitions for NDC and NOC Codes in § 513.20 which have the same meaning as set forth in 42 CFR 427.20. As discussed in section II.G.4.d. of this final rule, CMS is not finalizing our proposal at § 513.500(e), to reduce the incremental GLOBE Model rebate amount for a GLOBE Model drug that is a biosimilar biological product when there is a severe supply chain disruption due to the finalization of the provision excluding Part B rebatable drugs that are biosimilar biological products from the GLOBE Model. Therefore, we are removing and not finalizing a definition for ''severe supply chain disruption'' at § 513.20. Additionally, as the term, Original Medicare or OM, has the same meaning as Medicare fee-for-service and the traditional Medicare program, we have made minor terminology updates to reflect this in 42 CFR part 513.

We received many comments that discuss the overall model, the CMS Innovation Center's authority to carry out the model, and broad legal concerns. Below are summaries of these comments and our responses:

*Comment:* Multiple commenters believed that the GLOBE Model exceeds the statutory authority granted to the CMS Innovation Center under section 1115A of the Act. Commenters stated that: (1) section 1115A of the Act requires that models be expected to preserve or enhance quality of care as a threshold condition—not merely reduce expenditures; (2) the statute does not authorize ''savings-first'' experimentation that may compromise patient outcomes; and (3) CMS should not use demonstration authority to achieve outcomes, such as de facto price controls or restructuring of Medicare Part B, that Congress has not explicitly authorized. Other commenters further remarked that CMS has not demonstrated how the GLOBE Model would benefit patients. Accordingly, commenters recommended the GLOBE Model be withdrawn.

*Response:* We agree with commenters that section 1115A of the Act directs CMS to test innovative payment and care delivery models that preserve or enhance quality of care. Under section 1115A of the Act, Congress has granted CMS broad authority to test payment and service delivery models that aim to reduce program expenditures while preserving or enhancing quality of care furnished to beneficiaries. We believe the GLOBE Model is consistent with the statutory language, as it tests whether changes to payment incentives and reduced beneficiary coinsurance for certain Part B drugs can maintain or improve quality of care outcomes, for example, by alleviating affordability-related barriers to care and support continued access to needed treatment, while reducing program expenditures.

Previous studies—mentioned in the background section of the GLOBE Model proposed rule (90 FR 60247)—have shown that high drug costs can create barriers to care by limiting access to treatment, leading to poorer health outcomes and deficits of care. Consistent with these findings, financial distress has been identified as a risk factor for mortality following cancer diagnosis, and high coinsurance amounts may limit the utilization of certain cancer treatments.[85] [86] For beneficiaries who rely on high-cost Part B drugs, financial barriers and disruptions in access may adversely affect treatment continuity and, in turn, health outcomes. To address cost-related barriers to care, GLOBE Model beneficiaries are expected to receive a coinsurance reduction. As discussed in section II.G.7. of this final rule, using illustrative 2024 data for drugs identified in Table 4, 94 percent of illustrative GLOBE Model drugs would have a beneficiary coinsurance percentage between 2 and 12 percent—well below the standard 20 percent coinsurance. While beneficiaries with supplemental insurance may not directly benefit from the coinsurance reduction, this reduction has the potential to meaningfully increase access for OM Part B beneficiaries who bear the full cost of the coinsurance directly. Additionally, all OM Part B beneficiaries may see reduced Part B premiums regardless of supplemental coverage. As discussed in section IV.D. of this final rule, the GLOBE Model is expected to generate $177 million in total out-of-pocket savings, benefiting a substantial number of OM Part B beneficiaries. As such, we disagree with the assertion that CMS has not stated how the GLOBE Model would benefit patients.

As discussed in section II.J. of this final rule, CMS will assess the model's effects on quality through a comprehensive monitoring and evaluation framework that includes measurable, patient-level indicators such as: beneficiary financial liability;

[85] Ramsey, Scott D., et al. *Financial Insolvency as a Risk Factor for Early Mortality Among Patients With Cancer.* Journal of Clinical Oncology, 2016, 34(9): 980–986. doi: 10.1200/JCO.2015.64.6620.

[86] Horn, D., Alpert, A., Duggan, M., Jacobson, M. *The impact of immunotherapy on reductions in cancer mortality: Evidence from Medicare.* Journal of Health Economics, 2026, 106. doi: 10.1016/j.jhealeco.2026.103115.

utilization and prescribing patterns; access to Part B drugs; continuity of care; site of care; and downstream health care utilization. This framework will enable CMS to evaluate whether the model preserves or enhances quality of care and to identify and address any unintended consequences. Further, quality preservation or improvement is a co-equal, not secondary, objective of the GLOBE Model, and the monitoring framework is designed to ensure this standard is met throughout the GLOBE Model performance period.

Further, the GLOBE Model does not mandate or restrict how manufacturers respond to the model. Manufacturers retain full discretion in how they choose to respond to the model. CMS notes that manufacturers retain the operational flexibility to set pricing and to implement targeted pricing or contracting.

For these reasons, CMS disagrees that the GLOBE Model exceeds the statutory authority granted to the CMS Innovation Center under section 1115A of the Act and declines to withdraw the model on this basis.

*Comment:* Many commenters stated the GLOBE Model is not a payment and service delivery model under section 1115A of the Act because it changes manufacturer-to-government rebate obligations rather than Medicare payments or care delivery. Commenters stated that the GLOBE Model rebate payments are not considered a ''payment'' under section 1115A of the Act because the payment methodology does not alter Medicare payments to plans and providers, and the rebate obligation arises later than the underlying drug payment.

Commenters further stated the GLOBE Model seeks to impose a ''fine or sanction (via) rebate when manufacturers' domestic prices exceed foreign reference prices'' or that the mandatory rebates are ''taxes levied on manufacturers.'' Commenters stated that ''service delivery'' implies a change in how care or payment is conveyed and structured, not merely the payment amount, and that the GLOBE Model satisfies neither prong. Commenters further stated that the GLOBE Model does not change how care or drugs are furnished, coordinated, prescribed, dispensed, or managed, so it fails the ''payment and service delivery'' requirement under section 1115A of the Act. Commenters believed that the enumerated examples under section 1115A of the Act include both ''payment and service delivery'' elements and therefore, reflect Congress's intent that models include both components. For these reasons, commenters recommend the GLOBE Model be withdrawn.

*Response:* CMS disagrees with commenters that the GLOBE Model is not an appropriate model for testing under section 1115A of the Act. In section 1115A of the Act, ''payment and service delivery'' is a categorical descriptor for the types of models CMS may test; it is not a requirement mandating that every model include both payment and service delivery components simultaneously. We further disagree with the characterization that CMS's model selection authority must be understood only considering the expressly enumerated model types. While section 1115A of the Act enumerates 27 model types for testing, the statute, by its own terms, does not limit CMS's authority to those listed types. Examples of CMS Innovation Center models that did not include both payment and service delivery elements include models such as the Bundled Payments for Care Improvement (BPCI) Model[87] and the Part D Senior Savings Model.[88]

CMS acknowledges that the GLOBE Model represents a novel application of CMS Innovation Center authority under section 1115A of the Act. However, we disagree that the GLOBE Model rebates are not a ''payment'' under section 1115A of the Act. The GLOBE Model is not the only model in which manufacturers' obligations include rebates using authority under section 1115A of the Act. In the CGT Access Model, manufacturers that participate are required to provide states that participate in the model with supplemental rebates that reflect model-negotiated terms.[89] [90] Under the CGT Access Model, if a Medicaid beneficiary who receives a covered therapy does not benefit from it, the state Medicaid program will be entitled to a rebate from the manufacturer equal to a portion of the therapy's cost. Congress enacted section 1115A of the Act to encourage the CMS Innovation Center to test approaches that have not yet been tried, not to replicate existing programs and approaches.

CMS also disagrees with the commenters' suggestion that the GLOBE Model is not a payment model or that it imposes a sanction or tax on manufacturers because it changes manufacturer rebate obligations, which commenters do not view as payments. Section 1115A of the Act directs the CMS Innovation Center to test payment and service delivery models for the purpose of reducing program expenditures and improving quality. CMS notes that the Medicare Part B Drug Inflation Rebate Program reduces the net cost of payable drugs for Medicare, and the GLOBE Model tests a change to the rebate amount calculation. The GLOBE Model rebate is tied directly to a pricing benchmark and functions as an adjustment to a mandatory monetary obligation. The fact that the rebate is invoiced and paid subsequent to the underlying drug transaction does not diminish its character as a ''payment'' under Medicare. Moreover, we note that Congress has treated rebates as a payment-related topic. For example, in enacting statutory language requiring Part B rebates, Congress chose to house its language in section 1847A of the Act, entitled ''Use of average sales price payment methodology.'' The same is true of the Medicaid drug rebate program created by section 1927 of the Act, entitled ''Payment for covered outpatient drugs.'' In addition, CMS notes that numerous Medicare payment mechanisms, including retrospective reconciliation payments, shared savings distributions, and quality-based adjustments, are similarly calculated and remitted after the point of care. For example, Accountable Care Organizations (ACOs) in ACO REACH and the Medicare Shared Savings Program may owe payment to CMS if their spending exceeds the benchmark. These examples show payment systems that involve downside risk inherently involve a repayment or reconciliation made back to the government rather than affirmative payments to participants from CMS.

Furthermore, section 1115A of the Act does not restrict ''payment'' to transactions involving healthcare providers or plans. To the contrary, the statute's broad reference to ''program expenditures'' and ''program costs'' supports an interpretation that encompasses any mandatory monetary obligation that affects what Medicare ultimately pays for covered items and

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[87] Centers for Medicare & Medicaid Services. Bundled Payments for Care Improvement (BPCI) Initiative: General Information. Available at: *https://www.cms.gov/priorities/innovation/innovation-models/bundled-payments.* Under the BPCI, organizations entered into payment agreements that included financial and performance accountability for episodes of care.

[88] Centers for Medicare & Medicaid Services. Part D Senior Savings Model. Available at: *https://www.cms.gov/priorities/innovation/innovation-models/part-d-savings-model.* This model tested the impact of enhanced alternative Part D plan options that offered lower out-of-pocket costs for insulin as supplemental benefits.

[89] Centers for Medicare & Medicaid Services. 2024 Report to Congress. Available at: *https://www.cms.gov/priorities/innovation/data-and-reports/2024/rtc-2024.*

[90] Centers for Medicare & Medicaid Services. CGT Model. Available at: *https://www.cms.gov/priorities/innovation/innovation-models/cgt.*

services—including manufacturer rebates.

For these reasons, CMS concludes that the GLOBE Model constitutes a payment model within the meaning of section 1115A of the Act, and that manufacturer rebate obligations under the model represent ''payments'' that directly affect Medicare's net expenditures for covered drugs. As such, CMS declines to withdraw the model.

*Comment:* A commenter stated that the GLOBE Model rule ignored the spirit of the Regulatory Bill of Rights, referring to a set of principles set forth in section 6 of Executive Order 13924.[91]

*Response:* CMS acknowledges the commenter's reference to the Regulatory Bill of Rights.

CMS notes that the principles reflected in the Regulatory Bill of Rights—including transparency, regulatory clarity, and meaningful opportunity for public participation—are consistent with the administrative process CMS followed in developing the GLOBE Model. At all points in the process, CMS has complied with the requirements of the Administrative Procedure Act and section 1871 of the Act: CMS published a proposed rule (90 FR 60244), accepted public comments over a 60-day comment period, and considered and responded to those comments in this final rule. As described herein, we have made modifications to certain proposals in this final rule based on our consideration of public comments including, for example, the addition in the final GLOBE Model regulations of exclusions for orphan-only drugs,[92] plasma-derived products as set forth in 42 CFR 427.400, and drugs listed by FDA as Approved Cellular and Gene Therapy products. The GLOBE Model's terms, drug selection criteria, rebate calculation methodology, and applicable exclusions are set forth in detail in this final rule, providing manufacturers and other stakeholders with clear notice of their obligations.

For these reasons, CMS disagrees that the GLOBE Model ignored the spirit of the principles the commenter identifies and CMS declines to withdraw the model on this basis.

*Comment:* A few commenters stated that the GLOBE Model raises separation of powers and nondelegation doctrine concerns under the premise that the model effectively amends or supplants congressionally enacted drug-pricing frameworks. The commenters specifically cited *FCC* v. *Consumers' Research,* 606 U.S. 656 (2025), in which the court stated that Congress is required to ''set out an intelligible principle to guide what it has given the agency to do.'' These commenters specifically stated that section 1115A of the Act does not permit CMS to implement sweeping Most Favored Nation (MFN)-style rebates through a CMS Innovation Center model test.

*Response:* We disagree with these comments. The GLOBE Model does not violate the separation of powers or the nondelegation doctrine of the Constitution, and it does not amend or supplant any congressionally enacted drug pricing framework. The CMS Innovation Center was established by section 1115A of the Act for the purpose of testing ''innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care'' provided to individuals who receive benefits from Medicare, Medicaid, or CHIP. This authority does not violate separation of powers or the nondelegation doctrine because Congress provided a statutory framework that both authorizes and constrains CMS's development and testing of models. Under the nondelegation doctrine, a delegation of authority to an executive agency is permissible where Congress has provided an ''intelligible principle'' to guide the agency's exercise of that authority. See *Whitman* v. *Am. Trucking Ass'ns,* 531 U.S. 457 (2001). Section 1115A of the Act satisfies this standard because, as discussed herein, section 1115A of the Act contains intelligible limiting principles.

Commenters cited *FCC* v. *Consumers' Research,* which reaffirmed the longstanding intelligible principle standard for evaluating delegations of legislative authority to executive agencies—the same standard articulated in *Whitman* v. *American Trucking Ass'ns,* and its predecessors. As discussed previously, section 1115A of the Act readily satisfies this standard. Congress did not delegate open ended or standardless authority to CMS; rather, it enacted a detailed, purpose-specific statutory framework that identifies the goals of model testing (reducing program expenditures while preserving or enhancing quality of care), authorizes specific waivers of certain Medicare and Medicaid requirements only as necessary to carry out model tests, and establishes binding criteria governing when a model may be expanded. These provisions collectively constitute a robust intelligible principle that meaningfully guides and constrains CMS's exercise of authority under section 1115A of the Act. The GLOBE Model has been designed in accordance with the limitations of section 1115A of the Act to generate evidence about the effects on Medicare expenditures and beneficiaries' quality of care of considering international drug pricing information in alternative payment methodologies for drugs payable under Medicare Part B. This evidence can inform future policy decisions by Congress, as envisioned by section 1115A(g) of the Act which states that reports to Congress on activities under section 1115A of the Act ''shall provide such recommendations as the Secretary determines are appropriate for legislative action to facilitate the development and expansion of successful payment models.'' Thus, testing the GLOBE Model is precisely the kind of evidence-generating function that section 1115A of the Act was designed to support.

The intelligible principle supplied by Congress is not merely present in the abstract; it is directly operative in shaping the design and boundaries of the GLOBE Model itself. Accordingly, *FCC* v. *Consumers' Research* does not provide a basis for concluding that section 1115A's delegation of authority is constitutionally inappropriate as applied to the GLOBE Model. Section 1115A of the Act establishes the scope of permissible models, the parameters for defining populations for testing, the authority to waive Medicare and Medicaid requirements as deemed necessary to test a model, and the criteria for expansion. These statutory conditions and goals meaningfully direct CMS's development and testing of models. Congress constrained CMS's authority to test time-limited models by requiring that models be tested for the specific purpose of reducing program expenditures while preserving or enhancing quality of care, evaluated against statutory criteria, and expanded in duration and scope if such expansion meets the requirements set forth in section 1115A(c) of the Act. For these reasons, Congress granted CMS broad, yet constrained, authority under section 1115A of the Act, rather than delegating its legislative powers to the executive branch. This structure satisfies the constitutional requirements of separation-of-powers concerns and does

[91] *Regulatory Relief to Support Economic Recovery,* Exec. Order No. 13924, 85 FR 31353 (May 22, 2020).

[92] Orphan-only drug means a drug that is designated as a drug for only one or more rare diseases or conditions under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) and for which the only approved indication (or indications) is for one or more such rare diseases or conditions. Refer to § 513.130(c) for the GLOBE Model drug exclusion criteria.

not implicate the nondelegation doctrine. With respect to the GLOBE Model specifically, CMS is not amending statutory drug pricing frameworks. Instead, as discussed in the GLOBE Model proposed rule (90 FR 60338) and in this final rule, the GLOBE Model is limited to testing an alternative approach to the calculation of rebates for certain Part B rebatable drugs and biological products under the Medicare Part B Drug Inflation Rebate Program established under the IRA for the purpose of evaluating whether this approach would reduce program expenditures while maintaining or enhancing quality of care for Medicare beneficiaries. The GLOBE Model would not implement sweeping MFN-style pricing; it would test a targeted alternative approach to an existing rebate calculation methodology within the bounds of the authority under section 1115A of the Act.

*Comment:* A commenter stated that the GLOBE Model effectively amends the IRA's rebate scheme without going through the constitutionally mandated bicameralism and presentment requirements.

*Response:* We disagree that the GLOBE Model raises bicameralism and presentment concerns. The bicameralism and presentment requirements of Article I, Section 7 of the Constitution apply to the enactment of legislation by Congress and does not constrain an executive agency's exercise of authority that Congress has delegated by statute to such agency. Agency rulemaking and program implementation are executive, not legislative, functions, and are therefore distinct from the lawmaking process that bicameralism and presentment are designed to govern.

The GLOBE Model would be implemented pursuant to section 1115A of the Act, a duly enacted statute that passed both chambers of Congress and was signed into law. Section 1115A of the Act grants the Secretary broad authority to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care. Congress deliberately crafted this delegation with wide latitude, anticipating that CMS would exercise significant discretion in model design. The GLOBE Model falls squarely within this grant of authority, and its implementation is a lawful exercise of delegated power, not an end-run around the legislative process.

CMS's exercise of authority under section 1115A of the Act does not implicate the bicameralism or presentment requirements, as CMS is not enacting new legislation; rather, it is acting within the bounds of authority Congress has already granted. The commenter has not identified any authority suggesting that model design decisions, including those that interact with other statutory provisions, must independently satisfy bicameralism and presentment requirements.

*Comment:* A commenter stated strong support for the inclusion of severability language in the GLOBE Model, stating that such language would ensure that existing statutory provisions remain unaffected should any provision included in the GLOBE Model proposed rule be deemed invalid or unenforceable by a court. The commenter indicated that severability protections are an important safeguard for the integrity of the broader rule and the statutory framework within which the GLOBE Model operates.

*Response:* CMS agrees that severability language is an important structural safeguard for the integrity of the rule and the statutory framework within which the GLOBE Model operates.

As finalized in this rule, the severability provision is designed to ensure that, should any individual provision of the GLOBE Model be found invalid or unenforceable by a court of competent jurisdiction, the remaining provisions of the rule would continue in full force and effect to the maximum extent permitted by law. This approach reflects CMS's intent that each provision of the GLOBE Model be capable of operating independently, and that the invalidation of any single provision not be construed to affect the validity or enforceability of the rule as a whole or of the underlying statutory authority granted to the CMS Innovation Center under section 1115A of the Act.

CMS believes that the inclusion of severability language is consistent with sound regulatory drafting practice and supports the long-term operational stability of the GLOBE Model. Accordingly, CMS is finalizing the severability provision at § 513.1(d) as proposed.

*Comment:* Multiple commenters state that the GLOBE Model exceeds CMS's statutory authority under section 1115A of the Act. Commenters believed that the GLOBE Model exceeds the permissible boundaries of a CMS Innovation Center model by attempting to regulate pricing relationships between the U.S. and other countries. Specifically, commenters contended that: the use of international reference pricing (foreign benchmark prices) as the basis for manufacturer rebates effectively imports foreign price controls into the U.S. Medicare system; the CMS Innovation Center's statutory authority is limited to testing payment and service delivery models within the Medicare and Medicaid programs and does not extend to regulating international pharmaceutical pricing or trade; and this approach raises significant concerns regarding the rule of law, separation of powers, and the appropriate scope of executive agency authority. Commenters believed this aspect of the model independently renders it unlawful and outside the scope of the CMS Innovation Center's mandate.

Additionally, a few commenters stated that the model does not take a phased approach as directed by statute, whereby Phase I is meaningfully constrained before any broader expansion via rulemaking. Commenters went on to note that the biotech and pharmaceutical market is nationwide because manufacturers cannot isolate their global research, development, and pricing activities to specific geography or sector; therefore, commenters stated the model would operate as a functionally mandatory, nationwide program, which goes beyond the CMS Innovation Center's intended demonstration authority. For these reasons, commenters recommend the GLOBE Model be withdrawn.

*Response:* CMS disagrees with these comments. The CMS Innovation Center was established by section 1115A of the Act for the purpose of testing ''innovative payment and service delivery models to reduce program expenditures . . . while preserving or enhancing the quality of care furnished to individuals'' who receive benefits from Medicare, Medicaid, or CHIP. CMS's reliance on this authority for the GLOBE Model does not violate the rule of law, separation of powers, or the non-delegation doctrine because Congress provided an adequate statutory framework that both authorizes and constrains CMS's development and testing of models. Specifically, section 1115A of the Act defines the scope of permissible models, grants the authority to waive certain Medicare and Medicaid requirements as necessary to test a model, and sets criteria for evaluation and expansion of models, among other provisions. These statutory conditions and goals meaningfully direct CMS's development and testing of models. Furthermore, as discussed previously, section 1115A of the Act readily satisfies the ''intelligible principle'' standard. Congress did not delegate open-ended or standardless authority to CMS; rather, it enacted a detailed, purpose-specific statutory framework

that identifies the goals of model testing (reducing program expenditures while preserving or enhancing quality of care), defines the permissible scope of models and the populations that may be tested, authorizes specific waivers of certain Medicare and Medicaid requirements only as necessary to carry out model tests, and establishes binding criteria governing when a model may be expanded. These provisions collectively constitute a robust intelligible principle that meaningfully guides and constrains CMS's exercise of authority under section 1115A of the Act.

Congress further constrained CMS's authority by requiring that models be evaluated against statutory criteria, and expanded only if the model meets the statutory requirements for expansion under section 1115A(c) of the Act. For these reasons, Congress granted the CMS Innovation Center broad, yet constrained authority under section 1115A of the Act, rather than delegating its legislative powers to the executive branch.

With respect to the GLOBE Model specifically, CMS is not amending statutory drug pricing frameworks. CMS disagrees with commenters that the GLOBE Model is functionally a mandatory, nation-wide program that exceeds the agency's statutory authority. Rather, the GLOBE Model is limited to testing an innovative payment methodology for the Medicare Part B drug inflation rebate amount calculation for GLOBE Model drugs. As discussed in section II.G.1.e. of this final rule, this methodology uses international drug pricing information to establish a benchmark reflecting prices paid in a set of economically comparable countries.

Section 1115A(a)(5) of the Act expressly authorizes the Secretary to ''limit testing of a model to certain geographic areas.'' Consistent with this authority, the GLOBE Model is limited to a random selection of ZCTAs representing approximately 25 percent of OM Part B enrollees, as outlined in section II.F. of this final rule. Other mandatory CMS Innovation Center models have similarly employed randomization: the Ambulatory Specialty Model (ASM) and the Transforming Episode Accountability Model (TEAM) each randomly selected eligible Core Based Statistical Areas (CBSAs) into their respective intervention groups—approximately 40 percent for ASM and 25 percent for TEAM.

The GLOBE Model is a time limited test, focused on specific geographic areas, and applies only to a defined subset of high-expenditure, Part B rebatable drugs. These design features are consistent with the ''testing'' framework contemplated by section 1115A of the Act and distinguish the GLOBE Model from a broad restructuring of drug pricing policy.

With respect to the model's randomization ratio, as described in II.D. of the GLOBE Model proposed rule and this final rule, CMS considered establishing a 1:1 intervention-to-comparison ratio. However, CMS determined that the randomized design eliminates concerns about selection bias and the need for post-hoc matching of comparison group beneficiaries. Accordingly, CMS adopted a 1:3 intervention-to-comparison ratio, which enables a sufficiently large selection of beneficiaries into the GLOBE Model while maintaining analytical rigor. CMS expects this approach will reduce program expenditures for OM Part B while preserving or enhancing the quality of care furnished to beneficiaries.

CMS also disagrees that the GLOBE Model imports foreign price-setting systems, foreign price controls, or a Most Favored Nation-style approach into the Medicare Part B program. As explained in sections II.A. and II.B. of this final rule, the GLOBE Model is a time-limited test focused on a subset of Part B rebatable drugs to evaluate whether an alternative rebate amount calculation reduces Medicare spending while preserving or enhancing the quality of care for Medicare beneficiaries. The GLOBE Model tests an alternative approach to the Medicare Part B drug inflation rebate amount calculation, as described in section II.G.3. of this final rule. The existing Medicare Part B program structure remains in place, and all applicable Medicare Part B program rules continue to apply under the GLOBE Model.

Further, the GLOBE Model does not mandate or restrict how manufacturers respond to the model. Manufacturers retain full discretion in how they choose to respond to the model. CMS notes that manufacturers may tailor their response to the areas selected for the GLOBE Model, if they choose to do so. While CMS acknowledges that some manufacturer responses may have national implications, manufacturers retain the operational flexibility to implement targeted pricing or contracting strategies in selected geographies, and the model does not compel a nationwide response.

Importantly, the GLOBE Model does not incorporate or rely upon any foreign country's legal policies, formulary rules, coverage rules, or health technology assessment (HTA) processes in its alternative rebate amount calculation. Nor does the GLOBE Model require that populations in foreign countries have the same clinical or disease profiles as the Medicare population in the U.S. CMS has selected a set of economically comparable reference countries to derive the international benchmark for a GLOBE Model drug because CMS believes significant disparities between U.S. drug prices and prices in economically comparable countries are contributing to potentially excessive expenditures for drugs payable by Medicare Part B and harms to beneficiaries' quality of care. Therefore, testing an alternative approach to the rebate amount calculation in the Medicare Part B Drug Inflation Rebate Program that relies on an international benchmarks for certain Part B rebatable drugs to reduce program expenditures while preserving or enhancing quality of care is consistent with the CMS Innovation Center's authority under section 1115A of the Act and does not reflect an impermissible importation of foreign price controls. Further, the use of foreign prices in the international benchmark serve as a proxy for the payment levels drug manufacturers are willing to accept for their products, from drug manufacturers' perspectives–despite what foreign payors are willing to spend or how lower foreign prices are developed. Given that the international benchmarks are illustrative of payment levels that drug manufacturers may accept for these products, we believe testing a targeted alternative to the rebate amount calculation under the Medicare Part B Drug Inflation Rebate Program using these international benchmarks to reduce program expenditures while preserving or enhancing quality of care represents a reasoned and valid innovative payment model duly authorized by section 1115A of the Act. The evidence generated by this model can inform future policy decisions by Congress, as envisioned by section 1115A(g) of the Act which states that reports to Congress on activities under section 1115A of the Act ''shall provide such recommendations as the Secretary determines are appropriate for legislative action to facilitate the development and expansion of successful payment models.''

Additionally, CMS notes that there is no language in section 1115A of the Act that limits model tests to only those models that have completely contained direct effects. CMS has previously tested models that have, in practice, had some spillover effects and downstream effects, including spillover effects on patients, providers, payers, and health

systems that were not the primary target of the model's payment incentives. We present a non-exhaustive list of examples next.

- The Oncology Care Model (OCM) saw spillover impacts as participating practices implemented standardized workflows, 24/7 nursing lines, patient navigation, and expanded screening for all cancer patients regardless of payer.[93] These benefits extended well beyond OCM-aligned Medicare beneficiaries and reflected practice choices to adopt OCM-driven improvements system-wide.
- The Pioneer Accountable Care Organization (ACO) Model documented that approximately 45 percent of physicians reported that the model ''influenced how I care for ALL my patients, even those not aligned with the ACO,'' and 28 percent of ACO physicians reported being more likely to deliver higher quality care for non-ACO patients.[94]
- The Next Generation ACO (NGACO) Model documented that the proportion of visits that the comparison group obtained from Medicare ACO-affiliated providers increased significantly, ranging from 14 to 18 percent during the baseline and first performance year.[95]
- The Comprehensive ESRD Care (CEC) Model produced anecdotal evidence from qualitative data collection that care process changes occurred for patients not aligned to the model as well as those within it.[96]
- The Global and Professional Direct Contracting Model, later modified and renamed by CMS as the ACO REACH Model, generated evidence from annual ACO surveys showing that approximately half of ACOs were implementing model strategies in MA populations, approximately one third were applying strategies to original Medicare populations not aligned to the model, and some were extending strategies to commercial and Medicaid beneficiaries as well.[97]

Some CMS Innovation Center models also produced infrastructure and tool adoption spillovers, where model developed innovations were adopted broadly beyond the model's direct participants. For example:

- The Accountable Health Communities (AHC) Model generated spillovers through the broad adoption of its health-related social needs screening tool. Beneficiaries assigned to the control group received community referral summaries, and the community advisory boards likely had broad impacts beyond those who were screened and received navigation services, with those impacts likely persisting after the model ended.[98]
- The Kidney Care Choices (KCC) Model and the ESRD Treatment Choices (ETC) Model produced spillovers as participants made electronic health record modifications and added care coordinators, patient education programs, and new roles to support home dialysis and transplantation—infrastructure changes that were likely available to all providers and patients within an organization or health system, not just those aligned to the model.[99] [100]
- The BPCI Advanced model generated anecdotal evidence from interviews and site visits that care redesign best practices—including enhanced preoperative optimization, changes to interdisciplinary rounding, establishment of new care protocols, employment of care navigators, and formation of preferred post-acute care networks—spread to other hospitals within the same health system that were not participating in the model.[101]
- The Strong Start for Mothers and Newborns initiative generated community and referral network spillovers. The main spillover effect was the adoption of universal screening tools and related care improvements, along with strengthened community partnerships, referral networks, care coordination, and expanded access to services like group prenatal care beyond the original target population.[102]
- The State Innovation Models (SIM) Initiative generated State level, multipayer infrastructure spillovers that were sustained by design. Analyses found that the Arkansas Medicaid Patient Centered Medical Home Program, using funding from the SIM Initiative, had spillover effects on commercial populations for early adopting practices, increasing access to outpatient care.[103]

Evidence from across the CMS Innovation Center portfolio suggests that model participants may voluntarily apply care delivery changes, infrastructure investments, and practice transformation efforts learned through model participation beyond the model's targeted populations. The GLOBE Model is designed as a geographically targeted intervention, and any broader health system impact would reflect participants' independent adoption of model informed practices rather than the scope or intent of the model's design.

CMS also notes that section 1115A(c) of the Act separately provides for later expansion of the duration and the scope of a tested model, if statutory criteria are met, which could include testing the GLOBE Model on a nationwide basis. Contrary to commenters' allegations, the current design of the GLOBE Model is consistent with a Phase I test, and the CMS Innovation Center will determine at a later time whether to expand the GLOBE Model, as authorized under section 1115A(c) of the Act. CMS does not believe that the GLOBE Model as

[93] Hassol et al. (2021). *Evaluation of the Oncology Care Model: Participants' perspectives.* Abt Associates. Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services. *https://www.cms.gov/priorities/innovation/data-and-reports/2021/ocm-ar4-eval-part-persp-report.*

[94] L&M Policy Research, LLC (2016). *Evaluation of CMMI Accountable Care Organization Initiatives.* Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services. *https://www.cms.gov/priorities/innovation/files/reports/pioneeraco-finalevalrpt.pdf.*

[95] Lowell et al. (2018). *Next Generation Accountable Care Organization (NGACO) Model Evaluation: First Annual Report.* NORC at the University of Chicago. Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services. *https://www.cms.gov/priorities/innovation/files/reports/nextgenaco-firstannrpt.pdf.*

[96] Marrufo et al. (2021). *Comprehensive End-Stage Renal Disease Care (CEC) Model: Performance Year 4 Annual Evaluation Report.* The Lewin Group. Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services. *https://www.cms.gov/priorities/innovation/data-and-reports/2021/cec-annrpt-py4.*

[97] NORC. Evaluation Report 3: Evaluation of the ACO REACH Model, 2026. Available at: *https://www.cms.gov/priorities/innovation/data-and-reports/2026/aco-reach-3rd-eval-report.*

[98] Beil et al. (2026). *Accountable Health Communities (AHC) Model Evaluation: Final Report.* RTI International. Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/priorities/innovation/data-and-reports/2026/ahc-final-report.*

[99] The Lewin Group. Kidney Care Choices (KCC) Model: Second Annual Evaluation Report, Performance Year 2023, 2026. Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/priorities/innovation/data-and-reports/2026/kcc-2nd-annual-report.*

[100] Negrusa et al. The Lewin Group. End-stage Renal Disease Treatment Choices (ETC) Model Second Annual Evaluation Report, January 2024. Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services. Available at: *https://www.cms.gov/priorities/innovation/data-and-reports/2024/etc-2nd-eval-rpt.*

[101] Henke et al. The Lewin Group. CMS Bundled Payments for Care Improvement Advanced Model: Fifth Annual Evaluation Report, 2024. Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/priorities/innovation/data-and-reports/2024/bpci-adv-ar5.*

[102] Hill et al. Urban Institute. Strong Start for Mothers and Newborns Evaluation: Year 5 Project Synthesis (Volume 2: Awardee-Specific Reports, 2018. Centers for Medicare & Medicaid Services. Available at: *https://downloads.cms.gov/files/cmmi/strongstart-prenatal-finalevalrpt-v2.pdf.*

[103] Hinde, J. M., et al. (2020). *Did Arkansas' Medicaid Patient-Centered Medical Home Program Have Spillover Effects on Commercially Insured Enrollees?* INQUIRY: The Journal of Health Care Organization, Provision, and Financing, 57. *https://doi.org/10.1177/0046958019900753.*

proposed will qualify or function as a Phase II expanded model. For these reasons, CMS declines to withdraw the GLOBE Model.

*Comment:* A few commenters stated that the GLOBE Model implicates the major questions doctrine, which requires Congress to ''speak clearly'' before an agency may make decisions of ''vast economic and political significance.'' *Util. Air Regul. Grp.* v. *EPA,* 573 U.S. 302, 324 (2014) (internal quotation marks omitted). Commenters stated that the proposed GLOBE Model would impose approximately $11.9 billion in new rebates—totaling tens of billions of dollars in new manufacturer obligations; fundamentally alter net drug payments under OM Part B by tying rebates to foreign reference prices rather than domestic inflation benchmarks; and address a question—international reference pricing—that Congress has actively debated and deliberately declined to enact when it passed the IRA. Commenters believed that Congress specifically evaluated and removed international pricing provisions prior to passing the IRA, opting instead for domestic benchmarks. Given this context, commenters stated that CMS cannot rely on the CMS Innovation Center's general ''test'' and ''waiver'' authority to unilaterally implement a sweeping international reference pricing regime. Commenters believed that the Supreme Court's decisions in *West Virginia* v. *EPA,* 597 U.S. 697 (2022), and *Biden* v. *Nebraska,* 600 U.S. 477 (2023), confirm that such broad agency action requires clear congressional authorization, which commenters state is absent here. Commenters also cited *Loper Bright Enterprises* v. *Raimondo,* 603 U.S. 369 (2024), and stated that courts must give statutory text its ordinary meaning in context. Commenters further cited *Learning Resources, Inc.* v. *Trump,* 607 U.S. 229 (2026), and noted that the Supreme Court has stated that ''both separation of powers principles and a practical understanding of legislative intent'' suggest that Congress does not delegate ''highly consequential power'' through ambiguous language.

*Response:* CMS disagrees with commenters that the GLOBE Model raises concerns under the major questions doctrine. Congress created the CMS Innovation Center for the specific purpose of testing ''innovative payment and service delivery models,'' expressly authorized the Secretary to waive under section 1115A(d)(1) of the Act any Medicare requirements ''as may be necessary solely for the purpose of carrying out this section,'' and expressly bounded the authority with limiting conditions. CMS is not invoking broad, general statutory language to claim transformative power; rather, CMS is acting within a detailed, purpose-specific statutory framework that Congress designed precisely for this type of model test in the context of a voluntary Spending Clause program (Medicare). Notably, section 1115A of the Act does not merely confer a general or open-ended mandate; it establishes a structured testing framework and includes an illustrative list of model types that Congress itself identified as falling within the scope of the authority. The GLOBE Model fits squarely within that framework, further confirming that CMS is not claiming power from vague or ancillary text but is instead acting within the specific contours of the authority Congress deliberately designed.

The major questions doctrine is directed at agencies that claim extraordinary power from vague or ancillary statutory text over issues of vast economic and political significance—the framing the Supreme Court applied in *West Virginia* v. *EPA.* The GLOBE Model, by contrast, derives its authority from section 1115A of the Act, which provides a clear and express statutory basis for the model's design and scope. The GLOBE Model is a time-limited and narrowly scoped test designed to understand whether changing the Medicare Part B drug inflation rebate amount calculation will reduce Medicare spending while preserving or enhancing quality of care furnished to beneficiaries. This structural limitation is itself significant for purposes of the major questions doctrine. The doctrine is animated by concern about agencies making lasting, transformative policy changes without clear congressional authorization. Because the GLOBE Model operates within this inherently provisional framework, it cannot produce the kind of sweeping, enduring transformation that triggers concerns under the major question doctrine. Congress built this limitation directly into the statute, demonstrating that it deliberately constrained the scope of the authority it was delegating.

CMS's approach in designing the GLOBE Model is consistent with the manner in which the CMS Innovation Center has exercised its section 1115A authority across a wide range of models throughout its history. Since its establishment, the CMS Innovation Center has routinely tested alternative payment methodologies that test an alternative approach to how Medicare pays for items and services, including alternative approaches for existing statutory payment formulas. For example, OCM tested, and the Enhancing Oncology Model (EOM) is testing, episode-based payment approaches that alter standard Medicare fee-for-service reimbursement for cancer care. The BPCI and BPCI Advanced models restructured Medicare payment for episodes of care across a broad range of clinical conditions. The CJR Model—which, like the GLOBE Model, was implemented on a mandatory basis—altered Medicare payment for lower extremity joint replacement procedures across geographically selected markets. The MA Value-Based Insurance Design Model tested modifications to cost-sharing structures for MA enrollees. In each of these models, the CMS Innovation Center exercised its section 1115A authority to waive existing Medicare payment requirements and substitute alternative payment approaches. Moreover, the very purpose of section 1115A of the Act is to test innovative policies that would reduce program expenditures while preserving or enhancing quality of care that Congress has not yet enacted; requiring prior congressional endorsement and/or the prior existence of the elements of each innovative payment and service delivery model proposed by CMS would render the innovative model-testing authority of section 1115A of the Act superfluous. In sum, in order to test innovative payment or service delivery models in accordance with the statutory objectives of section 1115A of the Act, the CMS Innovation Center must design innovative elements of the model test and, where applicable, waive statutory and regulatory provisions that would conflict with the testing of those innovative elements; that authority is squarely what CMS is exercising here. The GLOBE Model's alternative approach to the Medicare Part B drug inflation rebate amount calculation using international drug pricing information represents the same category of payment model innovation that the CMS Innovation Center was designed and authorized to test. The major questions doctrine does not require that every exercise of CMS Innovation Center authority be tied to a specific precedent; it requires only that the authority be grounded in clear statutory text, and, as discussed previously, section 1115A of the Act provides exactly that.

CMS also does not believe the GLOBE Model implicates the concerns raised in *Biden* v. *Nebraska.* In that case, the Supreme Court held that, under the HEROES Act, the Secretary of Education could not rely on authority to waive or

modify statutory or regulatory provisions applicable to student financial assistance programs as deemed necessary in connection with a war or other military operation or national emergency, to implement a broad student loan forgiveness program, as the latter was statutory provisions that had vast economic and political significance without clear congressional authorization. The GLOBE Model is distinguishable on the basis that the model falls squarely within the purpose-specific statutory framework of section 1115A of the Act that expressly authorizes the CMS Innovation Center to test time-limited innovative payment models, waive any Medicare requirement ''as may be necessary solely for the purpose of carrying out this section with respect to testing models,'' and evaluate the results against defined statutory criteria. Unlike the action at issue in *Biden* v. *Nebraska,* which canceled approximately $430 billion in Federal student loans and completely erased the debts of 20 million borrowers pursuant to the claimed authority under the HEROES Act, the GLOBE Model (1) tests a targeted alternative rebate amount calculation under the Medicare Part B Drug Inflation Rebate Program in accordance with section 1115A of the Act's statutory objectives of reducing program expenditures while preserving or enhancing quality of care, (2) is limited to a random selection of ZCTAs representing approximately 25 percent of OM Part B enrollees, (3) focuses on a subset of Part B rebatable drugs, (4) operates only for a limited test period from January 1, 2027 to March 31, 2034 (further discussed in section II.A. of this final rule), (5) is estimated to produce overall savings of $440 million [104] in Medicare Part B net spending (where overall total OM Part B drug spending was $81.90 billion according to 2025 claims data), (6) is evaluated for impacts to program expenditures and quality of care in accordance with section 1115A(b)(4) of the Act, (7) is subject to specific statutory requirements for expansion should the CMS Innovation Center seek to expand the duration and the scope of the model test pursuant to section 1115A(c) of the Act, and (8) is subject to regular reporting to Congress under section 1115A(g) of the Act. Thus, the GLOBE Model does not represent the type of action at issue in *Biden* v. *Nebraska.* Accordingly, CMS does not believe the GLOBE Model presents the type of sweeping, transformative agency action that the major questions doctrine is intended to constrain.

Commenters also cited *Loper Bright* for the proposition that courts must give statutory text its ordinary meaning in context, and they suggested that this principle undermines CMS's reliance on section 1115A authority for the GLOBE Model. CMS disagrees. *Loper Bright* held that courts must independently interpret statutory text and are not required to defer to an agency's reading of an ambiguous statute. However, *Loper Bright* does not alter the outcome here because CMS's authority to implement the GLOBE Model does not rest on a strained or ambiguous reading of section 1115A of the Act—it rests on the plain text of the statute itself. Read according to its ordinary meaning, section 1115A of the Act expressly authorizes the Secretary to test ''innovative payment and service delivery models'' and to waive any Medicare requirements ''as may be necessary solely for the purpose of carrying out this section with respect to testing models.'' The ordinary meaning of this language provides CMS with the authority to test an innovative payment model to reduce program expenditures while preserving or enhancing quality of care that is time-limited and geographically scoped where CMS waives section 1847A(i)(3) of the Act as related to calculation of rebate amounts as necessary so that the rebate amount calculation can incorporate certain international drug pricing information. *See Loper Bright,* 603 U.S. at 395 (''When the best reading of a statute is that it delegates discretionary authority to an agency, the role of the reviewing court under the APA is, as always, to independently interpret the statute and effectuate the will of Congress subject to constitutional limits. The court fulfills that role by recognizing constitutional delegations, fixing the boundaries of the delegated authority, and ensuring the agency has engaged in reasoned decision making within those boundaries'') (cleaned up).

Far from requiring deference to a contested agency interpretation, the plain text of section 1115A of the Act, read in its full statutory context, affirmatively supports CMS's authority here. *Loper Bright* instructs courts to apply the best reading of the Act's statutory provision, consistent with its text, structure, and purpose. Here, CMS believes the best reading of section 1115A of the Act is that it authorizes the GLOBE Model. The statute was enacted by Congress with the deliberate purpose of enabling the CMS Innovation Center to test innovative Medicare payment models, and the GLOBE Model falls squarely within that purpose. Accordingly, *Loper Bright* does not provide a basis for concluding that the GLOBE Model exceeds CMS's statutory authority.

Commenters finally cited *Learning Resources, Inc.* v. *Trump* and noted that the Supreme Court has stated that ''both separation of powers principles and a practical understanding of legislative intent'' suggest that Congress does not delegate ''highly consequential power'' through ambiguous language. CMS disagrees that this principle undermines its authority here. As an initial matter, the GLOBE Model does not rest on ambiguous statutory language. Section 1115A's text is clear and expansive: it expressly grants the Secretary broad authority to test innovative payment and service delivery models and to waive any Medicare requirements as necessary to carry out such testing. The GLOBE Model represents a time-limited, geographically scoped model designed to test the effect of incorporating international drug pricing information into rebate amount calculations, which falls squarely within the core of the Secretary's expressly delegated testing authority under section 1115A of the Act. This is not an instance of CMS claiming sweeping or transformative regulatory power through a strained reading of ambiguous text; it is a straightforward exercise of authority that Congress plainly conferred. Accordingly, *Learning Resources* does not alter CMS's conclusion that section 1115A of the Act provides sufficient statutory authority for the GLOBE Model.

CMS also respectfully disagrees with the characterization that Congress ''actively debated and deliberately declined to enact'' international reference pricing when passing the IRA, and that this legislative history forecloses the GLOBE Model. The fact that a Congress subsequent to the one that enacted section 1115A of the Act considered and did not adopt a particular policy approach in the specific context of the Negotiation Program does not foreclose the CMS Innovation Center from testing an approach that uses certain international drug pricing information within the limited bounds of its statutory authority under section 1115A of the Act. Section 1115A of the Act, which predates the IRA and was enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111–148), provides the CMS Innovation Center with express, independent authority to test innovative payment and service delivery models, including models that explore alternative rebate and pricing

[104] Overall Medicare Part B net spending savings are calculated by adding OM Part B benefit savings and MA payment savings and then subtracting the premium offset.

methodologies. The GLOBE Model does not purport to implement the international reference pricing provisions that Congress considered and did not adopt in the context of the Negotiation Program; rather, it is a time-limited, narrowly scoped model test conducted pursuant to the CMS Innovation Center's distinct statutory mandate.

Commenters' position that the CMS Innovation Center cannot test the GLOBE Model due to the major questions doctrine and the rejection of using foreign reference prices specifically in the context of the Medicare Drug Price Negotiation during the passage of the IRA constrains Congress in a manner that has heretofore never been recognized by law. Rather than allowing the CMS Innovation Center to test this model pursuant to its statutory authority under section 1115A of the Act—a model that has undergone notice and comment rulemaking and is limited in geographic scope, limited in the drugs subject to the Model, and limited in duration—in order to understand whether this alternative payment methodology that incorporates certain international drug pricing information preserves or enhances beneficiaries' quality of care while reducing program expenditures, commenters' position asserts that Congress is prevented from relying on this duly authorized, limited kind of testing in the first place to understand the consequences of particular policy approaches on beneficiaries' quality of care and Federal spending before enacting legislation with significant, nationwide ramifications. That is not an outcome required by current law.

As discussed elsewhere in this section of this final rule, CMS does not believe that the presence of spillover effects means that the GLOBE Model would constitute a nationwide model, that it would bring about sweeping changes to the Medicare program, or that it would transform the negotiation framework that Congress established. CMS disagrees that the GLOBE Model constitutes a nationwide drug pricing change. As discussed in the GLOBE Model proposed rule (90 FR 60338) and this final rule, the model would apply to a randomly selected subset of geographic areas representing 25 percent of OM beneficiaries, a limited subset of Part B rebatable drugs, and a defined test period. These limitations are inconsistent with the characterization of the model as a nationwide restructuring of drug pricing. The limited footprint of the GLOBE Model stands in stark contrast to the types of agency actions that courts have found to constitute claims of ''highly consequential'' or transformative power, such as nationwide vaccine mandates, sweeping emissions regulations affecting entire industries, or broad student loan cancellation programs with economy-wide consequences. The GLOBE Model does not eliminate or wholesale replace the existing rebate framework, does not apply universally across the Medicare program, and does not impose new obligations across the broader healthcare system. Where the real-world impact of an agency action is this circumscribed and targeted, the major questions doctrine provides no basis for invalidation.

Finally, CMS notes that Congress' silence on international reference pricing in the IRA or other legislation does not prohibit the CMS Innovation Center from testing models under section 1115A of the Act. While section 1115A of the Act enumerates twenty-seven model types for testing that do not include drug pricing tests, the statute, by its own terms, does not limit CMS's authority to those listed types. Section 1115A(b)(2)(A) of the Act provides that the models selected for testing ''may include, *but are not limited to,* the models described in subparagraph (B).'' (Emphasis added.) The Supreme Court has held that ''the expansive phrasing of 'may include' points directly away from the sort of exclusive specification'' that commenters' argument requires. *See Chevron U.S.A.* v. *Echazabal,* 536 U.S. 73, 80 (2002) (quoting 42 U.S.C. 12113(b)); *see also NationsBank of N.C., N.A.,* v. *Echazabal,* 536 U.S. 73, 80 (2002) (quoting 42 U.S.C. 12113(b)); *NationsBank of N.C., N.A.,* v. *Variable Annuity Life Ins. Co.,* 513 U.S. 251, 258 n.2 (1995) (upholding Comptroller of the Currency's ''discretion to authorize activities beyond those specifically enumerated'' in statute). Here, section 1115A of the Act provides abundant ''contrary indications'' that Congress intended broad model-testing authority: the statute's stated purpose is to ''test innovative payment and service delivery models to reduce program expenditures''; the illustrative models encompass approaches as varied as promoting payment and practice reform in primary care, utilizing medication therapy management services, and familiarizing individuals with coverage availability for qualified psychologist services (sections 1115A(b)(2)(B)(i), (vii), and (xxvi) of the Act). This breadth of categories demonstrates that Congress did not intend the list to cabin CMS's authority within narrow topical boundaries.

The absence of an express statutory provision permitting international reference pricing does not establish a prohibition; had Congress intended to foreclose this type of model testing, it could have done so expressly. Thus, the CMS Innovation Center is duly authorized to test the GLOBE Model under section 1115A of the Act.

*Comment:* A couple of commenters stated a distinct appropriations law concern under the anti-augmentation principle, codified in the Miscellaneous Receipts Act, 31 U.S.C. 3302(b). Commenters stated that this principle requires that any money received by the Federal government to be deposited into the Treasury's general fund, not into a specific trust fund, unless Congress has explicitly authorized otherwise. Commenters believed that, because the GLOBE Model would direct manufacturer rebate payments into the Federal Supplementary Medical Insurance Trust Fund, not the general Treasury, and because CMS lacks express congressional authorization to deposit those funds into the Federal Supplementary Medical Insurance Trust Fund, the model violates this long-standing principle of appropriations law.

*Response:* CMS disagrees with the commenters' argument that the GLOBE Model violates the anti-augmentation principle. CMS also disagrees with the commenters' contention that the GLOBE Model impermissibly augments congressional appropriation by directing new manufacturer payments into the Federal Supplementary Medical Insurance Trust Fund without express authorization.

The Medicare Part B Drug Inflation Rebate Program's statutory framework confirms that manufacturer rebate payments are properly credited to the Federal Supplementary Medical Insurance Trust Fund, as mandated by section 1847A(i)(6) of the Act. Further, Congress established the CMS Innovation Center under section 1115A of the Act to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing quality of care. The GLOBE Model does not augment agency appropriations through unauthorized means; rather, it operates pursuant to the CMS Innovation Center's explicit Congressional authorization to test an innovative payment model, where the CMS Innovation Center tests a targeted alternative approach to the rebate amount calculation under the Medicare Part B Drug Inflation Rebate Program and the rebates are deposited consistent with the requirements of the Medicare Part B Drug Inflation Rebate Program

into the Federal Supplementary Medical Insurance Trust Fund as required by Congress under section 1847A(i)(6) of the Act.

*Comment:* A few commenters stated that the GLOBE Model violates the Anti-Deficiency Act, codified at 31 U.S.C. 1341–1342 and 1511–1519, which bars employees of the Federal government from obligating funds in advance of or in excess of appropriations. Specifically, the commenters stated GLOBE impermissibly directs new incremental rebate payments into the Federal Supplementary Medical Insurance Trust Fund rather than the Treasury's general fund, effectively boosting the Federal Supplementary Medical Insurance Trust Fund's available resources without congressional authorization. The commenters believed this is an end-run around Congress's power of the purse.

*Response:* CMS disagrees that the GLOBE Model violates the Anti-Deficiency Act. The Anti-Deficiency Act prohibits Federal employees from obligating or expending funds in advance of or in excess of available appropriations. The GLOBE Model operates within the existing statutory framework, wherein Congress authorized rebate payments under the Medicare Part B Drug Inflation Rebate Program, section 1847A(i) of the Act. Under that framework, rebate payments from manufacturers are already directed to the Federal Supplementary Medical Insurance Trust Fund by statute. The GLOBE Model does not create a new or independent funding stream; rather, it creates an alternative methodologyby which the rebate amount is calculated for certain drugs tested under the model, consistent with the CMS Innovation Center's authority under section 1115A of the Act. Because the GLOBE Model substitutes an alternative rebate amount calculation for the otherwise applicable statutory rebate amount, rather than establishing a wholly new category of payment obligation, the destination of those funds remains consistent with the existing statutory framework. No new appropriation is required, and no funds are obligated in advance of or in excess of available appropriations. Congress itself established both the Federal Supplementary Medical Insurance Trust Fund as the repository for Medicare Part B drug inflation rebates and the CMS Innovation Center's broad authority to test alternative payment models. The GLOBE Model operates squarely within both of those congressional mandates.

Furthermore, the Anti-Deficiency Act's prohibition on obligating funds in excess of appropriations is not implicated here because the GLOBE Model does not direct CMS to spend funds beyond what has been appropriated. On the contrary, the model is designed toreduceMedicare expenditures by testing whether an alternative payment methodology produces lower net drug costs for the Medicare program while preserving or enhancing quality of care. Any rebate payments collected under the model flow through the same statutory channels already established by Congress for the Medicare Part B Drug Inflation Rebate Program. For these reasons, CMS does not believe the GLOBE Model violates the Anti-Deficiency Act, and the related concerns articulated by commenters are not present here.

*Comment:* Many commenters raised broader policy concerns about the GLOBE Model's potential impact on biomedical innovation and patient access. Commenters stated that tying U.S. drug reimbursement to foreign prices, which are often set by foreign governments through price controls, would introduce uncertainty into Medicare Part B reimbursement. Commenters also stated the GLOBE Model would import process controls that undervalue biomedical innovation and reduce incentives for research and development (R&D), particularly for treatments for rare diseases. A commenter stated that Part B spending is concentrated in biological products and that use of price controls ''disproportionately affects products with no therapeutic substitutes and limited pricing flexibility,'' which would affect investment in these areas. Commenters also stated that reduced R&D investment would ultimately limit the development of new therapies, harm patient access to innovative treatments, shorten lifespan, diminish health outcomes, and that the IRA already includes carefully calibrated exceptions (for example, the orphan drug exclusion) to protect innovation incentives, while the GLOBE Model contains no such safeguards. A commenter believed that implementing foreign price controls would ''circumvent the generic and biosimilar pathway'' in the U.S. that delivers ''affordability through market entry and competition.'' Another commenter cited studies and stated that drug prices in the U.S. are not exorbitant and price controls harm innovation. Commenters further expressed concerns about threats to intellectual property, job losses, market distortions, economic harm, and loss of U.S. global leadership in biopharmaceutical innovation (potentially shifting to countries like China and other foreign competitors). A commenter further believed that the GLOBE Model will result in a net negative for state and Federal government savings and that states such as California, New York, and Texas will ''suffer the most'' with respect to potential job losses and economic harm (for example, tax revenue, earnings). Commenters further stated that these policy tradeoffs related to innovation are precisely the type of major decisions that courts presume Congress intends to make itself, rather than delegate to agencies through ambiguous statutory language such as section 1115A of the Act. For these reasons, commenters recommended the GLOBE Model be withdrawn.

*Response:* CMS appreciates the thoughtful comments submitted regarding the potential impact of the GLOBE Model on biopharmaceutical innovation incentives. CMS takes seriously the concern that Federal drug pricing policies, individually and in combination, could affect manufacturer investment decisions in therapeutic areas of critical importance to Medicare beneficiaries, including rare diseases. However, CMS disagrees that the GLOBE Model will materially reduce biopharmaceutical R&D spending or innovation, shorten lifespan, or diminish health outcomes or patient access to treatments in the manner or to the extent suggested by commenters.

The model's rebate obligation, as a starting point, reaches only drugs exceeding $100 million in OM Part B allowed charges over a 12-month period—a threshold reflecting substantial market penetration—and affects only the OM Part B market, leaving commercial, MA, and ex-U.S. revenues unaffected. CMS also notes that commenters' analyses of potential model impacts on innovation and the U.S. pharmaceutical industry may not fully account for the range of ways in which manufacturers may adapt to changing market conditions—conditions that exist regardless of the GLOBE Model—through partnerships, portfolio management, operational efficiencies, and other strategies to sustain R&D activities and remain competitive in the U.S. market. Pharmaceutical manufacturers make R&D decisions in response to the broader domestic and global environment affecting expected returns, rather than based on any single payment model or drug-pricing initiative in one subset of the market. Pharmaceutical R&D investment is also influenced by development and other input costs, anticipated lifetime global revenues, and policies affecting the supply of and demand for drugs within

a given market, with expected revenues reflecting anticipated prices and sales across markets worldwide.[105] This broader environment includes numerous domestic and international drug-pricing and reimbursement policies, public and private payer arrangements, and market-specific conditions. Accordingly, any decision by a manufacturer to reduce, increase, or redirect investment—and any resulting impact on future innovation—would reflect the combined effect of these factors, rather than the singular effect of the GLOBE Model. There are numerous initiatives that are beyond the scope of this final rule that will influence R&D spending and innovation for new drugs. We direct the reader to the 2026 Council of Economic Advisors Report for a discussion of U.S. based drug pricing policy initiatives.[106] [107]

Furthermore, projections of reduced innovation are highly dependent on a series of assumptions regarding manufacturer, investor, and market responses; assumptions for which the magnitude and direction are inherently uncertain. Economic research on the relationship between drug pricing and innovation incentives is highly contested, and no established economic analysis posits a simple linear relationship between drug prices and innovation outcomes.[108] [109] Assuming such a simplified linear relationship could be established, if taken to its logical conclusion, this would justify any level of drug spending regardless of its proportionality or value to the Medicare program.

Researchers additionally have found no association between drug prices and amount of R&D investments; in other words, high drug prices are not necessarily due to high R&D costs but rather what the market is willing to pay.[110] [111] A substantial body of research suggests that pharmaceutical R&D incentives are strongly shaped by expected commercial returns, patent and exclusivity rules, and risk-adjusted profitability, which can steer investment toward known, high-revenue therapeutic areas, follow-on products, line extensions, and other incremental innovation rather than exclusively toward products with the greatest clinical value.[112] [113] [114] We note that the GLOBE Model does not alter any of these existing incentives. However, even if lower expected revenues led to fewer future approvals, it does not necessarily mean that patients would lose access to a proportional number of high value therapies; some foregone products would have offered limited incremental benefit.

CMS also disagrees that the GLOBE Model imports foreign price-setting systems or foreign price controls into the Medicare program or that the GLOBE Model would lead to significant uncertainty in Medicare Part B reimbursement. The GLOBE Model tests an alternative approach to the Medicare Part B drug inflation rebate amount calculation such that the GLOBE Model rebate for a GLOBE Model drug reflects the difference between a benchmark price, which is informed by international drug pricing information, and the specified amount, as described in section II.G.4. of this final rule. The existing OM Part B program structure remains in place, and all applicable OM Part B program rules continue to apply under the GLOBE Model. Importantly, the GLOBE Model does not incorporate or rely upon any foreign country's legal policies, formulary rules, coverage rules, or health technology assessment processes in its alternative rebate amount calculation or into the Medicare program. Therefore, we disagree that the use of foreign prices as a benchmark in the GLOBE Model would lead to limits in patient access, reduce lifespan, or diminish health outcomes as the model does not incorporate foreign price-setting systems or foreign price controls.

As stated previously, the use of foreign prices in the international benchmark serve as a proxy for the payment levels drug manufacturers are willing to accept for their products, from drug manufacturers' perspectives—despite what foreign payors are willing to spend or how lower foreign prices are developed. Given that the international benchmarks are illustrative of payment levels that drug manufacturers may accept for these products, we believe testing a targeted alternative to the rebate amount calculation under the Medicare Part B Drug Inflation Rebate Program using these international benchmarks to reduce program expenditures while preserving or enhancing quality of care represents a reasoned and valid innovative payment model duly authorized by section 1115A of the Act.

CMS also disagrees with the commenter's general statement that drug prices in the U.S. are not high compared to other countries. The data shows that U.S. prescription drug prices, particularly for U.S. originator drugs, exceed those found in other OECD countries, with 23.1 percent of U.S. patients skipping prescribed medicines because of costs.[115] In addition, prior studies on generic drug pricing in the U.S. have shown that generic drug prices in the U.S. generally compare to or fall below international comparisons, which suggests that high overall drug costs in the U.S. are primarily driven by originator, single source drugs or sole source biological products. Based on the high spending by OM Part B and Medicare Part B beneficiaries on single source drugs and sole source biological products, in this final rule, we finalized the GLOBE Model to test the impact of using international drug pricing information as a benchmark for an alternative Medicare Part B drug inflation rebate amount calculation for a subset of Part B rebatable drugs (certain single source drugs and sole source biological products that meet the criteria defined in § 513.130) to reduce

[105] Congressional Budget Office. Research and Development in the Pharmaceutical Industry, April 2021. Available at: *https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf.*

[106] The White House. Savings from Most-Favored-Nation Drug Pricing Policy, May 5, 2026. Available at: *https://www.whitehouse.gov/research/2026/05/savings-from-most-favored-nation-drug-pricing-policy/.*

[107] Congressional Budget Office. Research and Development in the Pharmaceutical Industry, April 2021. Available at: *https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf.*

[108] Light, D., Warburton, R. *Demythologizing the high costs of pharmaceutical research.* BIOSOCIETIES 6, 34–50 (2011). *https://doi.org/10.1057/biosoc.2010.40;* Accessed: April 10, 2026.

[109] M. Schlander et al., *How Much Does It Cost to Research and Develop a New Drug? A Systematic Review and Assessment,* 39 PHARMACOECONOMICS 1243 (2021), *https://doi.org/10.1007/s40273-021-01065-y.* Accessed: April 10, 2026.

[110] O. Wouters, L. Berenbrok, M. He, Y. Li, & I. Hernandez, *Association of Research and Development Investments With Treatment Costs for New Drugs Approved From 2009 to 2018,* 5 JAMA 9, 2022, doi:10.1001/jamanetworkopen.2022.18623 (Accessed: June 15, 2026).

[111] A. Angelis, R. Polyakov, O. Wouters, E. Torreele, M. McKee, *High drug prices are not justified by industry's spending on research and development,* 380 BMJ (2023), *https://doi.org/10.1136/bmj-2022-071710* (Accessed: June 15, 2026).

[112] E. Budish, B.N. Roin & H. Williams, *Do firms underinvest in long-term research? Evidence from cancer clinical trials,* 105 AM. ECON. REV. 2044 (2015), *https://doi.org/10.1257/aer.20131176* (Accessed: May 12, 2026).

[113] A.S. Kesselheim, J. Avorn & A. Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform,* 316 JAMA 858 (2016), *https://doi.org/10.1001/jama.2016.11237* (Accessed: May 12, 2026).

[114] A. Kapczynski, C. Park & B. Sampat, *Polymorphs and prodrugs and salts (oh my!): an empirical analysis of ''secondary'' pharmaceutical patents,* 7 PLOS ONE e49470 (2012), *https://doi.org/10.1371/journal.pone.0049470* (Accessed: May 12, 2026).

[115] The Commonwealth Fund. U.S. Health Care from a Global Perspective, 2026, May 2026. Available at: *https://www.commonwealthfund.org/publications/issue-briefs/2026/may/us-health-care-global-perspective-2026.*

Medicare program expenditures while preserving or enhancing quality of care.

CMS notes that the scope of the model is limited to approximately 25 percent of OM Part B beneficiaries and a subset of Part B rebatable drugs that meet certain criteria, as described in section II.B. of this final rule, and that, as noted previously, the model operates for the purpose of evaluating whether an alternative rebate amount calculation reduces Medicare spending while preserving or enhancing quality of care for Medicare beneficiaries. As such, we disagree with the assertion that the GLOBE Model contains no safeguards for biomedical innovation and patient access. Because the GLOBE Model is applicable to only 25 percent of the OM Part B beneficiaries, leaving commercial, MA, and ex-U.S. revenues unaffected, we believe the model's design itself provides a meaningful safeguard for innovation. In addition, in response to these and other comments expressing concerns about reduced incentives for R&D, particularly for treatments for rare diseases, CMS is adopting additional drug exclusions in the finalized GLOBE Model design, as discussed in section II.B. of this final rule, such that Part B rebatable drugs designated as a drug for one or more rare diseases or conditions under section 526 of the Federal FD&C Act (21 U.S.C. 360bb) and for which the only approved indication (or indications) is for one or more such rare diseases or conditions are excluded from the GLOBE Model (hereinafter the ''orphan-only drugs'').

CMS notes that biopharmaceutical research and investment decisions are influenced by a wide range of factors—including scientific feasibility, market size, competitive dynamics, regulatory pathways, and the broader policy environment—that are difficult to disentangle from the potential effects of a model test within the Medicare program. As part of the GLOBE model test, CMS will work with its evaluation contractor, as described in section II.P. of this final rule, and will address confounding factors and develop rigorous analytic approaches for assessing the GLOBE Model's contribution to any observed changes in innovation activity and will be transparent about the limitations of these analyses in its public evaluation reports, given the complexity of such analyses. Leveraging the randomized design of the GLOBE Model and CMS's extensive experience with evaluating models in complex, policy environments, the GLOBE Model evaluation, as described in section II.P. of the final rule, will be designed to isolate the model's effects on program expenditures and quality of care, including through the use of appropriate comparison groups and statistical methods.

Also, CMS disagrees with the comment that the GLOBE Model circumvents the generic and biosimilar pathway in the U.S. We assume the comment refers to the drug approval pathway and incentives to develop generics and biosimilars in the U.S. As stated in the GLOBE Model proposed rule (90 FR 60255 through 60256), only single source drugs and sole source biological products that are Part B rebatable drugs would be GLOBE Model drugs. As such, the GLOBE Model intentionally does not include multi-source drugs or biological products to prevent disruption to the generic and biosimilar approval pathways and their related incentives to develop such products in the U.S.

We acknowledge that the GLOBE Model focuses on high-spend Part B rebatable drugs that are single source drugs or sole source biological products. This focus is intentional, as the model is designed to test an alternative Medicare Part B drug inflation rebate calculation on high spend Part B rebatable drugs where access barriers—such as high costs—are likely to contribute to deficits in care. Further, the generic and biosimilar pathways commenters have referenced do not address the high prices of these high spend Part B rebatable drugs prior to generic or biosimilar entry in the U.S. and as such cannot address related deficits in care prior to such generic or biosimilar market entry in the U.S. In contrast, the GLOBE Model seeks to address Medicare's significant expenditure on these drugs and related access barriers or deficits in care prior to generic or biosimilar market entry in the U.S.

Additionally, we strongly disagree that the GLOBE Model will undermine U.S. biopharmaceutical leadership, domestic manufacturing (that is, job losses), market stability, or create a net negative in savings for state and Federal governments as suggested by the commenters. The GLOBE Model is a limited test of an alternative Medicare Part B drug inflation rebate amount calculation for a defined subset of drugs and beneficiaries, and commenters' predictions related to loss of capital, market stability, supply-chain relocations, or geopolitical effects depend on a series of uncertain assumptions about how manufacturers, investors, and foreign markets will respond. CMS has not identified record evidence sufficient to quantify those economy-wide effects with reasonable certainty for this time-limited model. CMS has nevertheless considered those risks in model design by limiting the model's scope, excluding orphan-only drugs, plasma-derived products, certain approved cellular and gene therapy products, and low-spend drugs, and monitoring access and utilization outcomes.

With respect to the commenters' statement that the policy tradeoffs such as those related to innovation presented by the GLOBE Model are of the type that courts presume Congress intends to resolve itself, rather than delegate to agencies, CMS disagrees that the major questions doctrine precludes the GLOBE Model as discussed more thoroughly previously. Section 1115A of the Act was enacted by Congress specifically to authorize the CMS Innovation Center to test innovative payment and service delivery models, including models that involve alternatives to existing payment and rebate structures, to reduce program expenditures while preserving or enhancing quality of care. The GLOBE Model is a targeted, time-limited test directly tied to the CMS Innovation Center's express statutory mandate. CMS does not rely on ambiguous or incidental statutory language to justify the GLOBE Model; rather, the model is a direct exercise of the authority Congress conferred in section 1115A of the Act.

For these reasons, CMS does not believe that the GLOBE Model must be withdrawn. Finally, CMS has responded to comments about intellectual property and patents in another comment summary and refer readers to our response related to the Patent Clause of the U.S. Constitution in this next comment.

*Comment:* Commenters stated that by imposing below-market, administratively determined benchmark prices on patented drug products prior to patent expiration or the end of FDA-granted exclusivities, the GLOBE Model conflicts with the Patent Clause of the U.S. Constitution and the Federal intellectual property framework established by Congress—both of which are designed to protect manufacturers' time-limited right to earn market-rate returns on their patented innovations.

*Response:* CMS disagrees that the GLOBE Model violates the Patent Clause or conflicts with the Federal intellectual property framework established by Congress. The Patent Clause of the U.S. Constitution provides Congress the power to ''promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective

Writings and Discoveries.'' U.S. Const. art. I, § 8, cl. 8. Critically, this is an affirmative grant of power to Congress, not a grant of rights to patent holders. It empowers Congress to create a patent system; it does not itself confer substantive rights on inventors or manufacturers, nor does it guarantee any particular economic outcome. Because the Patent Clause is an affirmative grant of power to Congress rather than a grant of rights to private parties, commenters have not identified a constitutional defect in the GLOBE Model under the Patent Clause. A constitutional challenge under the Patent Clause would require demonstrating that Congress exceeded or acted contrary to this grant of power, not merely that a Federal program affects the economic value of a patent. Commenters have not made that argument here. We also disagree that the GLOBE Model conflicts with the Federal intellectual property framework. The GLOBE Model is intended to reduce expenditures for certain high spend Part B rebatable drugs while preserving or enhancing the quality of care. The Federal intellectual property framework does not entitle drug manufacturers to particular payment levels or prices for their patented drugs or biological products. As such the GLOBE Model does not conflict with the Federal intellectual property framework as asserted by commenters. Further, Federal agencies routinely procure patented inventions, and Federal intellectual property frameworks do not require Federal agencies to bear whatever prices suppliers command. In sum, the GLOBE Model does not conflict with the Federal intellectual property framework.

We have addressed related concerns regarding economic impact and constitutional property protections in our responses to comments on Due Process and the Takings Clause, and would refer readers to those responses in other parts of this section of this final rule.

For these reasons, CMS disagrees with commenters that the GLOBE Model exceeds the CMS Innovation Center's statutory authority under section 1115A of the Act based on Patent Clause concerns. The GLOBE Model does not violate the Patent Clause, alter patent or exclusivity rights, or guarantee any price or revenue outcome—nor is CMS required to do so under the Patent Clause or any provisions of law.

*Comment:* A commenter stated that the use of an international reference price benchmark that is unilaterally established by CMS—without notice or an opportunity for review—combined with a mandatory rebate system lacking meaningful procedural protections constitutes a deprivation of manufacturer property rights without due process of law in violation of the Fifth Amendment. The commenter also stated that CMS has departed from the more robust procedural protections ordinarily afforded to CMS Innovation Center model participants in favor of procedures that parallel the Medicare Part B Drug Inflation Rebate Program, which the commenter characterizes as insufficiently protective. Several commenters also state that the GLOBE Model violates the Fifth Amendment Due Process Clause on the basis that CMS would deprive manufacturers of protected property interests without adequate procedural protections or that the international reference price benchmark would impose arbitrary or confiscatory prices without ensuring a reasonable return.

*Response:* CMS respectfully disagrees that the GLOBE Model would deprive manufacturers of property rights without due process of law, impose rebate obligations so excessive as to be confiscatory, or otherwise violate the Fifth Amendment's Due Process Clause.

Since the enactment of the Medicare and Medicaid programs in 1965, multiple courts have consistently rejected this precise argument. *See, for example, Garelick* v. *Sullivan,* 987 F.2d 913 (2d Cir. 1993), *see also Bristol Myers Squibb Co.* v. *Sec'y U.S. Dep't of Health & Hum. Servs.,* 155 F.4th 245, 256 n.10 (3d Cir. 2025), *cert. denied sub nom. Bristol Myers Squibb Co.* v. *Kennedy,* No. 25–751, 2026 WL 1377095 (U.S. May 18, 2026), and *cert. denied sub nom. Janssen Pharms., Inc.* v. *Kennedy,* No. 25–749, 2026 WL 1377134 (U.S. May 18, 2026). The Due Process Clause of the Fifth Amendment provides that no person shall be deprived of life, liberty, or property without due process of law. First, commenters' arguments do not identify a deprivation of a constitutionally protected property interest. When drug manufacturers voluntarily sell their goods to Medicare, there is no constitutionally protected interest in selling goods, patented or otherwise, to Medicare at a certain price level to which due process protections would apply. No court has recognized a constitutionally protected property interest in such circumstances. See *Nat'l Infusion Ctr. Ass'n* v. *Kennedy,* __F.4th __, 2026 WL 2517285, at *12 (5th Cir. Aug. 26, 2026); *Boehringer Ingelheim Pharms., Inc.* v. *HHS,* 150 F.4th 76, 94 (2d Cir. 2025), *cert. denied,* No. 25–799, 2026 WL 1377142 (May 18, 2026).

CMS notes that the procedural framework for the Medicare Part B Drug Inflation Rebate Program was established by Congress. The use of a similar procedural framework for the GLOBE Model reflects CMS's considered judgment that the framework in section 1847A(i) of the Act provides an appropriate reference and balance of procedural protection and administrative efficiency for a mandatory model test of an alternative rebate amount calculation. CMS disagrees that the GLOBE Model's procedures are constitutionally deficient as they are modeled on an existing congressionally established program.

Further, the GLOBE Model does not eliminate, abridge, curtail, or otherwise interfere with manufacturers' patent rights. Because the GLOBE Model does not deprive manufacturers of a protected property interest, the procedural protections required by *Mathews* v. *Eldridge,* 424 U.S. 319 (1976), are not triggered. The *Mathews* v. *Eldridge* balancing framework applies where the government seeks to deprive an individual or entity of an existing protected interest. Here, no such deprivation occurs: manufacturers continue to hold and exercise their patent rights in full.

We further note that manufacturers are not without due process under the GLOBE Model. The model's terms, drug selection criteria, rebate calculation methodology, and applicable exclusions are set forth in this final rule, providing manufacturers with advance notice of their obligations. Manufacturers receive preliminary rebate reports and preliminary reconciliation reports that are subject to a suggestion of error process under the model and can appeal civil monetary penalties imposed for failure to pay rebate obligations under the model, similar to the Medicare Part B Drug Inflation Rebate Program. These procedural protections are consistent with the requirements of the Due Process Clause.

We also disagree that the GLOBE Model imposes rebate obligations so excessive as to be ''confiscatory'' within the meaning of *Duquesne Light Co.* v. *Barasch,* 488 U.S. 299 (1989). That case was about utility rate regulation, where a government-imposed rate structure could, in theory, prevent a regulated utility from earning any return on its investment—effectively confiscating the utility's property. The commenter's extension of this notion to pharmaceutical manufacturer rebate obligations under a Medicare payment model is novel and unsupported.

We acknowledge that manufacturers may disagree with the GLOBE Model's rebate methodology and may believe that the rebate obligations are excessive.

However, disagreement with payment policy does not establish a constitutional violation. CMS further notes that the GLOBE Model is a time-limited model test under section 1115A of the Act, not a permanent statutory program. The procedural framework for the GLOBE Model is designed to be consistent with the model's objectives and operational requirements, and CMS retains the flexibility to adjust the framework as CMS gains experience with its implementation. For these reasons, we conclude that the GLOBE Model does not violate the Fifth Amendment's Due Process Clause and does not impose confiscatory rebate obligations.

We also disagree that we did not provide notice or opportunity for review of the international reference price benchmark rebate calculation methodologies in the GLOBE Model or that such methodologies are unilaterally established by CMS. In section II.G.1. of the GLOBE Model proposed rule (90 FR 60265 through 60273), we discussed the proposed international drug pricing information data sources, the requirements for existing data sources, and the hierarchy for using such existing data sources. The comments we received addressing very methodological questions for this section is evidence that CMS provided sufficient notice and opportunity for review. We refer readers to section II.G.1. of this final rule for our response to public comments related to existing data sources. As proposed and finalized in sections II.G.1.d. and II.G.6. of this final rule, manufacturers may also choose to voluntarily submit international drug net pricing data.

*Comment:* A commenter stated that by mandating manufacturer participation in the GLOBE Model, imposing below-market prices through a rebate scheme, and compelling the supply of patented drugs on nonconsensual terms, including at launch, CMS effectuates a forced transfer of constitutionally protected property interests for public benefit without just compensation, in violation of the Takings Clause of the Fifth Amendment.

Commenters stated that the GLOBE Model violates the Takings Clause of the Fifth Amendment, which prohibits the government from taking ''private property . . . for public use, without just compensation.'' Specifically, commenters contended that CMS's use of its CMS Innovation Center authority under section 1115A of the Act to establish new rebate requirements based on prices calculated from international reference pricing data would constitute an unconstitutional taking. Commenters note that both the Due Process Clause and the Takings Clause require the government to allow for a just or reasonable return on investment and prohibit the imposition of arbitrary or confiscatory prices. Commenters noted that the GLOBE Model imports reference prices from countries whose legal frameworks do not include equivalent constitutional protections, therefore the resulting ''calculated'' prices cannot satisfy these constitutional requirements. Commenters stated that forcing manufacturers to bear these financial burdens violates the constitutional principle that public burdens should be borne by the public, not imposed on private entities. For these reasons, commenters recommended the GLOBE Model be withdrawn.

*Response:* CMS disagrees that the GLOBE Model effects an unconstitutional taking of manufacturer property under the Constitution's Fifth Amendment. The Takings Clause of the Fifth Amendment provides that private property shall not ''be taken for public use, without just compensation.'' U.S. Const. amend. V. The commenter contends that the GLOBE Model's mandatory rebate structure effectuates a forced transfer of constitutionally protected property interests, including patent rights, for public benefit without just compensation and characterizes the GLOBE Model as compelling manufacturers to supply patented drugs on ''nonconsensual terms.''

As an initial matter, commenters have identified no deprivation of a constitutionally protected property interest under the Due Process or Takings Clauses. When drug manufacturers voluntarily participate in Medicare, there is no constitutionally protected property interest in selling goods to Medicare beneficiaries, patented or otherwise, at prices preferred by drug manufacturers. Thus, there can be no Takings Clause or Due Process Clause claim. Commenters' position stating that the GLOBE Model is an unconstitutional taking, by extension, would establish that sellers have a constitutionally protected property interest to command whatever price they desire from the Federal government, regardless of what the Federal government is willing or able to pay. That principle has never before been recognized by any court. Further, participation in the Medicare program, while practically significant for manufacturers of drugs covered by Medicare, is not legally compelled. Manufacturers retain the ability to withdraw their products from the Medicare market. *See Bristol Myers Squibb Co.* v. *Sec'y U.S. Dep't of Health & Hum. Servs.,* 155 F.4th 245, 260–61 (3d Cir. 2025). The practical significance of Medicare as a voluntary market does not transform a manufacturer's business decision to participate in that market into legally compelled conduct for purposes of the Takings Clause. In any case, the payment methodology under the GLOBE Model provides just compensation to drug manufacturers, as the use of foreign prices in the international benchmark serve as a proxy for the payment levels drug manufacturers are willing to accept for their products, from drug manufacturers' perspectives. This also belies any claim under the Takings Clause.

As discussed in this section of this final rule in response to other comments, CMS believes the model's rebate methodology is a permissible exercise of the CMS Innovation Center's broad model-testing authority and would not violate the constitutional limitations commenters have identified. For these reasons, we do not believe the GLOBE Model would violate the Takings Clause of the Fifth Amendment.

*Comment:* A few commenters stated that by setting Medicare payment levels based on foreign government prices and structuring incentives that directly influence manufacturer global pricing strategies and foreign market participation decisions, the GLOBE Model operates as an instrument of foreign economic regulation—a power vested exclusively in Congress and not delegated to CMS through section 1115A of the Act or any other authority. Specifically, a commenter stated that the GLOBE Model would ''operate as an instrument of foreign economic regulation in violation of the foreign commerce clause'' because it could influence manufacturer negotiations with foreign nations and impact manufacturer decisions about whether to enter or remain in foreign markets. They noted that the GLOBE Model would ''represent an agency instrument of foreign economic regulation that is not authorized by Congress and is beyond the scope of CMS authority.''

*Response:* CMS respectfully disagrees that the GLOBE Model operates as an instrument of foreign economic regulation in violation of the Foreign Commerce Clause, or that it exceeds the authority granted to the CMS Innovation Center under section 1115A of the Act. At the outset, the GLOBE Model would operate exclusively within the U.S. applying to approximately 25 percent of OM beneficiaries.

Using pricing data from reference countries to inform the GLOBE Model

rebate payment calculation does not constitute regulating foreign commerce. The use of pricing data from reference countries is an element of the domestic payment model authorized to be tested under section 1115A of the Act; the regulation of foreign commerce would require CMS to impose obligations on foreign markets or foreign commercial actors—which the GLOBE Model does not do. The commenter characterizes the GLOBE Model as an instrument of foreign economic regulation because it uses international reference prices as benchmarks for Medicare payment and because its incentive structure may influence manufacturer pricing decisions in foreign markets. CMS respectfully disagrees with this characterization. The GLOBE Model is, at its core, a domestic Medicare payment model. Its purpose is to test whether aligning Medicare drug payment with prices paid in comparable international markets can reduce Medicare program expenditures while preserving beneficiary access to innovative therapies. The model operates entirely within the domestic Medicare program: it applies to Medicare-covered drugs, imposes obligations on manufacturers of drugs payable under Medicare Part B, and directs any rebates collected to the Federal Supplementary Medical Insurance Trust Fund. The GLOBE Model does not adopt, replicate, or incorporate any foreign regulatory, coverage, or pricing framework.

The GLOBE Model does not purport to, or otherwise contain any provision that would, regulate the prices that manufacturers charge in foreign markets, does not impose obligations on foreign governments, and does not direct manufacturers to take any particular action in foreign markets.

The fact that the GLOBE Model uses international reference prices as an input into a domestic payment calculation does not transform it into an exercise of foreign commerce regulation. Federal agencies routinely reference foreign data, standards, and practices in designing domestic regulatory programs without thereby regulating foreign commerce. For example, the FDA routinely accepts foreign clinical trial data in support of domestic drug approval decisions; and the Occupational Safety Health Administration has incorporated the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals into its Hazard Communication Standard. In each of these cases, the use of internationally developed data, standards, or frameworks as an input into a domestic regulatory determination has not been understood to constitute an exercise of foreign commerce regulation. The GLOBE Model's use of international drug-pricing benchmarks as an input into a domestic Medicare payment calculation is consistent with this well-established regulatory practice and does not constitute the regulation of foreign commerce.

The relevant question is whether the GLOBE Model regulates foreign commerce, that is, whether it imposes legal obligations on foreign commercial transactions; the clear answer is that the GLOBE Model does not regulate foreign commerce since it is a domestic payment model authorized by Congress under section 1115A of the Act.

*Comment:* Several commenters believed that the GLOBE Model proposed rule did not provide the public adequate opportunity for notice-and-comment under the APA. Commenters claimed that the GLOBE Model proposed rule lacks key methodological and implementation information, such as the definition of ''international analog drugs,'' a data hierarchy, a process for validation, an audit and dispute framework, and a list of exempted drugs. Some of these commenters requested that CMS extend or reopen the comment period while others recommended the GLOBE Model be withdrawn.

*Response:* CMS disagrees with these comments. CMS provided the public with sufficient detail and a meaningful opportunity to comment on the GLOBE Model through the proposed rule, consistent with the requirements of the APA and section 1871 of the Act. Specifically, the proposed rule discussed the core structure of the model, the key requirements of the model test, the objectives and goals of the model, and CMS' statutory basis for testing the model. Additional details and clarifications on specific topics are provided in the relevant sections of the proposed rule and in response to comments throughout this final rule. CMS notes that some degree of uncertainty is inherent in every CMS Innovation Center model, because these models are designed to test whether a proposed approach achieves its intended objectives in practice. The inherent uncertainty associated with model testing does not establish that the public lacked adequate notice of the proposed policies, nor does it impose on CMS an obligation to resolve every implementation detail before publishing a proposed rule. The proposed rule described the core features of the GLOBE Model and provided sufficient information for the public to meaningfully comment on the model's scope, methodology, and implementation framework. Under the APA, an agency satisfies notice requirements if the proposed rule fairly apprises interested parties of the subjects and issues involved, even if every operational detail is not specified in advance, provided that the final rule is a logical outgrowth of the proposed rule. See *Long Island Care at Home, Ltd.* v. *Coke,* 551 U.S. 158, 174 (2007). To the extent commenters sought additional operational details—such as a precise definition of 'international net price,' a data hierarchy, a validation process, an audit and dispute framework, or a complete list of exempted drugs—CMS notes that the APA does not require every implementation detail to be included in the proposed rule, provided the public has been given a fair opportunity to comment on the meaningful substance of the proposed policies. CMS further notes that many of the specific items identified by commenters, including the definition of 'international net price,' the data hierarchy, the validation process, the audit and dispute framework, and the list of exempted drugs, are addressed in detail in the relevant sections of this final rule. Indeed, the volume and specificity of the comments received on these issues, including the detailed comments addressing very methodological questions, further demonstrate that the public had a meaningful opportunity to understand and comment on the proposed model. Therefore, CMS disagrees that it is necessary to extend or reopen the comment period and declines to withdraw the model.

*Comment:* Many commenters suggested alternatives to the GLOBE Model including, but not limited to: (1) prioritizing prevention, earlier intervention, and better management of chronic disease, (2) reforming pharmacy benefit manager (PBM) rebates and fees, (3) focusing on access barriers such as formulary restrictions that prevent patients from using guideline-directed therapy, (4) providing most favored nation pricing to all health plans (including commercial plans), (5) working on trade policies (for example, market access in foreign markets), (6) pursuing intellectual property rights, (7) strengthening oversight of Part B formulary and utilization managements, (8) directing rebates and savings to patients instead of intermediaries, (9) addressing foreign freeloading, (10) pursuing drug valuation and pricing system (for example, determine fair price, conduct independent pricing

assessment), (11) delaying when international reference pricing would apply to drugs and biological products, (12) coordinating complex care for cancer patients, and (13) pursuing outcomes-based agreements. With respect to item (11), a commenter stated that Medicare drug price negotiations are delayed for 7 years after FDA approval for small-molecule and 11 years for biological products and suggested that a similar delay be applied to international reference pricing under the GLOBE Model. Another commenter suggested the GLOBE Model should be delayed until the PBM reforms in the Consolidated Appropriations Act, 2005, Public Law 108–447, 118 Stat. 2809 (2004), have been enacted.

*Response:* CMS thanks the commenters for sharing their suggestions on alternatives to the GLOBE Model.

Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and CHIP expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of such programs. The GLOBE Model is focused on a defined 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 OM program. Accordingly, commenters' suggestions related to PBMs, formularies, commercial plans, trade policies, foreign freeloading, and intellectual property rights fall outside the scope of this final rule or are not directly part of the payment methodology for Medicare Part B drugs (for example, PBMs are not part of ASP + 6 percent payment methodology).

While we acknowledge commenters' suggested alternatives regarding intellectual property rights, trade policy, and addressing foreign freeloading, we believe these alternatives and GLOBE's time-limited model test serve different purposes. The GLOBE Model tests an innovative payment methodology that tests an alternative to the Medicare Part B drug inflation rebate amount calculation for GLOBE Model drugs using a benchmark relying upon international drug pricing information in a set of economically comparable countries. The model does not attempt to resolve broader intellectual property or trade-related policies.

We agree with commenters' suggestions to direct rebates and savings to patients. As reflected in section IV.D. of this final rule, we expect the GLOBE Model to result in reduced coinsurance for some beneficiaries and a potential reduction in Medicare Part B premiums for all beneficiaries.

At this time, we decline to include a drug valuation, pricing system mechanism, outcomes-based agreements, or coordination of complex care for cancer patients into the alternative approach to the Medicare Part B drug inflation rebate amount or to delay when the GLOBE Model would apply to Part B rebatable drugs. We also decline to modify the GLOBE Model to include coordination of complex care for cancer patients as this type of care is out-of-scope for testing an alternative Medicare Part B drug inflation rebate amount calculation methodology for certain Part B rebatable drugs. We also note that the CMS Innovation Center has an active model test, EOM, that incentivizes oncology practices to deliver coordinated, high-quality, patient-centered care for Medicare beneficiaries receiving certain cancer therapies, including chemotherapy.[116]

We may consider modifications to the GLOBE Model in future rulemaking based on factors such as changes in Medicare Part B drug spending patterns, the emergence of new therapeutic areas with significant financial burden, and the results of ongoing model evaluation.

*Final Decision:* CMS is finalizing the GLOBE Model regulation at 42 CFR part 513 with modifications as discussed in this final rule.

*A. Model Test Period*

In proposed § 513.1(c), we proposed 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,[117] 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 § 513.100(d).[118] We noted that it is necessary to include 2 payment years after the end of the final performance year to allow for rebate invoicing and reconciliation activities, as CMS delivers the information defined in section 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 proposed 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 was illustrated in Figure 1 in the GLOBE Model proposed rule (90 FR 60252). As discussed in section II.G.4. of this final rule, we proposed to test the GLOBE Model to capture all applicable billing units for all OM Part B 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. Accordingly, we proposed that, given the length of time during and after the end of an applicable calendar quarter that is necessary to conduct the 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 set forth in proposed § 513.1(c). In Table 1 of the GLOBE Model proposed rule (90 FR 60253), we illustrated, at a high-level, the proposed key information for the first four reporting windows for voluntary manufacturer-provided data. We proposed that a reporting window is the period of time that a manufacturer would have to submit voluntary manufacturer-provided international drug net pricing data ahead of the deadline for that quarter. These time periods were further detailed within subsections of section II.G.6. of the GLOBE Model proposed rule.

The following is a summary of the comments received and our responses.

*Comment:* A few commenters expressed concern that the proposed model start date of October 1, 2026 may not provide sufficient time for implementation, given the scope and complexity of the model. Commenters also stated the proposed model start date would leave CMS with a very limited window to issue a final rule, conduct stakeholder engagement, establish monitoring safeguards, and

[116] Centers for Medicare and Medicaid Services. EOM. Available at: *https://www.cms.gov/priorities/innovation/innovation-models/eom.*

[117] This period is a restatement of what was proposed in the NPRM, so it reflects the proposed model timeline. CMS is finalizing a 5 year performance timeline of April 1, 2027 through March 31, 2032 and associated payment timeline of April 1, 2027 through March 31, 2034.

[118] Through this final rule, as specified in § 513.1(c), the GLOBE Model test period will be January 1, 2027 through March 31, 2034.

develop a beneficiary educational campaign. Commenters further stated that the compressed implementation timeline could create operational strain and administrative burden for stakeholders, particularly if systems, beneficiary communications, and monitoring safeguards are not fully developed prior to the start of the model performance period, potentially leading to disruptions in care delivery and patient access.

*Response:* We appreciate commenters expressing concern over the short period of time before the start of the model. We recognize commenters' concerns regarding potential operational complexity of the model, including the need for sufficient time for CMS to finalize notice and comment rulemaking, conduct stakeholder engagement, and establish appropriate monitoring and beneficiary communication processes. In response to these comments, we are revising the model start date to January 1, 2027, to provide additional time for implementation and stakeholder readiness. As a result of this shift, we have determined that it is necessary to also shift by 2 calendar quarters (relative to what we proposed) the beginning of the first performance year such that GLOBE Model rebates and beneficiary coinsurance and adjusted payments to providers and suppliers, as applicable, would begin on April 1, 2027.

Under this revised timeline, the GLOBE Model test period will begin on January 1, 2027, allowing for an initial reporting period during Q1 2027, followed by the start of the first performance year and payment year on April 1, 2027. As further discussed in section II.A. of this final rule, the initial reporting period allows time during which manufacturers may submit international drug pricing data for the applicable ASP calendar quarter ending December 31, 2026, to CMS following model start and prior to the first applicable calendar quarter of performance year 1. We have reviewed and confirmed the viability of the GLOBE Model data management, systems, and operational requirements for implementation, monitoring, and evaluation under the revised timeline. In doing so, CMS considered the extent to which GLOBE Model operations would build on existing CMS systems, processes and infrastructure, as applicable. The revised timeline is reflected in Figure 1 and Table 1 of this final rule.

*Comment:* A few commenters expressed concern that the proposed 5 performance years, within a 7-year test period, may be too lengthy for a model and suggested that CMS consider shortening the GLOBE Model test period.

*Response:* We thank commenters for their feedback. We disagree that the GLOBE Model test period is too lengthy for a model. The duration of the GLOBE Model is consistent with the length of many models tested by the CMS Innovation Center, which commonly span multiple years to allow for robust evaluation of impacts on cost and quality. For example, CMS Innovation Center models frequently include test and evaluation periods spanning approximately 5 to 10 years, with several models—including the Maryland Total Cost of Care Model, the Financial Alignment Initiative, and the Next Generation ACO (NGACO) Model—having test periods of similar or greater duration as measured from initial implementation through final evaluation reporting.

A 7-year GLOBE Model test period, including 5 performance years, provides CMS with sufficient time to complete payment and rebate operations, consistent with our authority under section 1115A of the Act. The duration of the test period is driven primarily by the operational time needed to complete these activities. The 7-year GLOBE Model test period is necessary to complete rebate invoicing and reconciliation processes for all five performance years. We note that many CMS Innovation Center models such as the EOM and OCM also include reconciliation processes in their model timeline, as is necessary and appropriate for models including performance-based recoupments.

Evaluation of the model will occur on a separate timeline. As described in sections II.L. and II.P., we will conduct ongoing monitoring throughout the model test period and will release early evaluation findings as they become available. These activities will inform the CMS Innovation Center regarding the model's initial impacts and may inform potential modifications, as appropriate. We will also coordinate closely with the independent evaluation team to ensure that interim findings are assessed in a timely manner and, where appropriate, inform model refinements consistent with section 1115A of the Act.

*Final Decision:* After consideration of the public comments, including requests for additional time to support stakeholder engagement, operational readiness, monitoring infrastructure, and implementation of data reporting processes, and further considerations of the time necessary to implement operational and systems changes, including modifications to the Medicare claims processing systems, CMS has decided to delay the start of the GLOBE Model to January 1, 2027. Therefore, CMS is finalizing as set forth in § 513.1(c) that the GLOBE Model test period begins on January 1, 2027 and ends on March 31, 2034 and the GLOBE Model test period consists of a 1 quarter voluntary manufacturer submission period (initial reporting period) beginning on January 1, 2027, a 5-year performance period beginning April 1, 2027 and ending March 31, 2032 (unless sooner terminated in accordance with § 513.100(d)(4)) and a 7-year payment period beginning April 1, 2027, and ending March 31, 2034, or upon the completion of all model payment activities, whichever is later (unless sooner terminated in accordance with § 513.100(d)(4)).

Accordingly, CMS is finalizing with modifications related definitions in § 513.20, such that the definition of ''performance year'' (PY) means a 12-month period beginning on April 1 and ending on March 31 during the first 5 years of the GLOBE Model test period, ''GLOBE Model performance period'' means the 5 year period beginning April 1, 2027, and ending on March 31, 2032, ''payment year'' means a 12-month period beginning on April 1 and ending on March 31 during the GLOBE Model test period, and ''GLOBE Model payment period'' means the 7-year period beginning April 1, 2027, through March 31, 2034, or upon the completion of all model payment activities, whichever is later, as specified in § 513.1(c). CMS is adding a definition to § 513.20 providing that the ''GLOBE Model test period'' means the period beginning on January 1, 2027 (the model start date) and ending on March 31, 2034, or upon the completion of all model payment activities, whichever is later, unless sooner terminated in accordance with § 513.100(d)(4). In conjunction with this addition, CMS has revised the title and body of § 513.100(b) to incorporate a reference to the newly defined GLOBE Model test period.

CMS has also made technical corrections to the regulatory text at § 513.1(c), § 513.1(c)(1), and § 513.1(c)(2) to address a drafting error involving incorrect citation. As corrected, both § 513.1(c)(1) and § 513.1(c)(2) reference § 513.100(d)(4), and § 513.1(c) references paragraphs (c)(1), (c)(2), and (c)(3) of that section.

The finalized GLOBE Model test period is illustrated in Figure 1 and Table 1 provides a summary of the key data timelines, including the first four reporting windows for voluntary

manufacturer-submitted international drug net pricing data.

**FIGURE 1: GLOBE MODEL TEST PERIOD**[119]

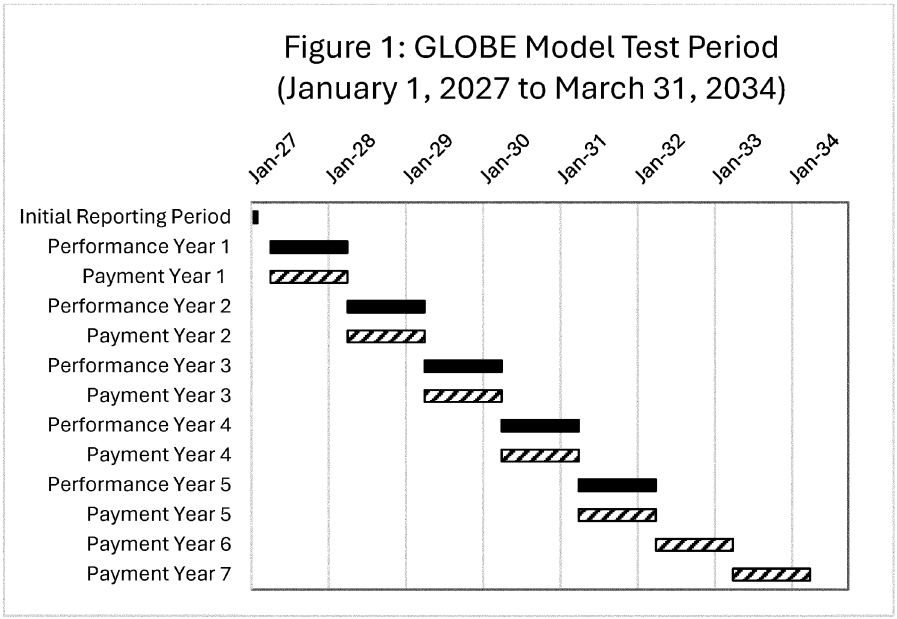



**TABLE 1: KEY DATA TIMELINES FOR GLOBE MODEL PROVISIONS**

| | Reporting Window 1 Q1 2027 | Reporting Window 2 Q2 2027 | Reporting Window 3 Q3 2027 | Reporting Window 4 Q4 2027 |
|---|---|---|---|---|
| Applicable calendar quarter | Q2 2027 | Q3 2027 | Q4 2027 | Q1 2028 |
| Applicable ASP calendar quarter | Q4 2026 | Q1 2027 | Q2 2027 | Q3 2027 |
| Reduced coinsurance and rebate liability based on Method I or Method II benchmark effective | Q2 2027 | Q3 2027 | Q4 2027 | Q1 2028 |
| GLOBE Model rebate payments associated with applicable calendar quarter due | Q1 2028 | Q2 2028 | Q3 2028 | Q4 2028 |

*B. GLOBE Model Drugs*

CMS proposed the 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 there are potentially avoidable high program expenditures and access barriers due to high costs which likely contribute to deficits in care. Analysis of historical OM Part B drug spending and non-U.S. OECD spending for similar drugs and biological products has highlighted U.S. originator drugs without generic [120] or biosimilar biological product [121] competition in the U.S. (called ''single source drug'' and ''sole source biological product'' for purposes of the GLOBE Model proposed rule and this final rule) as the main contributor to high drug spending within OM Part B and globally.

The majority of OM Part B drug spending is also concentrated in a select number of drugs and biological products. For example, as illustrated in Table 2 of the GLOBE Model proposed rule (and repeated as Table 2 in this final rule), spending for the top 50 OM Part B 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.

[119] Payment Years 6 and 7 are for rebate invoicing and reconciliation for Performance Years 4 and 5.

[120] Drugs approved under an Abbreviated New Drug Application (ANDA) submitted under section 505(j) of the FD&C Act.

[121] Biosimilar biological product is defined in section 1847A(c)(6)(H) of the Act as ''a 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.''

**TABLE 2: SUMMARY OF TOP 50 DRUGS AND BIOLOGICAL PRODUCTS BY SPENDING IN 2024 FOR MEDICARE PART B**

| Therapeutic Area | 2024 Medicare OM Part B 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 | - |

*Note: As of January 1, 2026, OM Part B payment for skin substitutes was revised such that payment for certain products is no longer based on the methodology in section 1847A of the Act.[122]

Increased drug costs limit 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 a report by ASPE, between 2008 and 2021, the average annual payment for OM Part B drugs grew by 8.8 percent.[123] In contrast, OM Part B program payments for separately payable Medicare Part B drugs in the therapeutic areas of oncology, immunology, endocrinology, and rheumatology grew by an average of 10.8 percent annually,[124] suggesting that these therapeutic areas experienced faster spending growth. The same ASPE report also found that ophthalmologists[125] had the highest average annual growth rate of OM Part B drug spending at 15 percent, 1.7 times higher than the overall average annual payment growth for all OM 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 OM Part B drugs using the standardized USP DC criteria and a Food and Drug Administration (FDA) label review. These therapeutic areas are associated with the following USP DC categories listed in Table 3 of the GLOBE Model proposed rule (90 FR 60254) (and repeated as Table 3 in this final rule).

**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.

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 likelihood of nonadherence to medications leading to potentially worse health status.[126] [127] [128] Thus, CMS proposed to scope the GLOBE Model to target potential deficits of care in specific USP DC categories as shown in

[122] See Section K. at 90 FR 49486.

[123] 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: Assistant Secretary for Planning and Evaluation, June 2023. Available at: *https://www.ncbi.nlm.nih.gov/books/NBK605978/pdf/Bookshelf_NBK605978.pdf*).

[124] 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*).

[125] Ophthalmologists are more likely to have prescribed or used drugs in the ophthalmic agents category.

[126] 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.*

[127] 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.*

[128] 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. 2023;29(1):4–16. *https://doi.org/10.18553/jmcp.2022.21270.*

Table 3 and defined in proposed § 513.130.

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 biological products. As such, we proposed to scope this model to focus on testing drugs and biological products where high program expenditures are most likely to arise and are potentially avoidable.

To achieve this objective, we also proposed to identify, in advance of each applicable calendar quarter and using information available to CMS, the single source drugs and sole source biological products within the drug categories identified in Table 3 that would qualify as GLOBE Model drugs for that quarter, by applying the criteria described in section II.B.1. of this final rule. By applying such 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 OM Part B 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. which may be subject to unique market dynamics that would confound the model test. We note the definition of Part B rebatable drugs includes single source drugs and have chosen to re-iterate 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 Medicare Part B drug inflation rebate amount calculation. 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 final rule). As further described in section II.B.1. of this final rule, CMS would identify GLOBE Model drugs and add them to the GLOBE Model Drug HCPCS Codes 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 HCPCS Codes List would be maintained quarterly to add and remove drugs as appropriate in accordance with the inclusion criteria. We proposed to identify a GLOBE Model drug using the same applicable billing and payment code (that is, HCPCS code) that is identified for the 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, we proposed to treat FDA-approved 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 (as defined under section 1847A(b)(8)(B)(iii) of the Act) are not Part B rebatable drugs.

We note that qualifying biosimilar biological products (as defined under section 1847A(b)(8)(B)(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 § 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 as applicable.

We believe there are observable differences in pricing dynamics of sole source and multi-source biological products that lead to unique market dynamics in the U.S. 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 (as defined at § 513.20), when reference biological products and their biosimilar biological products that are licensed 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 the U.S. When competing biosimilar biological products are available in the U.S., manufacturers may provide discounts to providers through price concessions and rebates that impact Medicare spending. In response to the GLOBE Model, manufacturers may change these discount strategies depending on how many patients are within a GLOBE Model geographic area. As such, manufacturers may provide lower discounts to clinics with more GLOBE Model eligible beneficiaries in GLOBE Model geographic areas than to clinics with fewer GLOBE Model eligible beneficiaries because of the rebates the manufacturer would be required to pay under the GLOBE Model. This difference in incentives may lead to providers switching utilization between FDA-approved products (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 such biosimilar biological products than their reference biological products. The discussion in section II.B.1. of this final rule further describes our proposed approach to exclude Part B rebatable drugs that are biosimilar biological products and their reference biological products.

1. GLOBE Model Drug Inclusion Criteria

We proposed 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, CMS proposed in § 513.130 to identify the GLOBE Model drugs for that applicable calendar quarter by applying these criteria to Part B rebatable drugs, as identified by CMS in accordance with 42 CFR 427.101: (1) are 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 USP DC; (2) are single source drugs or sole source biological products as set forth in proposed § 513.20; (3) have OM Part B spending greater than $100 million over a 12-month period (as further specified in proposed § 513.130(d)); and (4) are drug or biological products that are not excluded from the GLOBE Model under proposed § 513.130(c). We proposed that a Part B rebatable drug would have to meet all 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 proposed to use the USP DC 2025 [129] 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 proposed 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 identified as a Part B rebatable drug after the GLOBE Model's start and may not appear in USP DC 2025. As such, we proposed 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 proposed that once CMS has identified the USP DC category or categories as falling within the GLOBE Model's list of included categories, the drug would remain in the GLOBE Model's drug category or categories for the entire model duration. We also proposed that, when posted on the GLOBE Model website, the GLOBE Model Drug HCPCS Codes List would include the USP DC category for each GLOBE Model drug HCPCS code. Table 4 in the GLOBE Model proposed rule shows the associated USP DC category for an illustrative list of HCPCS codes (90 FR 60260). The USP DC 2025 has 50 categories of which 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 Part B rebatable drug categories. Analysis of 2024 OM Part B rebatable drug spending data indicates that these 7 USP DC categories were responsible for most OM Part B rebatable drug spending (91 percent), with antineoplastics having the highest proportion of any single category at approximately 47 percent. Given the high disparity in prices for originator drugs in the U.S. as compared to other OECD member countries,[130] [131] [132] we believe this data further substantiates that there are potentially avoidable expenditures among Medicare beneficiaries who rely upon these high spend Part B rebatable drugs.

We also proposed that if USP creates a new drug category that stems from the drug categories set forth in § 513.130(b)(1), then such newly created drug categories would be incorporated into the GLOBE Model drug inclusion criteria. We proposed that CMS may 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 recognized by definition, only single source drugs are Part B rebatable drugs and proposed 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 (NDA) approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. 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 1847(A)(6)(E) of the Act, are pharmaceutically equivalent and bioequivalent, as determined under section 1847(A)(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 proposed to define ''sole source biological product'' in § 513.20 for the purposes of the GLOBE Model as a biological product licensed by the FDA 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 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 most recent publication of ''Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations'' (the ''Purple Book'') and be identified as sold or marketed as set forth in 42 CFR 427.20. We note that the proposed definition for sole source biological product 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 product 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 proposed to use the definition for ''sold or marketed'' established in 42 CFR 427.20, which means CMS would use marketing data as listed in either the ASP data reported to CMS by a manufacturer or the NDC directory to identify a start marketing date for the biosimilar biological product in the U.S. prior to the applicable calendar quarter when the product meets one of the following criteria: (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 proposed, 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

[129] The USP Drug Classification 2025 file can be found here: *https://www.usp.org/health-quality-safety/usp-drug-classification-system.*

[130] Berkemeier, Fabian, Christopher Whaley, and James C. Robinson. *Increasing Divergence in Drug Prices Between the United States and Germany After Implementation of Comparative Effectiveness Analysis and Collective Price Negotiations.* Journal of Managed Care & Specialty Pharmacy 25, no. 12 (2019): 1310–17. *https://doi.org/10.18553/jmcp.2019.25.12.1310.*

[131] Gong, Dan, Jonathan S. Chang, Miriam Barbany, et al. *Comparison of United States and International Ophthalmic Drug Pricing.* Ophthalmology (United States) 126, no. 10 (2019): 1358–65. *https://doi.org/10.1016/j.ophtha.2019.04.018.*

[132] Vokinger, Kerstin N., Thomas J. Hwang, Paola Daniore, et al. *Analysis of Launch and Postapproval Cancer Drug Pricing, Clinical Benefit, and Policy Implications in the US and Europe.* JAMA Oncology (United States) 7, no. 9 (2021): e212026. *https://doi.org/10.1001/jamaoncol.2021.2026.*

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 in the U.S. We proposed that, if a biosimilar biological product is marketed in the U.S., 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 product [133] for such biosimilar biological product would not be included as a GLOBE Model drug for the applicable calendar quarter. We proposed that for an applicable calendar quarter CMS would conduct this analysis prior to the applicable calendar quarter to update the GLOBE Model Drug HCPCS Codes List.

We recognized for the GLOBE Model that authorized generics and unbranded biological products in the U.S. share the same NDA approved by the FDA or 351(a) licensure as the original drug and biological product and therefore meet the proposed definitions of single source drug and sole source biological. As such, authorized generics and unbranded biological products that are Part B rebatable drugs could potentially be GLOBE Model drugs. In the U.S., authorized generics are drugs sold, licensed, or marketed under a NDA approved by the FDA under section 505(c) of the FD&C Act that is marketed, sold or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand drug. In the U.S., unbranded biological products are biological products sold without their brand name by the original manufacturer or a third party under the BLA of the original biological product. Since, in the U.S., 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 § 513.130(c), it could 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 in § 513.20 if such product was 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 proposed to identify the Part B rebatable drugs with total OM Part B allowed charges greater than $100 million over a 12-month period using separately payable final action claims (spend threshold). As specified in § 513.130(d) in the GLOBE Model proposed rule, we proposed that CMS would identify OM Part B 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. We stated that, for example, if the applicable calendar quarter is Q1 2027, all separately payable final action claims with OM Part B 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 OM Part B 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 OM Part B 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 proposed that 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 calendar quarter and subsequent applicable calendar quarters. To illustrate this proposal in the GLOBE Model proposed rule, we provided the following example (90 FR 60256). 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 applicable calendar quarters and would retain inclusion in the GLOBE Model.

Historical analysis of OM Part B 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 OM Part B 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 OM Part B 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 OM Part B drug spending. A threshold of $100 million would therefore focus the GLOBE Model on a majority of OM 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.

The following is a summary of the comments received and our responses.

*Comment:* A commenter stated support for CMS's efforts and recommended the inclusion of immunosuppressive therapies such as belatacept and similar medications and stated that expanding affordability and access to these medications will significantly improve graft survival and provide an option for patients unable to continue other immunosuppressive regimens.

*Response:* We thank the commenter for sharing their support of the GLOBE Model. We agree that access to immunosuppressive agents such as belatacept is important for graft survival and for patients who may not be able to tolerate alternative immunosuppressive regimens. One of the GLOBE Model's inclusion criteria is the USP DC category of immunological agents, which includes belatacept and other immunosuppressive agents. We note that GLOBE Model drugs will be identified through the GLOBE Model Drug HCPCS Level II Codes List as set forth in § 513.130(e).

*Comment:* A couple of commenters stated their support for the proposed drug inclusion and exclusion criteria, including Part B rebatable drugs experiencing significant spending growth, such as those used in ophthalmology, rheumatology, and oncology.

*Response:* We thank the commenters for sharing their support of the GLOBE Model drug inclusion and exclusion criteria. We agree that including Part B rebatable drugs experiencing significant spending growth—such as those used in ophthalmology, rheumatology, and oncology—is consistent with the GLOBE Model's objectives of reducing program expenditures while preserving or enhancing beneficiaries' quality of care.

*Comment:* A couple of commenters supported CMS's use of the USP DC in the GLOBE Model. A commenter stated that using the most recent version of the USP DC for drug categories will promote clarity, reduce administrative burden, and help mitigate unintended

[133] Reference product is defined in section 1847A(c)(6)(l) 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.'' *https://www.ssa.gov/OP_Home/ssact/title18/1847A.htm.*

consequences such as formulary gaps or disruptions in patient access.

*Response:* We thank the commenters for sharing their support for use of the USP DC system. As proposed in the GLOBE Model proposed rule (90 FR 60255), we will use the USP DC 2025 to identify all Part B rebatable drugs that meet the USP DC categories in Table 3 at model start for the first applicable calendar quarter of the GLOBE Model performance period. We proposed to use the USP DC 2025 for identification of the USP DC categories at model start as the categories listed in Table 3 were identified using the USP DC 2025. We also proposed to use the most recently published version of the USP DC to identify drug categories for Part B rebatable drugs not previously assigned a USP DC category. We agree that using the most recently published version of the USP DC for Part B rebatable drugs not previously assigned a category promotes clarity and helps reduce administrative burden.

*Comment:* A commenter recommended that CMS explain in the final rule why the 7 USP DC categories were selected over others and what criteria would govern any future expansion.

*Response:* We thank the commenter for sharing their feedback. As shown in Tables 2 and 3 of the GLOBE Model proposed rule (90 FR 60244 through 60254) and this final rule, the 7 USP DC categories are associated with the therapeutic areas representing the highest percentage of total OM Part B drug spending among the top 50 separately payable Medicare Part B drugs by expenditure in 2024. CMS also considered other USP DC categories, including: antimyasthenic agents, cardiovascular agents, dermatological agents; genetic, enzyme, or protein disorder: replacement, modifiers, treatment; and respiratory tract/pulmonary agents. However, CMS believes that initially focusing the model test on these 7 high expenditure USP DC categories will target beneficiaries receiving treatment in these therapeutic areas with potentially avoidable expenditures and beneficiaries who are most likely to experience significant financial burden and greater deficits of care due to high drug costs, consistent with the GLOBE Model's objectives of reducing program expenditures while preserving or enhancing quality of care.

Regarding future expansion of included therapeutic areas, CMS may consider adding USP DC categories in future rulemaking based on factors such as changes in Part B rebatable drug spending patterns, the emergence of new therapeutic areas with significant beneficiary financial burden, and the results of ongoing model evaluation. Any updates to the GLOBE Model drug categories set forth in § 513.130(b)(1) would be subject to notice-and-comment rulemaking, as appropriate.

*Comment:* A commenter suggested that CMS monitor USP DC categories that represent areas of active research and development for potential impacts on innovation. The commenter also suggested a prioritization method that identifies drugs with the highest likelihood of being priced above their true patient-centered value and drugs in therapeutic areas with substantial ongoing research and development activity. The commenter further suggested the use of the Generalized Risk Adjusted Cost-Effectiveness framework to evaluate drugs that exceed their value. The commenter also stated that price controls targeting therapeutic areas with little ongoing research activity would have less impact on innovation. Another commenter suggested that CMS only include drugs assessed as providing low or no added therapeutic benefit, regardless of USP DC category, to preserve stronger price signals for high-value innovation.

*Response:* We thank the commenters for sharing their feedback. As stated in the GLOBE Model proposed rule (90 FR 60244 through 60254), the purpose of the GLOBE Model is to test whether an alternative approach for calculating the Medicare Part B drug inflation rebate amount for GLOBE Model drugs—using international drug pricing information to establish a benchmark reflecting prices paid in economically comparable countries—would reduce Medicare Part B program expenditures while preserving or enhancing beneficiaries' quality of care. As such, we disagree that the model needs a separate prioritization method or framework to determine if a drug exceeds its value. We proposed that GLOBE Model drugs would be a subset of Part B rebatable drugs that: (1) are designated as one of the seven listed USP DC categories set forth in § 513.130(b)(1); (2) are single source drugs or sole source biological products; (3) have total OM Part B allowed charges greater than $100 million over a 12-month period ending 6 months prior to the start of the applicable calendar quarter (as further specified in §§ 513.130(b)(3) and 513.130(d)); and (4) are not excluded from the GLOBE Model as proposed in § 513.130(c). CMS continues to believe it is essential to focus the model test where model impacts on program expenditures are most likely to be observed during the evaluation period. We believe the finalized criteria for identifying GLOBE Model drugs set forth in § 513.130 would best achieve this goal.

Regarding the commenter's suggestion to monitor USP DC categories for potential impacts on innovation, CMS will conduct ongoing monitoring and evaluation throughout the GLOBE Model payment period, which will include assessment of model impacts on drug availability, program spending, and access to GLOBE Model drugs. With respect to cost-effectiveness and therapeutic benefit frameworks, while we appreciate the commenters' suggestions, we do not believe a separate cost-effectiveness framework is necessary to achieve the model's objectives. Furthermore, the GLOBE Model is not designed to evaluate drugs based on cost-effectiveness, patient-centered value assessments, or therapeutic benefit.

*Comment:* A commenter stated that the proposed drug inclusion criteria related to spending—using HCPCS Level II codes for the $100 million in total OM Part B allowed charges during a 12-month period—means that different strengths and dosage forms of the same active moiety or active ingredient from the same holder of a NDA will not be aggregated. The commenter suggested using inclusion criteria that align with the Negotiation Program to avoid manufacturer gaming.

*Response:* We thank the commenter for sharing their feedback regarding the use of HCPCS Level II codes for the drug inclusion criteria related to spending. We also acknowledge the commenter's concern regarding the potential for manufacturer gaming. As proposed in § 513.130(d)(1), the criteria are not based on active moiety or active ingredient level but rather based on how OM Part B identifies drugs and biologicals. This approach allows CMS to assess the spend threshold during the applicable 12-month period for any billing and payment code that includes the drug or biological. Our proposed approach aligns with the methodology for identifying Part B rebatable drugs under section 1847A of the Act for the Medicare Part B Drug Inflation Rebate Program as set forth in 42 CFR 427.101. We believe this approach provides a consistent and administrable framework that limits the potential for manufacturer gaming. Further, as the GLOBE Model will test an alternative rebate amount calculation and adjusted coinsurance for certain Part B rebatable drugs, we believe it is essential that our approach be consistent with the methodology CMS uses to identify Part B rebatable drugs.

*Comment:* A commenter stated that CMS should maintain drugs in the GLOBE Model if their U.S. price exceeds the applicable international reference price, rather than updating the list quarterly to add and remove drugs in accordance with the inclusion and exclusion criteria.

*Response:* We thank the commenter for their feedback regarding the GLOBE Model drug inclusion and exclusion criteria. As proposed in § 513.130, once CMS identifies a Part B rebatable drug as a GLOBE Model drug and adds it to the GLOBE Model Drug HCPCS Level II Codes List, the drug will remain in the GLOBE Model unless it is no longer a single source drug or sole source biological or meets one of the exclusion criteria such as having a MFP under the Negotiation Program in effect or no longer being a Part B rebatable drug. We note that inclusion and exclusion would be based on the criteria set forth in § 513.130, not on a drug's U.S. price relative to an international reference price. We believe this approach will maintain model integrity and allow CMS to test an alternative Medicare Part B drug inflation rebate amount calculation for certain single source drugs and sole source biological products—with the goal of reducing Medicare program expenditures while preserving or enhancing quality of care.

*Comment:* A commenter stated that the GLOBE Model applies the minimum spend threshold as an inclusion criterion, whereas the GUARD Model applies it as an exclusion criterion, and stated that standardizing the approaches to the spend threshold across the two models could lead to operational efficiencies for manufacturers.

*Response:* We thank the commenter for their feedback regarding the GLOBE Model's drug inclusion criteria. The proposed GLOBE Model and proposed GUARD Model are two separate proposed CMS Innovation Center model tests, each designed to evaluate distinct policy interventions. As such, the proposed drug inclusion and exclusion criteria for each model are tailored to the specific objectives of that test, and standardization across models is not required. We are not persuaded that a difference in how a spend threshold would be applied across the two proposed models would create a meaningful operational burden for manufacturers, as both approaches require CMS to identify applicable drug spending data, calculate a sum, and compare the result to the applicable threshold.

*Comment:* A commenter requested clarification on how newly approved drugs billed under a NOC HCPCS code would be treated under the GLOBE Model. The commenter recommended that CMS explicitly exclude the 6-month drug launch period—during which a newly approved drug is billed under an unspecified or NOC HCPCS code before a permanent product-specific HCPCS Level II code is assigned—from all GLOBE Model spending threshold calculations, drug selection criteria, and rebate calculations.

*Response:* Under 42 CFR 427.101(b), certain product categories are excluded from the definition of a Part B rebatable drug, including products billed under a NOC code. In addition, to calculate the OM Part B allowed charges, as set forth in § 513.130(d), CMS would use any OM Part B final action claims that are used to describe a GLOBE Model drug. Because a claim billed under a NOC HCPCS code does not contain sufficient information for CMS to associate such claims with a specific drug or biological, such claims would not be included in spending threshold calculations for purposes of the GLOBE Model. Accordingly, we do not agree that a specific exclusion of the 6-month drug launch period is necessary.

*Comment:* A commenter recommended CMS provide clearer rules for how drugs transition between sole source and multi-source status as biosimilars enter the U.S. market, including time of exclusion and benchmark recalculations.

*Response:* We thank the commenter for sharing their feedback. In § 513.20, for purposes of the GLOBE Model, CMS proposed definitions for single source drug and sole source biological products. Further, as discussed in the GLOBE Model proposed rule (90 FR 60244 through 60254), CMS proposed to use the definition of sold or marketed as set forth in 42 CFR 427.20 to identify a sole source biological product. As such, CMS would use marketing data, as listed in either the ASP data reported to CMS by a manufacturer or the NDC directory, as available, to identify a start marketing date(s) and end marketing date(s), as applicable, for a biosimilar biological product(s) and its reference biological product. If a biosimilar biological product and reference biological product for such biosimilar biological product are marketed, as determined by CMS, as of the beginning of an applicable calendar quarter, CMS would identify that the biosimilar biological product(s) and reference biological product for such biosimilar biological product(s) would not be sole source biological products and would not be included as a GLOBE Model drug for the applicable calendar quarter. If CMS determines that a GLOBE Model drug is multi-source rather than a single source drug or sole source biological product, CMS would not identify benchmarks nor calculate a total GLOBE Model rebate amount or incremental GLOBE Model rebate amount for subsequent applicable calendar quarters during the GLOBE Model performance period for which a Part B drug is multi-source as it would not meet the inclusion criteria to be a GLOBE Model drug for such applicable calendar quarter(s). CMS proposed to identify GLOBE Model drugs for an applicable calendar quarter during the GLOBE Model performance period in advance of such applicable calendar quarter using information available to CMS, and CMS would add identified GLOBE Model drugs to the GLOBE Model Drug HCPCS Codes List for such applicable calendar quarter. We believe this approach provides clear rules that CMS would apply when a biological product in the U.S. would transition between sole source and multi-source for purposes of the GLOBE Model.

*Final Decision:* After consideration of the public comments received, CMS is finalizing the drug inclusion criteria at § 513.130(b) and § 513.130(b)(1) as proposed with minor terminology updates. CMS is finalizing § 513.130(b)(2) and § 513.130(b)(4) as proposed without modification. CMS is finalizing § 513.130(d) with modification to insert a table showing the consecutive 12-month period ending 6 months prior to the start of each applicable calendar quarter, a non-substantive technical correction to change ''GLOBE Model drug'' to ''Part B rebatable drug,'' and a change from ''billing and payment'' to ''HCPCS'' for clarification.

CMS has also made technical corrections to the regulation text at § 513.20 to address a drafting error related to the definitions of single source drug and sole source biological product. In the definition of single source drug, we removed the term ''biological product.'' In the definition of sole source biological product, CMS added the word ''product'', corrected ''PHSA'' to ''PHS'', corrected ''applicable ASP calendar quarter'' to ''applicable calendar quarter during the GLOBE Model performance period'', corrected ''in a BLA'' to ''under a BLA'', listed the full name of Purple Book, clarified ''sold or marketed'' to be as set forth in 42 CFR 427.20. CMS is also finalizing § 513.130(e) with technical correction change from ''paragraph (d)(2)'' to ''paragraph (e)(2)'' and with other minor terminology updates.

CMS also revised § 513.130(a) for clarity and to align with the preamble. Paragraph § 513.130(a) is changed from ''reserved'' to stating that, subject to § 513.130(b), for each applicable calendar quarter during the model performance period, CMS identifies the Part B rebatable drugs that are included in the GLOBE Model for purposes of (1) application of the coinsurance adjustment and adjusted Medicare payment as set forth in 42 CFR part 513 subpart C, and (2) for determining the total GLOBE Model rebate amounts as set forth in 42 CFR part 513 subpart F.

We refer readers to section II.B.4. of this final rule for discussion of additional modifications to the inclusion criteria.

2. 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 § 513.130(c)(1)(ii), we proposed to exclude from the GLOBE Model a Part B rebatable drug for which a MFP, as defined in section 1191(c)(3) of the Act, under the Negotiation Program is in effect. This proposal would mean that drugs that 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 appliable calendar quarters in which the MFP is in effect.[134] [135] 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 goes into effect on January 1, 2029, the GLOBE Model drug would exit the GLOBE Model after December 31, 2028. We note that the earliest date for which an 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 proposed to begin the GLOBE Model on October 1, 2026, we noted in the GLOBE Model proposed rule 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 (90 FR 60257). We proposed 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. As stated in the GLOBE Model proposed rule (90 FR 60257), we believe that excluding drugs when the Medicare Part B payment limit is based on an 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 proposed, in § 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 noted that, given the proposed GLOBE Model drug inclusion criteria in § 513.130(b), this exclusion would only be applied to drugs that meet all the proposed inclusion criteria.

We also noted that during the duration of the GLOBE Model, certain drugs or biological products may no longer be Part B rebatable drugs. As such, in § 513.130(c)(1)(iii) we proposed 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.

The following is a summary of the comments received and our responses.

*Comment:* A commenter asked CMS to publish a methodology outlining which drugs will be included and excluded in the GLOBE Model. For those excluded drugs, the commenter requested CMS outline the rationale for the exclusion.

*Response:* We thank the commenter for the feedback. We believe that the methodology described in this section of this final rule and in § 513.130 clearly outlines the information and process CMS would use to apply the spending threshold, USP DC categories, Part B rebatable drugs, and other criteria for identifying GLOBE Model drugs, including the specific inclusion and exclusion criteria. We refer the commenter to sections II.B.2. and II.B.5. of this final rule for additional information related to how CMS would identify included and excluded drugs. CMS will publish the GLOBE Model Drug HCPCS Level II Codes List for an applicable calendar quarter on the GLOBE Model website.

*Comment:* Many commenters requested that the GLOBE Model include explicit language excluding drugs and biologics approved exclusively for one or more rare diseases or conditions. Many commenters also stated that the GLOBE Model would understate the value of orphan drugs and disincentivize R&D in this area and emphasized existing legislation such as the Orphan Drug Act recognizing the special circumstances of orphan drugs. Commenters further stated that orphan drugs serve unique patient populations, do not exhibit traditional market dynamics through the global nature of their supply chain, require a complex and diverse array of technologies for manufacturing, are less likely to receive reimbursement recommendations in, or to launch in, other countries, are likely to be subject to outcomes-based arrangements (OBAs) for payment in reference countries where they are sold, and may be more likely to experience shortages. Several commenters stated that the Negotiation Program, the Working Families Tax Cuts Act (Pub. L. 119–21), and the 340B Drug Pricing Program (section 340B of the Public Health Services Act) include provisions for orphan drug exclusions and that the 2020 Most Favored Nation (MFN) Model Interim Final Rule included an orphan drug exemption.

A couple of commenters recommended that CMS adopt the following exclusion: ''A drug or biological product that is designated as a drug for one or more rare diseases or conditions under section 526 of the Federal FD&C Act and for which the only approved indication or indications are for one or more such rare diseases

[134] Centers for Medicare & Medicaid Services. *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://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.*

[135] 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 of an MFP. A Primary Manufacturer of a selected drug that reached an agreement on a negotiated price, the MFP, must provide access to the MFP 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.

or conditions (as defined in section 526(a)(2) of the Federal FD&C Act).''

A couple of commenters requested exclusion of genetically targeted therapies (GTTs), CAR-Ts, and personalized medicine treatments, stating these products were discovered and first commercialized in the U.S. and that these products treat underlying genetic cause of disease for some of the most serious and intractable disease with higher per-patient contact and public health burden. Commenters believe exclusion of these products from the GLOBE Model would ensure incentives for development of innovative medicines remain. A commenter suggested using exclusion language that leverages statutory definitions including 21 U.S.C. 360ff–1 (Targeted drugs for rare diseases). Specifically, the commenter requested CMS exclude ''drugs that incorporate or use a mechanism designed to modulate the function of a specific gene or its associated gene product through sequence-directed interaction with DNA or RNA (including antisense oligonucleotides [ASOs] and small interfering RNA [siRNA]).''

*Response:* We thank the commenters for sharing their feedback. We believe the proposed inclusion criteria of including drug or biological products with total OM Part B allowed charges greater than $100 million over a 12-month period focus the model test on drugs and biological products with high program expenditures and targets potentially avoidable expenditures and potential deficits of care while protecting personalized medicine incentives. For instance, our analysis of 2024 OM Part B allowed charges determined that, of the products listed on the FDA's Approved Cellular and Gene Therapy Products web page, only 2 (4 percent) products met or exceeded the OM Part B $100 million spending threshold. While we believe the proposed criteria are sufficient to focus the GLOBE Model on drugs with high program expenditures while protecting personalized medicine incentives, we also carefully considered the full range of public comments received, including detailed analyses provided by several commenters regarding the unique market dynamics of orphan drugs and the potential impact of the model on innovation in rare disease research and development.

We acknowledge commenters' concerns that orphan drugs may not exhibit traditional market dynamics, may be less likely to receive reimbursement recommendations in, or launch in, other countries, and they may be more likely to be subject to OBAs for payment. While we do acknowledge these concerns, our analysis of international drug pricing information showed that CMS would likely be able to calculate a GLOBE Model benchmark for these drugs. Although we disagree with commenters' concerns, we have decided to add exclusions for orphan-only drugs to avoid the possibility of commenters' concerns manifesting for these therapies. Our decision is out of an abundance of caution specifically for Medicare beneficiaries with rare diseases who may rely upon these drugs.

We also acknowledge commenters' suggestion to exclude GTTs to maintain incentive in development of innovative medicines which may be personalized such as being manufactured using a patient's cells. CMS declines to use the commenter's exclusion language for GTTs as 21 U.S.C. 360ff–1 includes a definition for genetically targeted drug and genetically targeted technology. The purpose of 21 U.S.C. 360ff–1 is targeted drugs for rare diseases. As such, this supports our decision to further refine the GLOBE Model drug eligibility criteria by adding an exclusion for orphan drugs. We note that we are adding an exclusion for products listed on the FDA's Approved Cellular and Gene Therapy Products web page (CGTs (for example, CAR-Ts)), which include a subset of GTTs; further discussion on this decision can be found in section II.B.5. of this final rule.

Accordingly, we will exclude a Part B rebatable drug that is designated as a drug for one or more rare diseases or conditions under section 526 of the Federal FD&C Act (21 U.S.C. 360bb) and for which the only approved indication (or indications) is for one or more such rare diseases or conditions.

*Comment:* A commenter stated that radiopharmaceutical drugs and biological products should be excluded from the GLOBE Model due to their unique characteristics, including their radioactive nature and short half-lives, that make them unsuitable for inclusion in the GLOBE Model, and further stated that, by definition, they are not Part B rebatable drugs.

*Response:* We note the commenter's observation regarding the unique characteristics of radiopharmaceuticals, including their radioactive nature and short half-lives. As a threshold matter, we confirm that separately payable radiopharmaceutical drugs and biological products that are not paid under section 1847A of the Act fall within an excluded product category for purposes of the Part B rebatable drug definition at 42 CFR 427.101(b)(4). As such, radiopharmaceutical drugs and biological products that are in this excluded product category would not satisfy the GLOBE Model inclusion criteria and therefore, would not be in the GLOBE Model.

*Comment:* A couple of commenters recommended excluding breakthrough therapy-designated drugs, stating that they are often transformative therapies and that their inclusion in the GLOBE Model could negatively affect future innovation. A commenter further stated that breakthrough therapy-designated drugs are often developed by small and mid-sized U.S. companies and that inclusion of these drugs would disproportionately harm small and mid-sized U.S. manufacturers. Another commenter stated the GLOBE Model harms innovation by including products that have FDA Breakthrough Therapy, Fast Track, or Priority Review designation(s) and that these programs were created to identify products that make a significant contribution to care.

*Response:* We thank the commenters for sharing their feedback. CMS recognizes that drugs receiving FDA Breakthrough Therapy, Fast Track, or Priority Review designations may offer important advances in care and has considered commenters' concerns that including such drugs in the GLOBE Model could affect future innovation. We disagree, however, that an exclusion criterion for breakthrough therapy-designated drugs or other drugs designated by FDA for expedited review, such as Fast Track or Priority Review, is warranted for the GLOBE Model. We do not believe that the GLOBE Model would deter investment in Breakthrough Therapy, Fast Track, or Priority Review designated drugs, nor do we believe the GLOBE Model would disproportionately impact small and mid-sized U.S. manufacturers.

The GLOBE Model does not change any policies related to Breakthrough Therapies, Fast Track, and Priority Review programs at the FDA so CMS does not expect the impacts of these programs to change due to the GLOBE Model. For example, drugs with breakthrough therapy designation have a lower late-stage clinical development time and higher immediate share price boosts, compared to drugs without breakthrough therapy designation,[136] and we expect that to continue. The model's rebate obligation reaches only drugs exceeding $100 million in OM Part B allowed charges over a 12-month

[136] Williamson, J, et al. *Unveiling the impacts of FDA Breakthrough Therapy Designation: a dual-perspective examination of economic and developmental outcomes for biotechnology companies,* Drug Discovery Today. 2024;29(4). doi: 10.1016/j.drudis.2024.103919.

period—a threshold reflecting substantial market penetration—and affects only the OM Part B market, leaving commercial, MA, and ex-U.S. revenues unaffected. Using illustrative 2024 data, CMS estimates these criteria would result in a single small-manufacturer participant. A categorical exclusion is therefore not necessary to address the commenters' concern about disproportionate effects on smaller or emerging firms.

CMS acknowledges commenters' concerns that including drugs with FDA Breakthrough Therapy, Fast Track, or Priority Review designations in the GLOBE Model could negatively affect future innovation, including the development of breakthrough or transformational therapies. In considering these concerns, CMS refers commenters to the Congressional Budget Office's (CBO) evaluation of Title I of H.R. 3 (2019).[137] Although this legislative proposal was broader than the GLOBE Model and differed from the GLOBE Model in many material respects, one of the mechanisms included was the use of international reference pricing to negotiate the prices of certain drugs. For this reason, we believe it illustrates the potential effects of international reference pricing on innovation. In this analysis, CBO projected that between eight to fifteen fewer new drugs could be approved and introduced in the U.S. market over a decade as a result of the drug pricing legislative proposal. This reduction was measured against a baseline of approximately 300 expected new drug approvals over a 10-year period, which means that CBO estimated a relatively small percentage decline in future approvals of new drugs. The estimate did not identify which drugs would not be developed; whether they would have been breakthrough therapies or modest incremental products; or whether patients would experience reduced access or downstream harms.

CBO's estimate projected a relatively small reduction in future drug approvals, and even this estimate does not by itself establish that Medicare beneficiaries would lose access to breakthrough or transformational drug therapies.

Additionally, the relationship between expected returns in a single U.S. payer market and innovation outcomes is contested in the economic literature and is not well described by a simple linear relationship. R&D investment reflects expected global lifetime revenues, development costs, and a range of domestic and international policies, including not only reimbursement but also policies related to patent length, market exclusivity, and regulatory approval. Any change in a manufacturer's investment would reflect the combined effect of these factors rather than the GLOBE Model in isolation.

Finally, we note that pharmaceutical manufacturers make research and development decisions in response to the broader domestic and global environment affecting expected returns, rather than based on any single payment model or drug-pricing initiative. Pharmaceutical research and development investment is influenced by expected lifetime global revenues, development costs, and policies affecting the supply of and demand for drugs, with expected revenues reflecting anticipated prices and sales across markets worldwide.[138] This broader environment includes numerous domestic and international drug-pricing and reimbursement policies, public and private payer arrangements, and market-specific conditions. Accordingly, any decision by a manufacturer to reduce, increase, or redirect investment—and any resulting impact on future innovation—would reflect the combined effect of these factors, rather than an effect of the GLOBE Model. There are numerous initiatives that are beyond the scope of this final rule that will influence research and development spending and innovation for new drugs. We direct readers to the 2026 Council of Economic Advisors Report for a discussion of U.S.-based drug pricing policy initiatives.[139] [140]

A Breakthrough Therapy, Fast Track, or Priority Review designated drug would only be included in the GLOBE Model if it meets the GLOBE Model inclusion criteria, including the spending threshold which ensures that the model is focused on drugs with the greatest potential impact on program costs. We note that evidence shows a majority of drugs or biological products that use FDA programs for expedited availability are orphan drugs.[141] Thus, we believe the GLOBE Model's exclusion of a Part B rebatable drug that is designated as a drug for one or more rare diseases or conditions under section 526 of the Federal FD&C Act (21 U.S.C. 360bb) and for which the only approved indication (or indications) is for one or more such rare diseases or conditions addresses commenters' concerns.

*Comment:* A few commenters stated that oncology drugs should be excluded from the GLOBE Model, as their inclusion could result in manufacturers limiting production or withdrawing products from the market to avoid rebate obligations or price reductions, thereby increasing the risk of drug shortages. The commenters further stated that such exclusion is necessary to preserve patient access and preserve financial incentives for the research and development of innovative cancer treatments.

*Response:* We thank the commenters for sharing their feedback. We disagree that an exclusion criterion for oncology drugs is warranted for purposes of the GLOBE Model. We believe the proposed inclusion criteria—requiring total OM Part B allowed charges greater than $100 million over a 12-month period (as further specified in § 513.130(b)(3) and § 513.130(d))—focus the model test on drugs and biological products with high program expenditures, where we can evaluate whether the proposed intervention would reduce program expenditures while maintaining or enhancing the quality of care for Medicare beneficiaries, and where the model's impact on affordability and access is most likely to be observed.

Regarding the commenter's concern about drug shortages, we note that the GLOBE Model's rebate mechanism does not impose price controls or production mandates on manufacturers. Manufacturers retain the ability to set prices and production levels, and the model's rebate obligation applies only to drugs that already have high Medicare Part B expenditures and only to the extent that such drug would be furnished to a GLOBE Model eligible beneficiary and such units of such drug would be included in the GLOBE Model rebate amount calculation. We do not believe the model's structure creates incentives for manufacturers to limit production of oncology drugs. Inclusion

[137] Congressional Budget Office. Effects of Drug Price Negotiation Stemming From Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare, October 11, 2019. Available at: *https://www.cbo.gov/publication/55722.*

[138] Congressional Budget Office. *Research and Development in the Pharmaceutical Industry.* April 2021. *https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf.*

[139] The White House. Savings from Most-Favored-Nation Drug Pricing Policy, May 5, 2026. Available at: *https://www.whitehouse.gov/research/2026/05/savings-from-most-favored-nation-drug-pricing-policy/.*

[140] Congressional Budget Office. Research and Development in the Pharmaceutical Industry, April 2021. Available at: *https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf.*

[141] Monge AN, Sigelman DW, Temple RJ, Chahal HS. *Use of US Food and Drug Administration Expedited Drug Development and Review Programs by Orphan and Nonorphan Novel Drugs Approved From 2008 to 2021.* JAMA Netw Open. 2022;5(11):e2239336. doi:10.1001/jamanetworkopen.2022.39336.

in the GLOBE Model does not impact a manufacturer's revenue in other markets, such as the commercial market or MA; the GLOBE Model only impacts the OM Part B market. We also note that an oncology drug would only be included in the model if it meets the GLOBE Model drug inclusion criteria, including exceeding the $100 million spending threshold (as further specified in § 513.130(b)(3) and § 513.130(d)), which is a high bar that reflects significant market penetration and commercial success. This ensures that the model is focused on drugs with the greatest potential impact on Medicare program costs.

Regarding the potential impacts of the GLOBE Model on innovation, there are many factors that contribute to decisions by manufacturers to invest in research and development for specific types of drugs, as discussed in a previous response, including but not limited to expected development costs, expected return on investments, domestic and foreign policies, and other factors. A complete discussion of the various drug pricing policy initiatives that may contribute to stakeholders' decisions to increase, reduce, or redirect pharmaceutical investment is beyond the scope of this final rule. However, we direct readers to the 2026 Council of Economic Advisors Report that discusses various drug pricing policy initiatives for more information.[142]

Finally, regarding the concern around patient access, we note that the GLOBE Model will test whether the intervention would reduce program expenditures while maintaining or enhancing the quality of care for Medicare beneficiaries. Given documented research around financial toxicity, we theorize that reducing the program expenditures, including oncology drugs, will reduce the financial toxicity levels faced by OM beneficiaries, thereby improving patient access. As discussed in section II.K. of this final rule, we believe the GLOBE Model reporting and monitoring plan, along with model education activities, will offer sufficient safeguards to protect beneficiaries' access to necessary drugs while also monitoring for any access disruptions that may arise.

*Comment:* A commenter stated their belief that the exclusion of biosimilars and their reference products has the effect of disproportionately harming non-biosimilars and non-reference products that compete in the same therapeutic space. As such, commenter suggested that CMS should also exclude Medicare Part B drugs and biological products that share the same or overlapping FDA-approved indications with an FDA-approved biosimilar or generic product that would be excluded.

*Response:* We thank the commenter for sharing their concern that an exclusion of biosimilar biological products and their reference products disproportionately harms non-biosimilar biological products and non-reference products that compete in the same therapeutic space. Our proposed exclusion policy is not based on indication but whether the drug or biological product is sole-source or multi-source. CMS's exclusion of biosimilar biological products and their reference products reflect the observable differences in pricing dynamics of sole source and multi-source biological products that lead to unique market dynamics in the U.S. We disagree that an exclusion of non-biosimilar biological products and non-reference products that share the same or overlapping FDA-approved indication as excluded biosimilar biological products and their reference products is necessary for purposes of the GLOBE Model because these products are not multi-source and thus, not subject to the same observable differences in pricing dynamics.

Further, the purpose of the GLOBE Model test is to reduce program expenditures while preserving or enhancing quality of care, and the CMS Innovation Center is testing, for certain single source drugs and sole source biological products, an alternative approach to the rebate amount calculation under the Medicare Part B Drug Inflation Rebate Program that incorporates international drug pricing information precisely because the extremely high price of these drugs in the U.S. compared to comparable economic countries suggests there are potentially avoidable expenditures that could be addressed while preserving or enhancing beneficiaries' quality of care.[143] Thus, including an exclusion for non-biosimilar biological products and non-reference products that compete in the same therapeutic space as biosimilar biological products and their reference products, which would carve out single source drugs and sole source biological products in these therapeutic areas, would disrupt the very purpose of this model test.

*Comment:* A commenter expressed concern that the GLOBE Model would negatively affect innovation and planned research and development for long-acting pre-exposure prophylaxis (PrEP) formulations designed to improve medication adherence.

*Response:* We thank the commenter for sharing their concerns on the GLOBE Model drug inclusion and exclusion criteria. We appreciate the commenter's concern regarding the potential impact of the GLOBE Model on innovation in long-acting PrEP formulations. HIV medications such as PrEP are identified as Antivirals in the 2025 USP DC classification system. Antivirals are not among the seven USP DC categories that CMS proposed to include in the GLOBE Model and, therefore, HIV medications like PrEP would not be in the proposed selection criteria for the GLOBE Model and would not be included as GLOBE Model drugs. Accordingly, we do not believe the GLOBE Model would negatively affect innovation or research and development in this therapeutic area.

*Final Decision:* After consideration of the public comments received, CMS is finalizing an additional drug exclusion criterion at new § 513.130(c)(1)(iv) to exclude from the GLOBE Model, a Part B rebatable drug that is designated as a drug for one or more rare diseases or conditions under section 526 of the Federal FD&C Act (21 U.S.C. 360bb) and for which the only approved indication (or indications) is for one or more such rare diseases or conditions. As further discussed in section II.B.5. of this final rule, CMS is also finalizing the exclusion of products listed on the FDA's Approved Cellular and Gene Therapy products website and plasma-derived products as set forth in 42 CFR 427.400.

Additionally, CMS has made a technical correction to the regulation text to remove the definition of maximum fair price from § 513.20 to remove redundancy. The exclusion for a Part B rebatable drug for which a maximum fair price under the Negotiation Program is in effect resides in § 513.130(c)(1)(ii) and for clarity, CMS is finalizing the regulatory text at § 513.130(c)(1)(ii) with a modification to add ''(as defined in section 1191(c)(3) of the Act)'' after the words maximum fair price. CMS is also finalizing the regulatory text at § 513.130(c)(1)(iii) without modification.

[142] The White House. Savings from Most-Favored-Nation Drug Pricing Policy, May 5, 2026. Available at: *https://www.whitehouse.gov/research/2026/05/savings-from-most-favored-nation-drug-pricing-policy/.*

[143] Andrew W. Mulcahy, Christopher M. Whaley, Mahlet G. Tebeka, 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.*

3. Summary of GLOBE Model Drug Inclusion and Exclusion

To summarize, CMS proposed that GLOBE Model drugs as set forth in § 513.130 in the GLOBE Model proposed rule 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 OM Part B spending greater than $100 million over a 12-month period (as determined by CMS under § 513.130(d)) ending 6 months prior to the start of the applicable calendar quarter; and (4) are not excluded from the GLOBE Model as proposed in § 513.130(c).

In addition, CMS proposed that once a Part B rebatable drug has been identified as meeting the criteria for inclusion in the GLOBE Model, it 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 § 513.130(c).

The drugs or biological products that meet the proposed definition of a GLOBE Model drug in § 513.20 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 OM Part B 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. OM Part B 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 percent [144] of annual OM Part B drug spending for separately payable Medicare Part B drugs based on an analysis of all 2024 OM Part B 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, and thus the beneficiaries who rely upon these drugs represent a population for which there are potentially avoidable expenditures and likely deficits of care due to high costs.

Table 4, Illustrative GLOBE Model Drug HCPCS Level II Codes List, provided in section II.B.6. of the GLOBE Model proposed rule (90 FR 60260), showed an illustrative list of how the GLOBE Model could apply to Part B drugs by HCPCS code using available claims information from calendar year (CY) 2024 after applying the proposed drug inclusion and exclusion criteria. As stated in the GLOBE Model proposed rule, this illustrative list may not fully capture all relevant HCPCS codes for potential GLOBE Model drugs and may include HCPCS 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

As stated in the GLOBE Model proposed rule (90 FR 60257), we considered including all Part B rebatable drugs in the GLOBE Model. However, OM Part B drug spending is concentrated among high expenditure drugs, with 50 drugs (by HCPCS code) accounting for 64 percent of 2024 OM Part B drug spending. We also noted that many Medicare Part B rebatable drugs have annual total OM Part B allowed charges of less than $100 million. For example, using separately payable claims, 302 Medicare Part B rebatable drugs had less than $100 million in total 2024 OM Part B drug spending each, representing 7 percent of total 2024 OM Part B drug spending. Similarly, 266 Medicare Part B rebatable drugs had less than $50 million in total 2024 OM Part B drug spending each, accounting for 3 percent of total 2024 OM Part B 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 the GLOBE Model proposed rule. However, the approximately 80 Part B rebatable drugs with greater than $100 million in 2024 OM Part B allowed charges accounted for 61 percent of 2024 OM Part B drug spending. As such, we considered that it may be too burdensome for the operational and administrative efforts to include Part B rebatable drugs with less than $100 million in total OM Part B 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 OM Part B spending without sacrificing the potential for meaningful model findings and learning. Therefore, we opted to not propose including all Part B rebatable drugs in the GLOBE Model and instead proposed 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, we noted that, 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 proposed to exclude biosimilar biological products licensed under 351(k) of the PHS Act and their reference biological products.

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. We noted that 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

[144] This statistic is based on an evaluation of all 2024 OM Part B claims that would meet the proposed GLOBE Model inclusion and exclusion criteria and does not account for any geography distinctions. Refer to section II.F. of this final rule for discussion on the GLOBE Model geographic areas.

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, we believe our proposed approach 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 HCPCS Level II Codes List for 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 OM Part B 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 beneficiaries with related conditions that are likely exposed to higher financial burden and greater deficits of care. We stated that CMS 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, but that any such expansion would be subject to notice and comment rulemaking. 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 HCPCS Level II Codes 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 Medicare Part B drug 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 OM Part B beneficiaries during a specified period; [145] and 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 also considered if the spend threshold (total OM Part B 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 welcomed 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 thereby demonstrating these beneficiaries are a population for which there are potentially avoidable expenditures, and who likely have a deficit of care allows for a transparent, consistent, and clear approach that would provide sufficient opportunity to observe the impacts of the model test on a sufficient number of OM beneficiaries who may receive a Part B rebatable drug. Our proposed approach would minimize complexity within the model implementation and evaluation and improve CMS's 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 section II.B. of the GLOBE Model proposed rule (90 FR 60252) and in this section of this final 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 welcomed comments on our process for identifying the USP DC categories, our proposed method for identifying and excluding certain drugs, and the alternatives we considered. We also welcomed comments on CMS's 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 sought 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 section 351(k) of the PHS Act but not sold during an applicable calendar quarter.

The following is a summary of the comments received and our responses.

*Comment:* A commenter stated their support for adjusting the $100 million sales threshold by CPI–U, stating that without the inflation index, lower-cost drugs that may not pose affordability concerns could be captured by the GLOBE Model's inclusion criteria.

*Response:* We thank the commenter for sharing their concern that without adjustment of the threshold to account for inflation, drugs that may not have affordability issues could be included in the GLOBE Model. We note that the commenter characterized this threshold as a $100 million sales threshold; we clarify that CMS proposed a spend threshold based on total OM Part B drug allowed charges, not a sales threshold. We also note that the GLOBE Model focuses on a subset of Part B rebatable drugs that meet certain inclusion criteria and there may be drugs outside the GLOBE Model that pose affordability concerns regardless of whether the spend threshold would be adjusted for inflation, such as adjusting

[145] The minimum number of beneficiaries who used a drug selected for the Medicare Drug Price Negotiation Program for initial price applicability year 2026 was 20,000. 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.

the spend threshold by the change in CPI–U.

After reviewing the public comments and the detailed analyses provided by several commenters, we have determined that updating the minimum spend threshold for each subsequent applicable calendar quarter by the percentage increase in the CPI–U for the consecutive 12-month period ending 6 months prior to the start of such applicable calendar quarter would be a reasonable approach for the GLOBE Model to maintain the model's focus on drugs that meet a meaningful minimum spend threshold over time, while maintaining predictability for manufacturers regarding the likelihood that a Part B rebatable drug would meet this inclusion criterion. We note that in rare circumstances, the CPI–U for the consecutive 12-month period ending 6 months prior to the start of an applicable calendar quarter may not be available from the Bureau of Labor Statistics, as determined by CMS. In such cases, CMS would use the percentage increase in the CPI–U for the most recent consecutive 12-month period prior to the specified 12-month period for which data is available, as determined by CMS. We note that should the change in CPI–U for a specified 12-month period be negative, the percentage increase for such period would be zero.

Accordingly, we are modifying § 513.130(b)(3) to specify how a GLOBE Model minimum spend threshold would be calculated for each applicable calendar quarter. Within these modifications, we are retaining our proposal that this inclusion criterion would be met if the Part B rebatable drug meets the spend threshold for at least one applicable calendar quarter during the GLOBE Model performance period. If the Part B rebatable drug meets this criterion for an applicable calendar quarter, it would continue to meet this criterion for subsequent applicable calendar quarters, even if the total OM Part B allowed charges falls below the GLOBE Model minimum spend threshold for any subsequent applicable calendar quarters. Part B rebatable drugs not previously included in the GLOBE Model would be evaluated each calendar quarter to determine if they meet the minimum spend threshold.

*Final Decision:* After consideration of the public comments received, CMS is finalizing § 513.130(b)(3) with modifications to specify that the minimum spend threshold for each subsequent applicable calendar quarter would be increased by the percentage increase in the CPI–U for the consecutive 12-month period ending 6 months prior to the start of such applicable calendar quarter, rounded to the nearest multiple of $10, and how CMS would determine the CPI–U in instances when the percentage increase in the CPI–U for a specified 12-month period is not available, as determined by CMS. CMS is also finalizing § 513.130(b)(3) to state if the Part B rebatable drug meets this criterion for an applicable calendar quarter, it continues to meet this criterion for all applicable calendar quarters thereafter during the model performance period, even if the OM Part B allowed charges falls below the applicable minimum spend threshold for any applicable calendar quarters thereafter during the model performance period. CMS is also modifying § 513.20 by adding a definition for ''CPI–U'' and specifying that CPI–U has the same meaning as set forth 42 CFR 427.20.

5. Considerations Related to Cell and Gene Therapies and Plasma-Derived Products

We also considered 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 sought 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 welcomed comments on whether the GLOBE Model should 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.4.d. of the GLOBE Model proposed rule (90 FR 60286).

The following is a summary of the comments received and our responses.

*Comment:* Many commenters stated that CGTs, including CAR-Ts, should be excluded from the GLOBE Model. Commenters cited several reasons, including: the lack of international pricing benchmarks for CGTs; the prevalence of outcome-based agreements internationally that make direct price comparisons difficult; and the existence of a separate CMS Innovation Center CGT Access Model. Commenters further believed that CGTs represent a unique class of medical products with complex storage and handling requirements, clinical development requirements, and no biologically similar comparators. Commenters stated that CGT manufacturing frequently occurs on a just-in-time basis, may require ''individualized production using each patient's own cells'', and that the complexity of the manufacturing process makes access challenging even in the U.S. Commenters expressed concern that the model's benchmarking approach does not account for these complexities or benefits, which may result in reimbursement rates that fail to cover actual development, delivery, and treatment costs. Commenters also stated that CGTs may involve a single administration that provides potentially curative treatment, distinguishing them from other pharmaceutical products.

In contrast, a commenter recommended that CGTs should be included in the GLOBE Model given their high costs. The commenter asserted that Medicare and its beneficiaries should benefit from any lower prices that other countries may be achieving for these treatments.

*Response:* We thank the commenters for their feedback, including support for and concerns regarding the exclusion of CGTs. We note that, per the FDA, cellular therapy products include cellular immunotherapies, cancer vaccines, and other types of autologous and allogenic cells for certain therapeutic indications, while gene therapy products modify or manipulate the expression of a gene or alter the biological properties of living cells for therapeutic use.[146] Collectively, we refer to these products as CGTs and use FDA's list of Approved Cellular and Gene Therapy Products for identification purposes.

The proposed inclusion criteria—specifically the requirement in § 513.130(b)(3) for including Part B rebatable drugs with total OM Part B allowed charges greater than $100 million over a 12-month period—are designed to focus the model test on drugs and biological products with high program expenditures to target Medicare beneficiaries for whom there are potentially avoidable expenditures and potential deficits of care. CMS believes the criterion meets the model's core intent.

We acknowledge commenters' concerns that CGTs represent a unique class of medical products with complex process, storage and handling requirements, and clinical development requirements. We further acknowledge concerns that these products may have unique international pricing

[146] Food and Drug Administration. Cellular & Gene Therapy Products. Available at: *https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products.*

characteristics due to the prevalence of outcome-based agreements and other pricing strategies for CGTs in other countries. While we acknowledge these concerns, our analysis of existing data sources for international drug pricing information showed that CMS would be able to identify a per unit GLOBE Model benchmark for these drugs. We also recognize that CGTs may involve a single administration with potentially curative outcomes, distinguishing them from other pharmaceutical products.

After careful consideration of the full range of comments received, and although we disagree with commenters' assertions that the benchmarking process does not account for the unique attributes of CGTs, out of an abundance of caution due to the complex manufacturing process required to develop CGTs (for example just in time basis, use of a patient's own cells), we have determined that it is reasonable to exclude products listed on FDA's Approved Cellular and Gene Therapy Products website from the GLOBE Model at this time.[147] Accordingly, we are modifying the GLOBE Model's drug inclusion and exclusion criteria to exclude CGTs, including CAR-Ts, from the model. We note that this decision is done out of an abundance of caution for the Medicare beneficiaries receiving CGT treatment to prevent the possibility of commenters' concerns manifesting for these products, and we may reconsider this topic in the future through notice and comment rulemaking.

*Comment:* A commenter suggested an alternative payment methodology for CGTs under the GLOBE Model that would test a three-party warranty contract structure involving the health plan, the manufacturer, and the Federal government.

*Response:* We thank the commenter for this feedback. While we appreciate the commenter's suggestion that CMS test a three-party warranty contract structure involving the health plan, manufacturer, and Federal government for CGTs, the GLOBE Model is designed to test an alternative rebate amount calculation to reduce Medicare Part B drug expenditures while preserving or enhancing quality of care. We believe it would be administratively complex to accommodate alternative payment contract structures of this nature within the model's framework and doing so could confound the model evaluation. Therefore, we decline to adopt the commenter's suggestion within the GLOBE Model test. We note that the CMS Innovation Center is currently testing the CGT Access Model which supports outcomes-based agreements between the Federal government, states and manufacturers within a framework that is designed to improve access to CGTs, lower prices for states, and ties payment to outcomes. We refer the commenter to the CMS Innovation Center's CGT Access Model website for additional information.

*Comment:* Many commenters stated that plasma-derived products should be excluded from the GLOBE Model to protect patient access. Commenters also stated that these products rely on a complex, donor-dependent supply chain that is uniquely vulnerable to disruptions, and that treating a single patient may require numerous plasma donations, making these therapies both resource-intensive and life-saving. Commenters wrote that plasma-derived products are excluded from the Negotiation Program and were exempted from the 2020 MFN Model Interim Final Rule, citing these precedents as support for exclusion from the GLOBE Model as well. In addition, commenters highlighted that plasma-derived products operate within different manufacturing ecosystems and reimbursement structures in foreign markets compared to the U.S. and expressed concern that applying international reference pricing to these products could lead to supply shortages and delays in patient access. A commenter requested CMS exclude Immunoglobulin G (IgG) products if plasma-derived products are included in the model.

*Response:* We thank the commenters for their feedback, including support for and concerns regarding the exclusion of plasma-derived products, including IgG products. The proposed inclusion criteria—covering drug or biological products with total OM Part B allowed charges greater than $100 million over a 12-month period—are designed to focus the model test on high-expenditure drugs and biological products to target Medicare beneficiaries for whom there are potentially avoidable expenditures and potential deficits of care. CMS believes this criterion meets model's core intent.

We acknowledge commenters' concerns that plasma-derived products rely on a complex, donor-dependent supply chain that is uniquely vulnerable to disruptions and that these therapies are life-saving for many patients who may require treatment derived from numerous plasma donations. We further acknowledge that plasma-derived products are excluded from the Negotiation Program and were exempted from the 2020 MFN Model Interim Final Rule, and we recognize these existing policy precedents as relevant considerations. We disagree that the GLOBE Model would likely create access implications for plasma-derived products as suggested by commenters, given the limited nature of the model in terms of its scope as discussed previously. Out of an abundance of caution for the Medicare beneficiaries that rely upon these products, however, we are refining the GLOBE Model's drug inclusion and exclusion criteria by excluding plasma-derived products to prevent the possibility of commenters' concerns manifesting for these products.

For purposes of identifying these products for exclusion, CMS would apply the definition at 42 CFR 427.400 for plasma-derived products. As set forth in 42 CFR 427.400, ''plasma-derived product'' means a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling. Accordingly, in § 513.20, we are finalizing the proposed definition of plasma-derived product.

*Final Decision:* After consideration of the public comments received, CMS is finalizing § 513.130(c) with modifications. Specifically, CMS is adding a new exclusion criterion at § 513.130(c)(1)(v) to exclude a product that is listed on the FDA's Approved Cellular and Gene Therapy products website.[148] CMS is also adding a new exclusion criterion at § 513.130(c)(1)(vi) to exclude a Part B rebatable drug that is a plasma-derived product as set forth in 42 CFR 427.400. CMS is also finalizing the definition of plasma-derived product in § 513.20 as proposed.

The GLOBE Model proposed rule included a definition of ''GLOBE Model drug'' in the regulatory text. Although the preamble did not separately propose the definition, the inclusion in the proposed regulatory text provided notice and an opportunity for public comment, and CMS is therefore finalizing the definition of ''GLOBE Model drug'' at § 513.20 with minor technical modifications.

6. Illustrative List of Proposed Performance Year 1 GLOBE Model Drugs

To create an illustrative GLOBE Model Drug HCPCS Level II Codes List

[147] Food and Drug Administration. Approved Cellular and Gene Therapy Products. Available at: *https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products.*

[148] Food and Drug Administration. Approved Cellular and Gene Therapy Products. Available at: *https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products.*

for the GLOBE Model proposed rule, 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 the GLOBE Model proposed rule. Using this approach, an illustrative GLOBE Model Drug HCPCS Level II Codes List was shown in Table 4 of the GLOBE Model proposed rule (90 FR 60260) and includes drugs and biological products that met the proposed criteria for at least one applicable calendar quarter in 2024. As stated in the GLOBE Model proposed rule, Table 4 (90 FR 60260) was 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, we stated that this illustrative list is based on CMS's initial analyses and proposals discussed in the GLOBE Model proposed rule and was provided for informational purposes only.

In response to public comments, and to illustrate the changes to the GLOBE Model's drug inclusion and exclusion criteria finalized in this rule, we direct readers to Table 4, Illustrative GLOBE Model Drug HCPCS Level II Codes List, in this final rule. This table reflects the additional exclusions for a Part B rebatable drug finalized under § 513.130(c). Specifically, a Part B rebatable drug is excluded from the GLOBE Model if it is (1) designated as a drug for one or more rare diseases or conditions under section 526 of the Federal FD&C Act (21 U.S.C. 360bb) and for which the only approved indication (or indications) is for one or more such rare diseases or conditions; (2) listed on the FDA Approved Cellular and Gene Therapy Product website; or (3) a plasma-derived product as set forth in 42 CFR 427.400. Readers should note that this is an illustrative list only, based on 2024 Part B rebatable drugs identified by CMS, and does not indicate that these drugs or biological products would be a GLOBE Model drug, that the manufacturer of such products would owe a GLOBE Model rebate, or that absence of a drug or biological product in this illustrative list means it would not be a GLOBE Model drug at model start.

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**TABLE 4: ILLUSTRATIVE 2024 GLOBE MODEL DRUG HCPCS LEVEL II CODES LIST***

| HCPCS Level II Code | Short Description | USP DC Category |
|---|---|---|
| J0129 | Abatacept injection | Immunological Agents |
| J0178 | Aflibercept injection | Ophthalmic Agents |
| J0490 | Belimumab injection | Immunological Agents |
| J0717 | Certolizumab pegol inj 1mg | Immunological Agents |
| J0881 | Darbepoetin alfa, non-esrd | Blood Products and Modifiers |
| J0897 | Denosumab injection | Antineoplastics/ Metabolic Bone Disease Agents |
| J1602 | Golimumab for iv use 1mg | Immunological Agents |
| J2323 | Natalizumab injection | Central Nervous System Agents |
| J2350 | Injection, ocrelizumab, 1 mg | Central Nervous System Agents |
| J2357 | Omalizumab injection | Immunological Agents |
| J2777 | Inj, faricimab-svoa, 0.1mg | Ophthalmic Agents |
| J2781 | Inj, pegcetacoplan, 1mg | Immunological Agents |
| J3111 | Inj. romosozumab-aqqg 1 mg | Metabolic Bone Disease Agents |
| J3245 | Inj., tildrakizumab, 1 mg | Immunological Agents |
| J3262 | Tocilizumab injection | Immunological Agents |
| J3380 | Inj vedolizumab iv 1 mg | Immunological Agents |
| J9022 | Inj, atezolizumab,10 mg | Antineoplastics |
| J9023 | Injection, avelumab, 10 mg | Antineoplastics |
| J9043 | Cabazitaxel injection | Antineoplastics |
| J9055 | Cetuximab injection | Antineoplastics |
| J9119 | Inj., cemiplimab-rwlc, 1 mg | Antineoplastics |
| J9144 | Daratumumab, hyaluronidase | Antineoplastics |
| J9173 | Inj., durvalumab, 10 mg | Antineoplastics |
| J9177 | Inj enfort vedo-ejfv 0.25mg | Antineoplastics |
| J9228 | Ipilimumab injection | Antineoplastics |
| J9271 | Inj pembrolizumab | Antineoplastics |
| J9272 | Inj, dostarlimab-gxly, 10 mg | Antineoplastics |
| J9299 | Injection, nivolumab | Antineoplastics |
| J9301 | Obinutuzumab inj | Antineoplastics |
| J9303 | Panitumumab injection | Antineoplastics |
| J9306 | Injection, pertuzumab, 1 mg | Antineoplastics |
| J9308 | Injection, ramucirumab | Antineoplastics |
| J9316 | Pertuzu, trastuzu, 10 mg | Antineoplastics |
| J9317 | Sacituzumab govitecan-hziy | Antineoplastics |
| J9354 | Inj, ado-trastuzumab emt 1mg | Antineoplastics |
| J9358 | Inj fam-trastu deru-nxki 1mg | 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. Defined Population*

As stated in section II.C. of the GLOBE Model proposed rule (90 FR 60261), 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 proposed to use a geographically randomized design such that the defined population for the GLOBE Model would be a set of CMS-selected OM Part B beneficiaries who are identified as eligible for inclusion in the model cohort as set forth in § 513.120 and receive a GLOBE Model drug (as set forth in § 513.130) during the model performance period for which separate Medicare Part B payment is made under the GLOBE Model. The OM Part B 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 proposed 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 final rule). We also proposed that, prior to model start and periodically thereafter, but no more frequently than weekly, CMS would identify eligible

OM beneficiaries (as set forth in § 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 proposed 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 OM beneficiaries who are eligible for inclusion in the comparison group, would be performed by CMS and would not be subject to review.

In § 513.120, we also proposed how CMS would identify the Medicare beneficiaries who would be eligible for inclusion in the model cohort and comparison group. In § 513.20, we proposed to define the term ''GLOBE Model eligible beneficiary.'' A GLOBE Model eligible beneficiary is 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 § 513.120. Specifically, in § 513.120(b), we proposed 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 Original 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 § 513.110(c)), as determined by CMS. These beneficiaries would encompass the 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 § 513.120(b)(2), we proposed 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 OM 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 § 513.110(c)), as determined by CMS. These beneficiaries would be assigned as being eligible for inclusion in the comparison group as described in the evaluation section II.P. of this final rule.

To maintain a clear record of which beneficiaries are eligible for inclusion in the model cohort, in § 513.120(c), we proposed 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 OM 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 § 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 § 513.120(d), we proposed 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 OM Part B as their primary payer, and beneficiaries who are enrolled in a MA 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, § 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 proposed 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's Medicare Beneficiary Database (MBD), System No. 09–70–0536, at the time CMS identifies beneficiaries for inclusion in the model. We also proposed to define in § 513.20 the term ''GLOBE Model geographic areas'' as the set of ZIP Codes identified as set forth in § 513.110 (as discussed in section II.F. of this final 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 OM 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's MBD being within the selected model geographic areas and then subsequently the beneficiary's address recorded in CMS's 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 OM or is otherwise ineligible for inclusion. Beneficiaries who become newly enrolled in OM due to becoming newly eligible for OM 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 OM or is ineligible for inclusion. Beneficiaries for whom OM Part B 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 OM 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's MBD that was not selected as a GLOBE Model geographic area and then had an address change to a GLOBE Model geographic area; and (2) newly enrolled OM Part B 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 amount calculation 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.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters stated that CMS does not reasonably identify a ''defined population'' with a demonstrated ''deficit of care'' as required under section 1115A(b)(2)(A) of the Act. Specifically, commenters stated that beneficiaries who receive a GLOBE Model drug within the randomly selected GLOBE geographic area do not constitute a stable or clinically coherent defined population. Commenters also stated that high Federal drug spending does not equate to a shortcoming in care leading to poor clinical outcomes or potentially avoidable expenditures, and that CMS provided no reasoned basis for distinguishing selected therapeutic categories from excluded ones. A commenter stated that by enacting the model through randomization, CMS is not identifying areas or populations with observed deficits of care through a baseline analysis. Additionally, commenters suggested that even if high spending were considered a valid deficit of care, CMS's proposal would not sufficiently rectify this deficit, because most beneficiaries have supplemental insurance that alleviates the coinsurance burden associated with Part B drugs. Further, a commenter stated that the model does not address access barriers that prevent patients from initiating or staying on guideline-directed therapy.

*Response:* We thank commenters for their feedback. While we acknowledge the concerns raised, CMS disagrees that the model does not have a defined population or a demonstrated deficit of care. Section 1115A(b)(2)(A) of the Act authorizes the Secretary to select models for testing 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.'' The GLOBE Model addresses a defined population for which there are potentially avoidable expenditures and likely deficits of care due to high costs. As stated in section II.B., CMS proposed the 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 there are potentially avoidable high program expenditures and access barriers due to high costs which likely contribute to deficits in care. Given the high disparity in prices for originator drugs in the U.S. as compared to other OECD member countries (single source drugs and sole source biological products),[149] [150] [151] we believe this data substantiates that there are potentially avoidable expenditures among Medicare beneficiaries who rely upon these high spend Part B rebatable drugs.

As stated in the GLOBE Model proposed rule, the GLOBE Model's defined population consists of Medicare beneficiaries residing in selected ZCTAs who receive a qualifying GLOBE Model drug. This population is defined in a non-arbitrary manner grounded in both geographic residence and drug utilization, providing a stable and identifiable basis for model participation. Further, randomizing ZCTAs enables a robust evaluation that identifies the effect of the Model on beneficiaries and produces generalizable results that can inform what would happen if the model were scaled nationally. Selecting geographic areas with the populations most affected by affordability challenges or access barriers would limit the generalizability of results.

We also note that other CMS Innovation Center models—including EOM, BPCI-Advanced Model, and the Comprehensive Care for Joint Replacement (CJR) Model—similarly define their populations based on an initiating therapy or an admission for an inpatient stay or specific procedure, rather than on clinical diagnosis alone. Other examples include the family of ACO models such as the ACO REACH Model which define their beneficiary population based on an Evaluation and Management visit with a participating provider. The selection of ZCTAs to represent 25 percent of Medicare beneficiaries strengthens the evaluation and testability of the GLOBE Model by enabling the formation of a treatment group that directly benefits from the model's intervention and a comparison group that does not, supporting a rigorous assessment of the model's impact.

Additionally, high drug costs lead to potentially avoidable expenditures and can limit access to care and treatment, which can result in poor clinical outcomes. For example, financial distress has been attributed as a risk factor for mortality after cancer diagnosis, and high coinsurance amounts likely limit the use of certain cancer treatments.[152] [153] Previous analyses have 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 biological products.

Further, CMS has initially focused the model test on seven USP DC categories that will target patients in therapeutic areas most likely to experience significant financial burden due to high drug costs. As shown in Tables 2 and 3 of the GLOBE Model proposed rule (90 FR 60244 through 60254), the seven USP DC categories are associated with the therapeutic areas representing the highest percentage of total OM Part B drug spending among the top 50

[149] Berkemeier, Fabian, Christopher Whaley, and James C. Robinson. *Increasing Divergence in Drug Prices Between the United States and Germany After Implementation of Comparative Effectiveness Analysis and Collective Price Negotiations.* Journal of Managed Care & Specialty Pharmacy 25, no. 12 (2019): 1310–17. *https://doi.org/10.18553/jmcp.2019.25.12.1310.*

[150] Gong, Dan, Jonathan S. Chang, Miriam Barbany, et al. *Comparison of United States and International Ophthalmic Drug Pricing.* Ophthalmology (United States) 126, no. 10 (2019): 1358–65. *https://doi.org/10.1016/j.ophtha.2019.04.018.*

[151] Vokinger, Kerstin N., Thomas J. Hwang, Paola Daniore, et al. *Analysis of Launch and Postapproval Cancer Drug Pricing, Clinical Benefit, and Policy Implications in the US and Europe.* JAMA Oncology (United States) 7, no. 9 (2021): e212026. *https://doi.org/10.1001/jamaoncol.2021.2026.*

[152] Ramsey, Scott D., et al. *Financial Insolvency as a Risk Factor for Early Mortality Among Patients With Cancer.* Journal of Clinical Oncology, 2016, 34(9): 980–986. doi: 10.1200/JCO.2015.64.6620.

[153] Horn, D., Alpert, A., Duggan, M., Jacobson, M. *The impact of immunotherapy on reductions in cancer mortality: Evidence from Medicare.* Journal of Health Economics, 2026, 106. doi: 10.1016/j.jhealeco.2026.103115.

Medicare Part B drugs by expenditure. Specifically, analysis of 2024 OM Part B rebatable drug spending data indicates that these 7 USP DC categories were responsible for 91 percent of OM Part B rebatable drug spending. Consistent with section 1115A of the Act, we believe the GLOBE model will reduce program expenditures and would not only preserve quality of care, but enhance it by addressing access barriers that may prevent beneficiaries from initiating or staying on guideline-directed therapy by improving affordability and access.

CMS believes that the GLOBE Model will result in meaningful cost savings, including through a reduction in total out-of-pocket expenditures for Medicare beneficiaries, as indicated in Table 14 in section IV.D. of this final rule.

*Comment:* Commenters raised concerns about potential detrimental effects on health equity and different population subgroups. Commenters expressed concern that excluding MA beneficiaries from the GLOBE Model would leave out a large share of underserved populations, such as Latino seniors, and would exacerbate inequities between OM and MA beneficiaries.

*Response:* CMS thanks the commenters for their feedback. CMS believes that the GLOBE Model has the potential to benefit beneficiaries residing in GLOBE Model-selected geographies by reducing their coinsurance when they receive a GLOBE Model drug and their Medicare Part B premiums as further discussed in section IV.D. CMS will monitor the impact of the GLOBE Model on beneficiary access to monitor and address potential access challenges that may arise under the model.

With respect to commenters' concerns about the exclusion of MA beneficiaries, CMS acknowledges that MA enrollment is disproportionately higher among certain underserved populations, including Latino seniors, and that excluding MA beneficiaries from the GLOBE Model may limit the reach of the model's potential benefits to those populations. However, CMS declines to include MA beneficiaries in the defined population at this time. This decision is consistent with the structure of the Medicare Part B Drug Inflation Rebate Program which, at this time, does not include MA units in Medicare Part B drug inflation rebate amount calculations due to operational considerations. Therefore, we are not including MA beneficiaries within the GLOBE Model. Beneficiaries who are eligible for the GLOBE Model defined population but subsequently enroll in a MA plan will no longer be GLOBE Model eligible beneficiaries. However, if such a beneficiary returns to OM during the GLOBE Model performance period, they would once again become a GLOBE Model eligible beneficiary. We will revisit this topic for future consideration should the Medicare Part B Drug Inflation Rebate Program include MA units in Medicare Part B drug inflation rebate amount calculations.

*Comment:* A commenter raised concerns about how they, as a health care provider, would meet compliance requirements such as monitoring drug inclusion lists and potential updates to billing systems. The commenter cited their own resource constraints, including direct financial risk exposure, acquisition cost-to-reimbursement instability, additional operation burdens, and long-term duration of the model test, as grounds for requesting an exemption from the model.

*Response:* CMS thanks the commenter for its concern. CMS believes that the GLOBE Model will not impose additional compliance requirements on providers, including on the specific commenter. Further, the allowable payment limits for separately payable GLOBE Model drugs will continue to be based on the applicable non-model methodology, generally ASP+6 percent, which is intended to provide a stable reimbursement baseline. As with the Medicare Part B Drug Inflation Rebate Program, when the GLOBE Model beneficiary coinsurance adjustment for GLOBE Model Drugs applies, 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, the Medicare payment amount is correspondingly adjusted and 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. As the GLOBE Model uses existing methods for provider reimbursement, providers do not need additional resource(s) because of the GLOBE Model. CMS has considered these concerns in the design of the GLOBE Model and declines to provide blanket exemptions at this time.

*Comment:* Several commenters raised concerns about equity arising from the reduced coinsurance benefit being limited to beneficiaries in GLOBE Model-selected regions, as well as concerns about the use of randomization at the ZCTA level. A commenter stated that geographic randomization may deepen existing racial and regional inequalities, noting that residential segregation and concentrated poverty often follow ZIP Code patterns. Another commenter raised concern that, given the rarity of orphan diseases, geographic randomization could disproportionately select beneficiaries with orphan diseases into the GLOBE Model. A commenter recommended that beneficiaries within a ZCTA be individually randomized into comparison or model intervention group, citing concerns about social determinants of health.

*Response:* We thank commenters for their thoughtful comments and sharing areas of concern. CMS believes that it is important to retain the geographic selection approach, under which a portion of Medicare beneficiaries are enrolled into the GLOBE Model, so that we can compare the outcomes of beneficiaries in GLOBE Model-selected areas to those in non-selected areas. Positive impacts observed among GLOBE Model beneficiaries could inform potential expansion of the model to all beneficiaries consistent with section 1115A(c) of the Act.

With respect to the use of ZCTAs as the unit of randomization, CMS believes that ZCTA-level selection is sufficiently granular to achieve a balanced representation of beneficiaries across important socioeconomic and clinical characteristics. Regarding concerns about patterns associated with ZIP Codes, CMS notes how ZCTAs differ from ZIP Codes. ZIP Codes are not geographic areas and are based on mail delivery routes. As a result, ZIP Codes create unequal sizes which, when randomized, can inadvertently over- or under-represent certain communities. ZCTAs are designed to enable better statistical analysis and can more uniformly represent communities compared to analyses based on ZIP Codes. CMS does not anticipate that the model will result in harm to beneficiaries, as the model reduces coinsurance for GLOBE Model beneficiaries and does not restrict access to covered drugs.

Further, in response to commenters' concerns about the potential disproportionate inclusion of beneficiaries who use orphan drugs, CMS has decided to exclude Part B rebatable drugs that are designated as a drug for one or more rare diseases or conditions under section 526 of the Federal FD&C Act (21 U.S.C. 360bb) and for which the only approved indication (or indications) is for one or more such rare diseases or conditions from the

GLOBE Model. This exclusion should address concerns about the potential disproportionate selection of beneficiaries using orphan-only drugs. Refer to section II.B.2. and § 513.130(c) for details on how we identify orphan drugs for exclusion.

*Comment:* A commenter stated that beneficiaries will not see the cost savings at the point of sale.

*Response:* CMS disagrees. As stated in § 513.210, beneficiaries in the GLOBE Model would benefit from reduced coinsurance as applicable when they receive a qualifying GLOBE Model drug, particularly beneficiaries who do not have supplemental insurance that covers the costs of coinsurance. In addition, CMS expects that Medicare beneficiaries will experience a reduction in Medicare Part B premiums as a result of the GLOBE Model.

*Final Decision:* After consideration of the public comments received, CMS is finalizing the provisions at § 513.120 with two technical modifications. Due to changes in the dates establishing the start of the model and the model performance period, CMS is revising § 513.120(b). CMS will establish the initial assignment of beneficiaries as eligible for the model cohort or comparison group approximately 30 days prior to the first model performance period which begins April 1, 2027, instead of the model start date. Due to operational constraints in the CMS claims processing systems, in § 513.120(c), CMS is finalizing that the GLOBE Model Eligible Beneficiary List updates will occur no more frequently than monthly. CMS has also made minor terminology updates to § 513.120(c)(2) for clarity. As discussed in the preceding comment-and-response section, these provisions establish model-specific requirements necessary to support the administration and evaluation of the GLOBE Model.

CMS has also made technical corrections to the regulatory text at § 513.20 to address a drafting error which inadvertently omitted a phrase from the definition of ''GLOBE Model geographic areas.'' As corrected, ''GLOBE Model geographic areas'' means the set of ZIP Codes in the U.S., excluding U.S. territories, identified in accordance with § 513.110. Finally, CMS has clarified the regulatory text at § 513.20 to address a drafting error which inadvertently omitted a phrase from the definition of ''GLOBE Model beneficiary.'' As corrected, ''GLOBE Model beneficiary'' means a Medicare beneficiary who has been identified by CMS as set forth in § 513.120 for inclusion in the model, added to the model cohort for all or a portion of the GLOBE Model performance period and is furnished a GLOBE Model drug for which OM Part B makes separate payment under the model as determined by CMS. We have also deleted § 513.120(e) as this definition is redundant with the definition of ''GLOBE Model beneficiary'' in § 513.20.

*D. 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. In developing our proposal, we 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 OM beneficiaries. To determine the geographic areas that CMS would use to identify approximately 25 percent of OM beneficiaries as GLOBE Model eligible beneficiaries, we proposed that CMS would select geographic regions to represent 25 percent of OM beneficiaries (as described in section II.F.2. of this final rule).

The following is a summary of the comments received and our responses.

*Comment:* A commenter expressed concern that only 25 percent of OM beneficiaries will benefit from reduced coinsurance under the GLOBE Model. The commenter asked whether the remaining 75 percent of beneficiaries would benefit from reduced cost sharing, and how CMS would ensure rebate dollars collected under the model are returned to beneficiaries.

*Response:* We thank the commenter for their feedback. Under the GLOBE Model, only eligible beneficiaries residing in a GLOBE Model-selected region—representing approximately 25 percent of OM beneficiaries and spending—as identified by CMS would benefit from reduced coinsurance when they receive a GLOBE Model drug. Limiting the coinsurance reduction to beneficiaries in selected regions is a deliberate design choice that allows CMS to evaluate the model's impact by comparing the experiences of beneficiaries in selected regions to those in non-selected regions.

Regarding the disposition of rebate dollars, GLOBE Model rebates collected by CMS would be deposited into the Federal Supplementary Medical Insurance Trust Fund. While rebates are not returned directly to individual beneficiaries, their deposit into the Federal Supplementary Medical Insurance Trust Fund would enable reductions in the Medicare Part B premium and help sustain the financial integrity of the Medicare Part B program, which benefits Medicare beneficiaries and American taxpayers broadly.

*Comment:* Commenters believed that only 0.3 percent of OM Part B beneficiaries would be exposed to changes in their cost-sharing under the proposed coinsurance methodology. The commenter posited that because the model reaches only a small fraction of the beneficiary population, CMS would be unable to generate reliable data sufficient to meaningfully ''test'' the model's effectiveness.

*Response:* We disagree with the commenters' assertion that CMS will lack sufficient data to test the effectiveness of the GLOBE Model.

While commenters cited a figure of 0.3 percent of OM Part B beneficiaries being exposed to cost-sharing changes, CMS notes that the relevant consideration for model testability is not solely the percentage of the total beneficiary population affected, but rather the absolute number of eligible beneficiaries in the defined population and the breadth and rigor of the evaluation design. The GLOBE Model is designed to select beneficiaries residing in ZCTAs representing approximately 25 percent of OM beneficiaries and OM spending, providing a substantial population from which to draw meaningful comparisons.

The model reduces the coinsurance liability for beneficiaries who use a GLOBE Model drug, thereby reducing direct out-of-pocket costs. Notably, even among beneficiaries with supplemental insurance coverage, the potential change in out-of-pocket spending yields a meaningful effect and sample size to test the model's effects on patient experience. CMS believes that the model's evaluation framework is designed to generate reliable and actionable data to assess the GLOBE Model's effectiveness.

*Comment:* Several commenters cited potential concerns about operational complexity stemming from the GLOBE Model's geographic design. Commenters stated that practices treating patients from both included and excluded geographic areas would effectively need to maintain parallel systems, potentially

resulting in two different reimbursement rates for the same drug and creating additional administrative and billing burdens. Additional specificity was requested regarding the mechanics of beneficiary cost-sharing adjustments, with a specific request for additional operational guidance and information to support providers in verifying reimbursement accuracy.

*Response:* CMS thanks commenters for their feedback and clarifying questions. For GLOBE Model drugs, provider payment continues to be based on the Medicare Part B allowed amount (in general ASP+6 percent, as applicable) regardless of whether a beneficiary participates in the GLOBE Model, ensuring that providers are not negatively impacted. CMS does not require that providers create or maintain systems separate from and parallel to existing claims reimbursement systems to account for different reimbursement and we do not believe that it would be necessary for providers to do so. CMS acknowledges that beneficiaries who are selected in the model may have a coinsurance reduction that does not apply to beneficiaries who are not selected in the model. Patient liability differences (deductibles, coinsurance, and copay) across patients is a common occurrence for a provider that serves a population with different types of health insurance coverage. While this business situation can be challenging and a potential source of abrasion for providers if all of what a patient owes is not collected by the provider, we note that when the GLOBE Model beneficiary coinsurance reduction would apply, the Medicare program would pay the provider an amount that is greater than the typical 80 percent of the Medicare Part B allowed amount, reducing provider exposure to uncollected amounts and expenses related to collection.

To assist providers to anticipate when the GLOBE Model beneficiary coinsurance adjustment may apply, CMS will publish the ZIP Codes that constitute the GLOBE Model geographic regions, which would enable providers to identify if their OM patients may have been selected into the model and therefore may qualify for reduced coinsurance. CMS will also publish quarterly the GLOBE Model Drug HCPCS Level II Codes List with the applicable GLOBE Model beneficiary coinsurance percentage. Providers will continue to be informed of the coinsurance amounts owed by their beneficiaries as part of usual Medicare claims processing. CMS does not anticipate that providers will require additional support beyond these resources and the usual existing claims process to ensure accurate collection of coinsurance from their beneficiaries. Further, because Medicare Part B payment limits for separately payable drugs are updated quarterly, we believe that providers have established expertise in adjusting their estimates of the coinsurance amounts that beneficiaries would owe and that any additional effort related to the GLOBE Model would be minimal, particularly because providers commonly identify beneficiary coinsurance after all applicable payers have adjudicated a claim.

In addition, to enhance awareness of the GLOBE Model including coinsurance adjustment, CMS will publish technical documents—including Frequently Asked Questions (FAQs) and factsheets—on the GLOBE Model website that will be publicly accessible to beneficiaries, providers, and other interested parties.

*Comment:* A commenter supports the approach whereby providers would not be required to calculate the adjusted beneficiary coinsurance or adjusted Medicare Part B rebatable drug payments.

*Response:* CMS acknowledges the commenter's support for our approach. We note that providers would not be required to calculate the GLOBE Model beneficiary coinsurance amount for a GLOBE Model drug because the usual Medicare Part B claims process will inform the provider of the beneficiary liability based on the GLOBE Model beneficiary coinsurance percentage and the adjusted Medicare payment when applicable.

*Comment:* A commenter requested clarification on how CMS would address circumstances in which a beneficiary relocates or seeks care outside their GLOBE Model selected geographic area, and how CMS will handle mid-year address changes or retroactive corrections with respect to their effect on beneficiary eligibility and cost-sharing under the model.

*Response:* We thank the commenter for this question. As described in section II.D. of the GLOBE Model proposed rule (90 FR 60244 through 60254) and codified at § 513.120, a beneficiary's eligibility in the GLOBE Model is determined solely by CMS in part by their address of record at certain points in time. Once eligibility is established by CMS, a beneficiary's subsequent change in address during the GLOBE Model performance period would not alter their eligibility status. Similarly, the location where a beneficiary seeks care, including care received inside or outside the GLOBE Model selected geographic area, would not affect their eligibility or their entitlement to the GLOBE Model reduced coinsurance applicable to GLOBE Model beneficiaries. If a need to correct a beneficiary's selection into the model is identified by CMS, CMS would make the appropriate corrections to the GLOBE Model Eligible Beneficiary List as determined by CMS as set forth in § 513.120.

*Comment:* A commenter stated that the GLOBE Model creates manufacturer administrative complexity by imposing different rebate methodologies depending on geographic area in which their Part B drugs are administered. The commenter further stated that this complexity is compounded because the same drug may be administered across multiple provider settings, which bill Medicare separately and may be located in different ZCTAs.

*Response:* We thank the commenter for raising this concern. CMS agrees that under OM, the provider setting plays a role in determining how a drug is covered, billed, and paid. That is, OM has separate payment systems for covered drugs delivered in inpatient, outpatient, and other healthcare settings. CMS also recognizes that the model's rebate methodology is restricted to GLOBE Model geographic areas. This restricted geographic approach enables testing and evaluation of the model's effects on reducing program costs while preserving or enhancing quality. CMS also does not expect a significant increase in administrative complexity for manufacturers under the model since there are no enrollment procedures and CMS handles rebate invoicing for the rebate methodologies employed under both the GLOBE and non-GLOBE regions. CMS estimates the paperwork burden on manufacturers who voluntarily submit international drug net pricing data will be marginal and that manufacturers should be able to absorb these reporting costs. We refer readers to section IV.D.3. of this final rule for additional discussion on paperwork burden. With respect to manufacturer obligations related to GLOBE Model rebates reports, invoicing, and reconciliation, we refer readers to section II.G.8. of this final rule for additional comment and responses.

*Comment:* A commenter recommended applying the GLOBE Model to 100 percent of Medicare beneficiaries, suggesting that the proposed 25 percent coverage would not constitute a large enough lever for influencing international pricing behavior or for assessing whether foreign markets would respond to the

model by adjusting their prices. An additional commenter asked CMS to elaborate on why it did not adopt a nationwide policy, beyond what is described in the GLOBE Model proposed rule regarding how the current geographic selection facilitates a representative comparison group.

*Response:* CMS thanks the commenters for their feedback. With respect to the suggestion to apply the GLOBE Model to 100 percent of Medicare beneficiaries, CMS believes that a national scope is not necessary to test the concept of the model. As provided in section 1115A(a)(5) of the Act, the Secretary may elect to limit testing of a model to certain geographic areas: the statute expressly contemplates limited geographic testing. The selection of geographic areas representing 25 percent of OM beneficiaries is consistent with this statutory authority and is designed to enable a rigorous evaluation of the model's effects.

A critical element of the GLOBE Model's evaluation design is the creation of a comparison group—beneficiaries who are not selected into the model—against which the outcomes of GLOBE Model beneficiaries can be assessed. If the model were implemented across 100 percent of OM beneficiaries, there would be no sufficiently sized comparison group of beneficiaries not selected into the model test, which would make it harder for CMS to reliably attribute observed changes in spending or quality to the model's intervention. Consistent with section 1115A of the Act, one goal of this model is to test if Medicare spending can be reduced while preserving or enhancing beneficiary quality of care. Influencing international pricing behavior and foreign markets is not the objective of the GLOBE Model and will not be assessed as part of the model.

*Final Decision:* After consideration of the public comments received and are discussed here and in section II.F. of this final rule regarding operational complexity, CMS is finalizing the provisions at § 513.110 with slight modifications. In § 513.110(a), CMS proposed to randomly select GLOBE Model geographic areas no later than 60 calendar days prior to the start of the model performance period. In response to comments, CMS is finalizing that CMS will randomly select GLOBE Model geographic areas no later than 90 calendar days prior to the start of the model performance period, April 1, 2027. In § 513.110(c), CMS proposed that no later than 30 calendar days in advance of the model start, CMS would provide a table on the GLOBE Model website that lists the GLOBE Model geographic areas by ZIP Code. In response to comments, CMS is finalizing that CMS will provide a table on the GLOBE Model website that lists the GLOBE Model geographic areas no later than 75 calendar days prior to the start of the model performance period, April 1, 2027.

*E. Model Participants*

1. Mandatory Participation of Manufacturers of GLOBE Model Drugs

In section II.E.1. of the GLOBE Model proposed rule (90 FR 60262), we proposed that model participation would be mandatory for all manufacturers of GLOBE Model drugs (as described in section II.B. of this final rule) that are furnished to a GLOBE Model beneficiary during the GLOBE Model performance period. We proposed 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 proposed that all manufacturers of a GLOBE Model drug would be required to participate in the GLOBE Model.

We proposed 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 § 513.100. We proposed 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 § 513.100(a), we proposed 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 exempt 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 the GLOBE Model proposed rule. 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 be too broad, diluting CMS's ability to rigorously evaluate the model's impact on costs and quality. Having considered these alternatives, CMS did not propose such exclusions. We also sought 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 sought 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 § 513.130). We also sought 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.

The following is a summary of the comments received and our responses. Comments received regarding manufacturers with existing sales or licensing agreements with other entities outside of the U.S are addressed in section II.G. of this final rule.

*Comment:* Several commenters recommended that CMS make the GLOBE Model voluntary rather than mandatory. These commenters stated that mandatory participation may create operational strain, undermine evaluation integrity, and introduce unintended market disruptions, particularly for providers and supply chain stakeholders.

*Response:* We disagree with the commenters. We believe mandatory participation is necessary to ensure sufficient sample sizes and reduce known areas of bias to increase the rigor and strength of the evaluation of the GLOBE Model's effects on program expenditures, access, and quality of care.

First, we believe that despite the potential for the GLOBE Model to lower beneficiaries' financial liability and reduce financial barriers to access, which could increase utilization of GLOBE Model drugs, manufacturers would likely not volunteer to participate, given that the model's rebate mechanism reduces their effective reimbursement. As such, we believe the GLOBE Model would have few voluntary participants. Mandatory participation also allows for a broader set of manufacturers with varying characteristics to be included in the model and limits selection bias inherent to any model in which participants elect whether they will participate. A voluntary model would therefore risk selection bias, may lead to no model participants, and therefore, undermine the integrity of the evaluation, limiting CMS's ability to draw meaningful conclusions about the model's impact on program expenditures and beneficiary quality of care.

Second, mandatory participation enhances the generalizability of model results, as participants are more broadly representative of all entity types that could be affected by the model, allowing CMS to observe the experiences of a diverse range of manufacturers of drugs with diverse characteristic types.

Third, CMS disagrees with commenters that mandatory participation would undermine evaluation integrity. Mandatory participation supports a more rigorous evaluation design by reducing self-selection and enabling more reliable comparisons across model and non-model populations. As described in section II.P., CMS has designed the model to support causal inference through geographic randomization and the use of comparison groups, which further strengthens evaluation integrity.

With respect to commenters' concerns regarding operational strain and market disruptions, CMS plans to monitor utilization, access, and quality of care throughout the model test period for unintended impacts on providers, supply chain stakeholders, and beneficiaries, as described in sections II.J., II.L., and II.P.

*Comment:* A couple of commenters supported CMS's proposal of mandatory manufacturer participation, stating that a mandatory approach is necessary to ensure consistent application of the model and enable meaningful evaluation.

*Response:* We thank the commenters for their support. We agree that a mandatory approach is necessary to ensure consistent application of the model and to support a robust and unbiased evaluation of its effects on expenditures, access, and quality of care, consistent with CMS's authority under section 1115A of the Act.

*Comment:* Many commenters expressed concern that mandatory participation would disproportionately affect small and mid-size biotechnology companies with limited product portfolios. Commenters stated that these companies may face financial constraints that limit their ability to absorb pricing changes and that such pricing changes could reduce investment in research and development. Several commenters also recommended that CMS consider exemptions or alternative thresholds for smaller manufacturers, including adjustments based on company size, revenue exposure, or stage of development.

Commenters recommended several potential exemptions, including exempting from the model drug manufactured by companies with fewer than 500 employees and no prior commercialized products from the $100 million Medicare Part B threshold; considering the length of time elapsed since a manufacturer's first FDA product approval as a criterion for defining a small manufacturer; excluding manufacturers whose Medicare Part B prescription drug spending constitutes less than 1.0 percent of total Medicare Part B prescription drug spending; and raising the $100 million Medicare Part B allowed charges threshold for drugs as an alternative means of limiting the model's applicability to small manufacturers.

*Response:* CMS recognizes commenters' concerns that mandatory participation could disproportionately affect small and mid-size biotechnology companies, including potential impacts on financial capacity and research and development investments. The GLOBE Model drug inclusion and exclusion criteria finalized in this final rule and codified at § 513.130, focus the model test on drugs and biological products with high program expenditures and target areas with the greatest opportunity to reduce Medicare spending, while excluding categories of products for which participation could confound the model test. Additionally, the GLOBE Model contains exclusions for orphan-only drugs,[154] plasma-derived products as set forth in 42 CFR 427.400, and drugs listed by FDA as Approved Cellular and Gene Therapy products out of an abundance of caution to prevent commenters' concerns on orphan-only drugs, CGTs, and plasma-derived products from manifesting for Medicare beneficiaries who may rely upon such drugs. These criteria are intended to appropriately scope the model and limit participation to drugs that meaningfully contribute to Medicare Part B spending, rather than targeting manufacturers based on company size, revenue exposure, or stage of development.

However, CMS considered the commenters' concerns in developing the final design of the model and in the regulatory impact analysis (RIA) included in this final rule. As discussed in section IV. of the final rule, CMS assessed the potential impact of the GLOBE Model on small entities and determined that the final rule will not have a significant economic impact on a substantial number of small entities by the GLOBE Model largely due to the final drug exclusions identified in § 513.130(c). Additionally, we note that the $100 million spending threshold is a high bar that is unlikely to be met by drugs from small or mid-sized manufacturers unless those drugs have achieved significant market penetration. As previously mentioned, an internal analysis found that a lower spending threshold of $50 million would increase the number of small manufacturer participants to 9. We refer the

[154] Orphan-only drug means a drug that is designated as a drug for only one or more rare diseases or conditions under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) and for which the only approved indication (or indications) is for one or more such rare diseases or conditions. Refer to § 513.130(c) for the GLOBE Model drug exclusion criteria.

commenters to the introduction of section II. and section II.B. of this final rule for our additional responses related to investments in research and development where we discuss in detail the reasons we do not believe the model will directly and materially affect investments and innovation.

CMS also considered, but declines to adopt, the alternative approaches suggested by commenters to exempt or tailor participation for small or mid-size manufacturers, including thresholds based on number of employees, time since first FDA approval, share of Medicare Part B spending, increased spending thresholds for included drugs, the number of approved products in a manufacturer's portfolio, or portfolio concentration. We note that we are excluding orphan-only drug drugs which is a drug-specific exclusion, not manufacturer-specific. Given that this model is not expected to have a significant impact on a substantial number of small entities, CMS does not believe additional exemptions are necessary or appropriate. Specifically, our RIA shows that this final rule will impact one small firm, with that impact estimated to represent 2.3 percent or less of that firm's annual U.S. revenue. CMS believes that applying the model's criteria uniformly is necessary to support a comprehensive evaluation of its effects on expenditures, access, and quality of care; adjusting participation for small or mid-sized manufacturers would limit CMS's ability to evaluate the effects of an alternative rebate amount calculation across a diverse and generalizable set of manufacturers.

*Final Decision:* After consideration of the public comments received, CMS is finalizing the provisions at § 513.100(a) with minor technical modification for clarity, which establishes the requirement for participation by all manufacturers of GLOBE Model drugs (as described in section II.B. of this final rule) that are furnished to a GLOBE Model beneficiary during the GLOBE Model performance period.

2. Model Participation Requirements

As discussed in section II.E.2. of the GLOBE Model proposed rule (90 FR 60263), in § 513.100, we proposed to codify GLOBE Model participant requirements during the GLOBE Model test period. During the GLOBE Model test period described in proposed § 513.100(b), we proposed that GLOBE Model participants must—

- Adhere to the proposed GLOBE Model rebate payment instructions as proposed in § 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 § 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 § 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 (which as shown in Table 1 in the GLOBE Model proposed rule (90 FR 60253) would align with the applicable calendar quarter for the proposed model start (fourth quarter of 2026)), we proposed that such GLOBE Model participants would be required to adhere to the requirements set forth in proposed § 513.620 and the GLOBE Model data agreement prior to the start of performance year 1.

Based on comments received and discussed in section II.A. of this final rule, CMS is modifying the model start date to be January 1, 2027 as specified in § 513.1(c). The initial reporting quarter for voluntary manufacturer-submitted international drug net pricing data begins on January 1, 2027, for the applicable ASP calendar quarter beginning October 1, 2026, which aligns with the first quarter of performance year 1 that begins on April 1, 2027.

We sought comments on our proposal for model participation requirements from potential GLOBE Model participants.

We refer readers to section II.G.6. of this final 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 proposed that the manufacturer must adhere to the requirements set forth in proposed § 513.610 and in the proposed GLOBE Model data agreement as described in proposed § 513.620.

We did not receive any comments on the proposed model participation requirements and are therefore finalizing § 513.100(b) and (c) with conforming modifications to align with the finalized model test period as set forth in § 513.1(c).

3. Standard Provisions

In section II.E.3. of the GLOBE Model proposed rule (90 FR 60263), we proposed that the Standard Provisions for CMS Innovation Center Models, originally established in 42 CFR part 512, subpart A and applicable to certain CMS 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 CMS Innovation Center models. Therefore, rather than applying the Standard Provisions, we proposed 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 proposed 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 proposed 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 proposed at § 513.100(d)(2) record access requirements to ensure that manufacturers maintain and give 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 proposed at § 513.100(d)(3) a 6-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 proposed 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 sought comment on our proposed requirements for audit, record access, and record retention, and model termination parameters for GLOBE Model manufacturers.

The following is a summary of the comments received and our responses.

*Comment:* A commenter stated that the GLOBE Model-specific requirements are vague and appear duplicative of standard CMS Innovation Center provisions and requested clarification on why GLOBE-specific requirements are needed to test and evaluate the model. Specifically, the commenter requested clarification on how the proposal at § 513.100(d)(1) in the GLOBE Model proposed rule (90 FR 60244 through 60336) differs from the general CMS Innovation Center model requirements at 42 CFR part 512(a). Additionally, the commenter requested clarification on § 513.100(d)(3) in the GLOBE Model proposed rule, stating that it is unclear which date CMS intends to use as the date of the ''last GLOBE model rebate payment'' that would substitute for the ''last payment determination'' under the model—for example, whether CMS intends to use the date of the Preliminary Rebate Report or Reconciliation Rebate Report.

*Response:* While the commenter referenced 42 CFR part 512(a), we interpret the comment to refer to 42 CFR 512 subpart A. With respect to the commenter's question about why GLOBE Model specific requirements are needed, while the general CMS Innovation Center model provisions at 42 CFR part 512 establish baseline requirements applicable to all mandatory CMS Innovation Center models, the GLOBE Model's unique design features—including its international reference pricing mechanism, manufacturer rebate structure, and geographic selection methodology—require model-specific administrative and operational provisions that are not addressed by the general framework at 42 CFR part 512. The provisions at § 513.100(d) are not intended to duplicate the general CMS Innovation Center requirements; rather, they establish the GLOBE Model-specific requirements necessary to support the administration and evaluation of the model.

With respect to § 513.100(d)(3), CMS intends to use the last issued Reconciliation Rebate Report as the reference point for the last GLOBE model rebate payment. The Reconciliation Rebate Report represents the final, settled rebate obligation after all adjustments have been made, and therefore provides the most definitive and administratively appropriate reference date for this purpose.

*Final Decision:* After consideration of the public comments received, CMS is finalizing the provisions at § 513.100(d) with minor technical modifications. In § 513.100(d)(2), CMS is also changing ''manufacturer'' to ''Model participant'' to align terminology. CMS also clarifies that, for purposes of § 513.100(d)(3), CMS will use the last issued Reconciliation Rebate Report for the last applicable calendar quarter of the performance period as the reference point for the last GLOBE model rebate payment.

*F. GLOBE Model Test Design and Geographic Areas*

In section II.F. of the GLOBE Model proposed rule (90 FR 60244 through 60336), we proposed the model test design, unit of analysis, and method for identification of GLOBE Model geographic areas.

1. Model Test Design

In § 513.110, for the model test design, we proposed a randomized design in which the GLOBE Model geographic reach would be determined by selection of geographic areas where approximately 25 percent of OM Part B beneficiaries have an address of record within CMS's MBD (as determined by CMS as set forth in § 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 proposed 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 OM Part B 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.

The following is a summary of the comments received and our responses.

*Comment:* A commenter expressed support for the GLOBE Model's methodology to test a new payment system for brand-name pharmaceutical products furnished to randomly selected 25 percent of Medicare beneficiaries with Medicare Part B coverage. Commenters raised concerns that the operational complexity of the GLOBE Model's geographic selection approach would result in an administrative burden of parallel billing systems for beneficiaries inside and outside the model, provider unfamiliarity with cost-sharing differences, and the need for manufacturers and patient groups to project revenue impacts. Commenters also said that the timeline for disclosing the selected model regions was too short. We received additional comments on the proposed model test design and have responded to them in section II.D. of this final rule.

*Response:* We thank the commenter for their support of GLOBE Model's methodology. Responses to comments on the proposed model test design can be found in section II.D. of the final rule. In response to those comments, CMS agrees to modify the policy to publicly release the selected beneficiary geographic areas no later than 75 calendar days prior to the start of the model performance period.

*Final Decision:* After consideration of the public comments received here and in section II.D. of this final rule regarding operational complexity, CMS is finalizing § 513.110 with slight modification to align with the finalized model start on January 1, 2027 and model performance period start on April 1, 2027. In § 513.110(a), CMS proposed to randomly select GLOBE Model geographic areas no later than 60 calendar days prior to the start of the model performance period. In response

to comments, CMS will randomly select GLOBE Model geographic areas no later than 90 calendar days prior to the start of the model performance period, April 1, 2027. In § 513.110(c), CMS proposed that no later than 30 calendar days in advance of the model start, CMS provides a table on the GLOBE Model website that lists the GLOBE Model geographic areas by ZIP code. In response to comments, CMS will provide a table on the GLOBE Model website that lists the GLOBE Model geographic areas no later than 75 calendar days prior to the start of the model performance period, April 1, 2027. CMS is finalizing § 513.110(b) as proposed, without modification.

2. Unit of Analysis

In developing the proposed GLOBE Model, CMS determined that conducting the proposed GLOBE Model test in the population of OM beneficiaries who may receive Part B rebatable drugs that are included in the model (as discussed in sections II.B. and II.C. of this final rule) would provide the best means for testing an innovative payment model using the alternative rebate amount 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 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.

We received comments on the proposed model test design including the unit of analysis and the defined population, that is, Medicare beneficiaries who receive a Part B rebatable drug, and have responded to them in section II.C. of the final rule.

*Final Decision:* After consideration of the public comments received, CMS is finalizing § 513.110 with modifications, as described in section II.C. of the final rule.

3. Method for Identification of GLOBE Model Geographic Areas

a. Geographic Unit of Randomization

As discussed in the GLOBE Model proposed rule (90 FR 60264), 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's review of existing defined geographic units that are suitable for statistical purposes, CMS, after consideration of alternatives, identified that ZCTAs would be an appropriate geographic unit for a limited scope model and for the proposed GLOBE Model specifically. ZCTAs are approximate area representations of U.S. Postal Service 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 proposed to identify the GLOBE Model geographic areas through a simple random selection of 25 percent of all ZCTAs in the U.S., excluding the U.S. territories. Specifically, in § 513.110(a), we proposed 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, we proposed that such new ZIP Code would not be reassigned to a GLOBE Model geographic area.

The following is a summary of the comments received and our responses.

*Comment:* A commenter stated their belief that CMS should not randomize beneficiaries into the GLOBE Model unless CMS can definitively assert that there will be no change in access or outcomes, or unless a beneficiary knowingly and voluntarily consents to their assignment. The commenter also stated that it is unclear if beneficiaries will be notified of their assignment and provided with a clear explanation of the model.

*Response:* We thank the commenter for their feedback. CMS does not anticipate any harm to beneficiaries as a result of their participation in the GLOBE Model. On the contrary, CMS expects that beneficiaries will benefit directly from participation through reduced coinsurance obligations. Additionally, CMS has established monitoring mechanisms to identify and address any access constraints that may arise in connection with the model. As described in section II.L. of this final rule, CMS will conduct ongoing monitoring throughout the GLOBE Model test period and will take appropriate action if monitoring identifies any adverse impacts on beneficiary access or quality of care.

To promote transparency and beneficiary awareness, CMS will publish technical documents—including Frequently Asked Questions (FAQs) and factsheets—on the GLOBE Model website that will be publicly accessible to beneficiaries, providers, and other interested parties. These materials will describe how beneficiaries may potentially benefit from reduced coinsurance if they reside in a selected GLOBE Model geographic area and utilize a GLOBE Model drug.

*Comment:* A few commenters raised concerns regarding the operational complexity associated with the GLOBE Model's approach to geographic selection. Commenters stated that CMS's proposed timeline for disclosing the selected beneficiary ZIP Codes is too short. Commenters raised practical concerns about beneficiaries who receive care with providers who are unfamiliar with the cost-sharing differences for beneficiaries inside and outside of the model. Specifically, a commenter was concerned about potential confusion and administrative burden, citing the example of providers potentially having to reconcile or refund beneficiaries for the difference between the Medicare-allowed amount and the cost-sharing provided by the GLOBE Model.

Commenters proposed that releasing the ZIP Codes earlier would provide manufacturers, providers and patient groups sufficient time to establish systems and better prepare for the model. In particular, commenters stated that earlier disclosure would allow providers to address the administrative burden of having parallel billing and reimbursement systems for beneficiaries selected into the model and those who are not. A commenter believed that earlier disclosure would allow companies additional time to project the

impact on their revenues and educate patient groups. Additionally, commenters stated that CMS should collaborate with plans, PBMs, and plan sponsors to ensure a predictable implementation. A commenter also asked whether the ZCTA files will be version-controlled and machine-readable.

*Response:* We thank the commenters for their feedback regarding requests for earlier disclosure of beneficiary ZIP codes that would be in the GLOBE Model. As described in section II.D. and section II.F of the final rule, CMS agrees to modify the policy to publicly release the selected beneficiary ZIP Codes earlier than originally proposed. CMS will publicly release the ZCTA files on the CMS website in a machine-readable format. Revised data, if any, will be distributed via incremental version updates. Regarding the request for coordination with plans, PBMs, and plan sponsors, CMS does not believe such coordination is necessary, as the GLOBE Model pertains exclusively to Part B drugs and does not impose requirements on plans or PBMs.

*Final Decision:* After consideration of the public comments received and as noted in section II.D. and section II.F. of the final rule, CMS is finalizing the proposed GLOBE Model Test Design and Geographic Areas at § 513.110 with slight modification. That is CMS is modifying § 513.110(a) to require that CMS randomly select the ZCTAs no later than 90 calendar days prior to the start of the model performance period, April 1, 2027, and CMS will provide a table on the GLOBE Model website that lists the GLOBE Model geographic areas no later than 75 calendar days prior to the start of the model performance period. CMS is finalizing § 513.110(b) as proposed, without modification.

b. Alternatives Considered

In the GLOBE Model proposed rule (90 FR 60264), we stated that 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 MAC regions were considered to reduce operational complexity but also were determined to be too large and heterogeneous.[155]

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's 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 OM Part B beneficiaries in the model eligible beneficiary cohort instead of our proposal to test the model in geographic areas with approximately 25 percent of OM Part B beneficiaries. We also considered an approach of initially testing the model in geographic areas with approximately 25 percent of OM Part B beneficiaries and then, after initial monitoring observations were assessed, increasing the model beneficiary cohort to include up to approximately 50 percent of OM Part B 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 noted 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 OM 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 welcomed 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 welcomed comment on our proposal to test the model with geographic areas that would include approximately 25 percent of OM Part B 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.

The following is a summary of the comments received and our responses.

*Comment:* A commenter stated that the model's geographic assignment does not align with how drugs are distributed, inventoried, or financially reconciled. The commenter requested clarification for how the GLOBE Model accounts for the fact that drug acquisition and distribution costs do not vary based on beneficiary residence.

*Response:* We thank the commenter for their feedback. CMS recognizes that distribution costs affect pharmacies, hospitals, and other dispensing entities whose patient population may span multiple ZCTAs. CMS maintains that the selection of geographies based on beneficiary residence will be sufficient to generate generalizable information and capture a representative variation in distribution costs faced by various dispensing entities. While CMS acknowledges that drug acquisition and distribution costs are largely determined at the dispensing entity level and are not directly tied to beneficiary residence, the geographic assignment is intended to support the evaluation and randomization design of the model test rather than to reflect or adjust for individual dispensing entity cost structures. Dispensing entities will not be required to alter their existing drug acquisition or distribution practices as a result of geographic assignment under the GLOBE Model.

We received no comments on the exclusion of U.S. territories. We received a few comments on the scale of inclusion of OM beneficiaries, addressed in section II.D. of the final rule.

*Final Decision:* After consideration of the public comments received for alternative considerations, CMS is finalizing § 513.110(a) as proposed with modifications as discussed in section II.F.3.a. of this final rule.

[155] Centers for Medicare & Medicaid Services. What's a MAC. Available at: *https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs/whats-mac.*

*G. Model Payment Test for GLOBE Model Drugs*

In accordance with section 1847A(i) of the Act as codified in 42 CFR part 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 proposed to test an alternative rebate amount 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 proposed to base the alternative calculation on a per unit GLOBE Model benchmark that is described in section II.G.2. of this final rule. To test two methods for establishing a per unit GLOBE Model benchmark using different data sources, CMS proposed that the per unit GLOBE Model benchmark for a GLOBE Model drug would be determined—subject to available information as determined by CMS, as described in section II.G.1. of this final rule—based on the greater of: (1) a per unit Method I GLOBE Model benchmark that reflects the lowest country-level price among a set of reference countries,[156] after applying an economic adjustment, as discussed in section II.G.2.a. of this final rule; or (2) 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, after applying an economic adjustment, as discussed in section II.G.2.b. of this final rule.[157] As discussed in section II.G.1.e. of the GLOBE Model proposed rule (90 FR 60270 through 60273), we proposed 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, as discussed in section II.G.3.a. and II.G.3.b. of the GLOBE Model proposed rule (90 FR 60280 through 60282), we proposed to apply an applicable threshold percentage and an 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 the GLOBE Model proposed rule (90 FR 60282 through 60283), we proposed that the per unit GLOBE Model rebate amount for an applicable calendar quarter would reflect the result of the alternative rebate amount calculation. That is, for a GLOBE Model drug, for an applicable calendar quarter during the model performance period, we proposed 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 § 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). As discussed in section II.G.4.b. of the GLOBE Model proposed rule (90 FR 60283), we proposed a methodology for identifying the included billing units of a GLOBE Model drug in the total GLOBE Model rebate amount calculation. As discussed in section II.G.4.c. of the GLOBE Model proposed rule (90 FR 60283 through 60284), we proposed 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 § 513.510(a), and the total number of GLOBE Model billing units, as identified by CMS as set forth in § 513.520. To facilitate the model test, we proposed 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 § 513.510(b), and the total number of GLOBE Model billing units, as identified by CMS as set forth in § 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 § 513.510(b) and discussed in section II.G.4.c. of the GLOBE Model 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 § 513.520, CMS proposed 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 OM Part B made separate payment. We also proposed, as discussed in section II.G.4.d. of the GLOBE Model proposed rule (90 FR 60286), 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 the GLOBE Model proposed rule (90 FR 60299), we presented 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, we proposed that CMS would delay Medicare Part B Drug Inflation Rebate Program invoicing for all manufacturers by up to 2 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, we proposed that CMS would use a separate invoicing process that would run approximately a month after the Medicare Part B Drug Inflation

[156] Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug pricing information in the 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.

[157] The economic adjustment would be based on differences in gross domestic product and purchasing power between the U.S. and reference countries.

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 sought comment on these alternative approaches for reporting, invoicing, and reconciliation and stated our intent to adopt only one approach for the model. We also stated CMS's intent 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 proposed 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 § 513.740, we proposed 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 identified the need to adjust the timing for providing reports and proposed using the CMS Innovation Center's waiver authority to do so as discussed in section II.G.8. of the GLOBE Model proposed rule and this final rule.

We also proposed 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.

We also proposed that the GLOBE Model would 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 final rule). As discussed in section II.G.7. of the GLOBE Model proposed rule (90 FR 60298 through 60299), we proposed 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 an applicable calendar quarter, we proposed 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 OM Part B 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 OM Part B 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 OM Part B 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 GLOBE Model monitoring and evaluation, we refer readers to sections II.L. and II.P. of this final rule, respectively.

1. International Drug Pricing Information Data Sources

In section II.G.1. of the GLOBE Model proposed rule (90 FR 60266), we discuss the proposed international drug pricing information data sources and the international drug pricing information that CMS proposed 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 final rule). We also discussed 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 acceptance criteria, be used by CMS to identify the per unit Method II GLOBE Model benchmark (as described in section II.G.2.b. of this final rule). We proposed 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.1.e. of this final rule, we discuss the finalized set of reference countries for the GLOBE Model (at § 513.310(b)) 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 final rule) and the per unit Method II GLOBE Model benchmark (as described in section II.G.2.b. of this final rule).

a. Existing Data Sources for International Drug Pricing Information

In section II.G.1.a. of the GLOBE Model proposed rule (90 FR 60267), we proposed to identify the per unit Method I GLOBE Model benchmark for a GLOBE Model drug using one or more existing 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) 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 proposed 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 final rule). Within available data sources, pricing information (such as sales and list prices) may 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 pricing information 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 final rule), particularly because we proposed 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.

As stated in the GLOBE Model proposed rule (90 FR 60267), we 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 information 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 MIDAS® [158] 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 MIDAS [159] 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,[160] 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.[161] IQVIA MIDAS is updated monthly and retains extensive historical data for 33 countries.

Another potential data source we assessed is GlobalData Pharmaceutical Prices (POLI) [162] 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,[163] includes pricing data for more than 100 countries, as well as tools to compare international drug pricing information (specifically, pricing across countries), and is another potential data source.

These data sources, if available, would likely provide adequate information to inform CMS's identification of a Method I GLOBE Model benchmark for the vast majority of GLOBE Model drugs (as discussed in section II.G.2.a. of this final 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 pose difficulties for CMS to routinely identify a Method I GLOBE Model benchmark for a broad set of proposed GLOBE Model drugs.

In § 513.310(c)(1), we proposed that CMS would use one or more existing data sources for international drug pricing information available to CMS to identify the per unit Method I GLOBE Model benchmark for a GLOBE Model drug. Specifically, we proposed 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. In § 513.310(c)(1)(ii), we proposed that 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 names and a standard method for identifying dosage form and 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.[164] We also proposed that the data source must use a standardized method for identifying drug names, dosage forms, and route of administration because the process that CMS proposed 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 codes that are associated with GLOBE Model drugs. We also proposed that the data source must use a standardized method for identifying strength or concentration

[158] The statements, findings, conclusions, views, and opinions contained and expressed in the GLOBE Model 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.

[159] IQVIA MIDAS Overview. Available at: *https://www.iqvia.com/solutions/commercialization/data-and-information-management/midas.*

[160] 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.*

[161] 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.

[162] GlobalData. Data Lake-Pharmaceutical Prices (POLI) Available at: *https://marketaccess.globaldata.com/product-solutions/data-lake-pharmaceutical-prices-poli/.*

[163] NAVLIN by Eversana. Available at: *https://www.navlin.com/products/navlin-price-access-data.*

[164] 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.*

and that they are expressed in internationally recognized measures such as milligrams or milliliters because this could be used to identify the quantity of drug and the billing units. Further, we proposed that the one or more data sources that CMS would use would contain international drug pricing information with corresponding volume data (for example, number of items, packages, or units sold) or data sources with only pricing information, where applicable. We proposed that the pricing information in the data sources would include sales data or pricing 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 proposed that 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 drugs, or reference products), and U.S. non-originator drugs and international non-originator drugs [165] (such as generics, biosimilars, biocomparable products, reference product equivalents, or off-patent products) and, at a minimum, distinguishes international generics and international biosimilar biological products. In addition, we proposed that the one or more data sources CMS would use must have mechanisms in place to maintain, update, validate, and correct, if necessary, the international drug pricing information in a data source on at least a quarterly basis. Further, we proposed that the data sources CMS 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. We stated that, based on CMS assessment of the available data sources, the current lag may be up to 90 days and our belief that a 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.

As discussed in section II.G.1.b. of this final rule, we also proposed that CMS would use a hierarchy to select the data source as set forth in § 513.310(c)(2) and (3). Whenever possible, to identify the per unit Method I GLOBE Model benchmark for a GLOBE Model drug, we proposed that CMS would use international drug pricing information from two calendar quarters prior to the first applicable calendar quarter for which the drug is a GLOBE Model drug and the 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 (as further discussed in section II.G.2.a. of this final rule). In the GLOBE Model proposed rule (90 FR 60268), we noted that, as an example, for GLOBE Model drugs to be included on the GLOBE Model Drug HCPCS Codes List for the first calendar quarter of performance year 1 (that is, the calendar quarter beginning October 1, 2026, as proposed in § 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 I GLOBE Model benchmark from January 1, 2024 to December 31, 2024, we proposed that CMS would 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 for which the drug is a GLOBE Model drug and the GLOBE Model rebate amount would apply are not used, we proposed that CMS would use international drug pricing information from the most recent ASP calendar quarter for which data are available.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters expressed concerns about CMS's use of international drug pricing information from existing data sources to identify the per unit Method I GLOBE Model benchmark. Commenters stated that such information may not be representative of actual net prices in reference countries, and this approach may create opportunities for manufacturers to manipulate data, resulting in unreliable international drug pricing information and diminished confidence in potential model impacts.

*Response:* We thank the commenters for sharing their concerns about the use of existing data sources and potential for strategic behavior by manufacturers that could result in unreliable international drug pricing information. These are issues that CMS carefully considered and sought to address in the design of the GLOBE Model.

In proposing to test the use of existing data sources for international drug pricing information to establish a per unit Method I benchmark (90 FR 60267 through 60268), CMS acknowledged that, within available data sources, pricing information may represent actual or calculated prices paid to the manufacturer by wholesalers and other distributors, such as retail prices, prices for other distribution channels, ex-manufacturer prices, list prices, or a combination thereof, which may be available as sales data, and may include corresponding volume data (that is, for example, the number of units, items, or packages sold). We noted that an existing data source may not incorporate or reflect all discounts, rebates, and other price concessions into its drug pricing information. CMS further noted that existing data sources may use proprietary data collection, harmonization, and projection methodologies. Accordingly, CMS acknowledged that country-level prices and a per unit Method I GLOBE Model benchmark may not represent actual net prices realized by manufacturers, and that confidential manufacturer rebates would not likely be reflected in available data resources—meaning that existing sources for international drug pricing information may overstate actual prices realized by manufacturers.

As set forth in § 513.310(c)(1), CMS would use existing data sources that meet specified requirements for content, standardization, and maintenance. CMS believes these requirements establish a

[165] Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug pricing information in the 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.

sufficient nexus between the pricing information in existing data sources and actual prices within a country for purposes of identifying an estimate of drug pricing. CMS further believes that applying additional adjustments to such country-level pricing data to inform the identification of a per unit Method I GLOBE Model benchmark is sufficient for purposes of the GLOBE Model, as the aim is to identify a reasonable estimate of international drug pricing to test use of existing data sources as the input for an alternative rebate amount calculation—particularly when voluntary manufacturer-submitted international drug net pricing data is not available.

CMS considered possible avenues for manipulation of pricing information and proposed the following model design elements to address the risk that a Method I benchmark could be based on unreliable international drug pricing information. The Method I benchmark would be based on international drug pricing information from existing data sources available to CMS at least 60 business days prior to the first applicable calendar quarter for which the drug is a GLOBE Model drug, when such information is available to CMS. CMS would apply a hierarchy as specified in § 513.310(c)(2) and (3) to identify the applicable data source and pricing information, including the possibility of using historical data when current international drug pricing information for the applicable ASP calendar quarter is not available. The data source would 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. In addition, the data source would be maintained by an organization that seeks to limit the data lag to no more than 90 days from the end of the calendar quarter for which drug pricing information is compiled to the time that updates are made available to users.

Further, in response to comments received, CMS is finalizing in this final rule that, for a GLOBE Model drug, for applicable calendar quarters when CMS has not yet identified a per unit Method I GLOBE Model benchmark, CMS would reassess quarterly the availability of international drug pricing information from existing data sources, as available.

CMS believes that these design elements mitigate the potential for manufacturers to limit the availability of international drug pricing information in existing data sources during the GLOBE Model performance period and minimize the possibility of CMS having no international drug pricing information to calculate the per unit Method I GLOBE Model benchmark. However, during the GLOBE Model performance period, CMS will monitor available international drug pricing information to assess whether additional safeguards may be appropriate and would address any such needs through model oversight activities.

To clarify the types of international drug pricing information that would be used by CMS from available existing data sources, we are making non-substantive modifications to § 513.310(c) to clarify and streamline the description of the international drug pricing information data source requirements. In § 513.310(c)(1)(i), we added the words ''and the U.S.'' to clarify the data source that CMS would use to calculate average U.S. price as set forth in § 513.410(d). In § 513.310(c)(1)(ii), we are clarifying that the data source must use a standardized method across countries within that data source for identifying the requirements listed in subparagraphs § 513.310(c)(1)(ii)(A) through (D), as determined by CMS, and to remove repetitious wording within each subparagraph. In § 513.310(c)(1)(ii)(D), we simplified the wording to clarify that the data source must use a standardized method for identifying the applicable regulatory approval pathway that at a minimum distinguishes international originator drugs, international generic drugs, international biosimilar biological products, and U.S. originator drugs. With respect to the international drug pricing information that the data source must contain, in § 513.310(c)(1)(iii), we are aligning this provision with the finalized data sources hierarchy in § 513.310(c)(2). In addition, in § 513.310(c)(1), we removed the words ''HCPCS Level II'' and inserted ''billing and payment'' for consistency.

*Comment:* A few commenters stated that it would be costly and burdensome for manufacturers to obtain and use existing data sources, and that doing so would be necessary to judge how CMS determined the Method I benchmark.

*Response:* The existing data sources we discussed in section II.G.1.a. of the GLOBE Model proposed rule (90 FR 60267) are widely used by interested parties within the biopharmaceutical industry, domestic and foreign governments and commercial organizations, as well as the health technology assessment and drug pricing research communities. As such, it may be likely that manufacturers of GLOBE Model drugs have access to and familiarity with these existing data sources, and that any financial burden associated with access to such data source related to participation in the GLOBE Model would be minimal.

*Comment:* A couple of commenters stated that CMS should not use international drug pricing information for international analogs that are international originator drugs for a reference country where international non-originator drugs are also sold because the pricing for such international originator drugs would reflect generic or biosimilar biological product competition within such reference country and the U.S. manufacturer should not be held responsible for rebates because the market in such reference country does not drive the U.S. manufacturer's price, which is separate from the international prices set for such a drug. Commenters expressed concerns about how such situation would be inconsistent with the exclusion of U.S. originator drugs and biological products that have generic or biosimilar biological product competition in the U.S. and would impact the GLOBE Model evaluation.

*Response:* We appreciate the concerns raised by these commenters. We disagree that such situation would raise concerns for GLOBE Model implementation or evaluation. In section II.G.2.a. of the GLOBE Model proposed rule (90 FR 60276 through 60277), CMS describes the process to identify the per unit country-level price if there is an international drug pricing information data source for an applicable international analog. In § 513.600 of the GLOBE Model proposed rule, CMS proposed to define an applicable international analog to mean, ''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.'' This means that in identifying an international analog only international drug pricing information from originator products would be included. In considering this design element, CMS considered that individual countries differ in the regulatory processes and standards governing approval of drugs and biological products including the timing for when non-originator products may be approved. Hence, CMS proposed to apply data checks and exclude certain records that could inappropriately contribute to the calculation of country-

level prices that reflect pricing for originator products. We believe that using international drug pricing information based on originator products in combination with the data checks and exclusions that CMS proposed are an appropriate methodology to identify an estimate of the lowest international price among the set of economically comparable countries for purposes of the GLOBE Model, including cases where drug pricing information for a reference country may reflect market factors such as the availability of non-originator products, therapeutic alternatives, and parallel importation.

Further, we do not believe that our proposed approach is inconsistent with the exclusion of U.S. originator drugs and biological products that have generic or biosimilar biological product competition in the U.S. because focusing the model test on U.S. originator products is an entirely separate, independent component of the model design from the benchmark methodology for testing an alternative rebate amount calculation. Data shows that, among the proposed reference countries listed in Table 5 in the GLOBE Model proposed rule (90 FR 60272), U.S. originator prices are between 339 and 703 percent higher than international originator drugs prices or, on average, 422 percent higher in the U.S.[166] Prices diverge sharply abroad for a variety of reasons, including generic or biosimilar biological product competition with branded originator drugs in such countries. The benchmarking methodology in this model is agnostic about the reasons why the prices in reference countries are different. For this model, the use of foreign prices in the international benchmark serve as a proxy for the payment levels drug manufacturers are willing to accept for their products, from drug manufacturers' perspectives–despite what foreign payors are willing to spend or how lower foreign prices are developed. Thus, the use of an international benchmark, regardless of whether the reference countries have international generic or biosimilar biological product competition, in an alternative rebate amount calculation under the Medicare Part B Drug Inflation Rebate Program for GLOBE Model Drugs is intended to reduce program expenditures while preserving or enhancing quality of care for Medicare beneficiaries and is thus a valid exercise of the CMS Innovation Center's statutory authority.

Moreover, this is not inconsistent with the exclusion of U.S. originator drugs and biological products that have generic or biosimilar biological product competition in the U.S from GLOBE Model drugs because (1) the inclusion of these products among GLOBE Model drugs could raise difficulties in attributing program spending reductions or quality of care impacts to the model intervention's alternative rebate amount calculation as opposed to the impacts of generic or biosimilar biological product competition in the U.S. more generally and (2), as discussed in the background section of this final rule, single source drugs and sole source drugs are the significant drivers of spending in the Medicare Part B spending which is why the model has been scoped to certain single source drugs and sole source biological products. The use of the international benchmark in the alternative rebate amount calculation, regardless of whether there is international generic or biosimilar biological product competition in such reference countries, does not raise the data evaluation issues discussed in the prior sentence, nor is it relevant to the scoping of this model to address the significant drivers of spending in the Medicare Part B program.

Additionally, we disagree that manufacturers of international originator drugs do not have control of prices of their international originator drugs for a country where international non-originator drugs are also sold as such manufacturers adopt a variety of strategies to maintain revenue streams from their products in those countries.

*Comment:* Several commenters questioned the use of international drug pricing information from existing data sources when the U.S. manufacturer does not sell international analogs of its GLOBE Model drug outside of the U.S. Many commenters stated that out-licensing non-U.S. sales is a common business strategy for small and medium-sized manufacturers that is critical to financing commercialization of drugs that treat rare diseases, including orphan drugs, within the U.S.

*Response:* As finalized in this final rule, CMS is modifying the criteria for GLOBE Model drugs such that Part B rebatable drugs designated as a drug for one or more rare diseases or conditions under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) and for which the only approved indication (or indications) is for one or more such rare disease or conditions (orphan-only drugs) would be excluded from the model. We believe that the exclusion of orphan-only drugs would significantly reduce the number of GLOBE Model drugs where the U.S. manufacturer or its affiliate does not sell international analogs to the GLOBE Model drug in the set of reference countries set forth in § 513.310(b). Based on our analysis of potential GLOBE Model drugs for performance year 1, we observed the U.S. manufacturer and manufacturer in a reference country are most often the same entity or affiliated entities. We recognize that there could be cases where the U.S. manufacturer of a GLOBE Model drug is not affiliated with the entity (or entities) that sell international analogs to a GLOBE Model drug in reference countries. CMS also recognizes that out-licensing is an important business practice, not just for small, mid-size, innovation intensive, rare disease, and pre-revenue manufacturers, but for any drug manufacturer.

Our analysis suggests manufacturers, including manufacturers that out-license or co-license in certain reference countries, are likely to be able to voluntarily report some pricing information and would likely do so to avoid model rebates based on a Method I benchmark that would be identified by CMS using available international drug pricing information from existing data sources. As discussed in section II.G.1.d. of this final rule, we are finalizing in this final rule that manufacturers would have an option as part of the voluntary manufacturer submission framework that would allow manufacturers to pursue the voluntary submission of international drug net pricing data even when they are unable to obtain all required data elements for every international analog. Specifically, for any data elements of an international product that they are unable to obtain due to out-licensing or co-licensing, manufacturers would submit an explanation as part of the reasonable assumptions, which would be subject to CMS review. We believe this option would mitigate commenters' concerns about the use of international drug pricing information when the U.S. manufacturer does not sell international analogs to its GLOBE Model drug in the set of reference countries set forth in § 513.310(b) because we believe that manufacturers would pursue the option that best favors their situation.

*Comment:* A few commenters expressed concern that CMS would have significant discretion in identifying Method I benchmarks and needs to clarify the meaning of ''available information'' and the standards CMS would use to identify

[166] 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://pmc.ncbi.nlm.nih.gov/articles/PMC11147645/.*

international analogs. Commenters suggested that available information should be limited to only include international drug pricing information when certain similarities exist between the GLOBE Model drug and international analogs, such as an international analog has the same strength and approved indications as the GLOBE Model drug, was approved under a system with regulatory standards comparable to the FDA, is used in the same population, or the U.S. and foreign manufacturer are the same.

*Response:* We thank the commenter for sharing their perspective regarding how international analogs could be identified and the need to clarify the meaning of ''available information'' to ensure the integrity of the GLOBE Model test. In terms of the ''available information'' used to determine the per unit GLOBE Model benchmark as set forth in § 513.400(b), CMS clarifies that, for the Method I benchmark, ''available information'' would be the international drug pricing information contained in the selected data source for a GLOBE Model drug that is extracted by CMS as set forth in § 513.410(a)(1). For the Method II benchmark, ''available information'' would be the manufacturer-submitted international drug net pricing data for a GLOBE Model drug contained in an applicable submission as set forth in § 513.610(a). We note that the proposed regulatory text at § 513.410(a)(3)(ii)(A) contains the words ''the available information (such as package labeling)'' which CMS intends to mean information associated with the selected data source as well as publicly available information such as package labeling or other documentation related to product licensing within a country as stated in the GLOBE Model proposed rule (90 FR 60275). As such, CMS declines to further define ''available information'' in the GLOBE Model regulations and will use our best practices in determining available information for purposes of the GLOBE Model.

We do not believe that it would be appropriate or necessary to add limitations to the international drug analogs that would be included as suggested by these commenters because the GLOBE Model would be focused on single source drug and sole source biological products, would only include products that align with the scientific or nonproprietary naming included in the GLOBE Model drug's HCPCS code long descriptor, and would exclude data for international data analogs that are not identified as originator products.

We note that we proposed that CMS would consider strength data to identify the presentation level data that would be used and to identify cases where it would be appropriate to accept and convert data. As set forth in § 513.410(a)(2)(i), we proposed to apply data checks to extracted data and discard international drug pricing information for an international analog when the product information (for example, product strength or package size) is inconsistent with the GLOBE Model drug's HCPCS Level II code long descriptor or not verifiable (using available product information such as product labeling or product approval information for that product). We believe that these steps would be sufficient to avoid identifying international analogs that have a strength that would not be comparable to the GLOBE Model drug. Therefore, we decline to add additional criteria regarding strength to how CMS would identify international analogs using existing data sources.

We also considered whether additional criteria would be necessary to limit international analogs to those with the same approved indications or use in the same populations within the U.S. and a reference country. We believe that originator products would be subject to sufficient regulatory standards within the proposed reference countries, regardless of the approved indications and population. In addition, because Medicare Part B drug coverage for indications that are not included on the FDA-approved labeling is allowable in appropriate cases and to maintain incentives for manufacturers to sell innovative products in the U.S. (including those for different populations), we do not believe it would be prudent to add additional criteria regarding approved indications or specific populations to how CMS would identify international analogs using existing data sources.

We also do not believe it would be appropriate or necessary to restrict international analogs based on attributes of the manufacturer because, as many commenters stated, various marketing strategies may be employed which could create gaming opportunities to avoid the impact of the GLOBE Model and compromise the integrity of the model test. We recognize that there may be cases where the U.S. manufacturer of a GLOBE Model drug is not affiliated with the entity (or entities) that sell international analogs to a GLOBE Model drug in reference countries and existing data sources would contain pricing information for such products. Based on our analysis of the illustrative GLOBE Model drugs shown in Table 4 in this final rule, we observed the U.S. manufacturer and manufacturer in a reference country are most often the same entity or affiliated entities. We also considered that existing data sources may contain available information for international analogs to a GLOBE Model drug that are sold by parallel importers, where the approval status of such products is unknown. Based on our review of available international drug pricing information from existing data sources for the illustrative GLOBE Model drugs shown in Table 4 in this final rule, we observed that pricing information associated with potential parallel importers tends to account for no more than a minimal amount of sales within a reference country or would not tend to meaningfully change a country-level price, because such pricing information is approximately the same as pricing information for other sources such as manufacturers and other distributors.

Therefore, to avoid creating an incentive for manufacturers to increase the instances where the U.S. manufacturer and manufacturer in a reference country would not be the same entity or affiliated entities to manipulate international analogs that would be identified by CMS using existing data sources, for purposes of identifying a per unit Method I GLOBE Model benchmark, we decline to add additional criteria to only identify international analogs when the U.S. and reference country manufacturers are the same. Further, to ensure that CMS does not exclude data that would encourage parallel importing behavior that could distort the available international drug pricing information from reference countries, CMS declines to adopt the commenter's suggestion to add criteria for how CMS would identify international analogs for purposes of identifying a per unit Method I GLOBE Model benchmark.

*Comment:* A few commenters asked CMS to clarify how an analog for a drug that is only sold in the U.S. or that does not have international comparators would be identified.

*Response:* For purposes of identifying the per unit Method I GLOBE Model benchmark, using the available existing data source, CMS would identify available international drug pricing information by aligning the GLOBE Model drug's HCPCS Level II code long description (including scientific or nonproprietary name, dosage form, route of administration 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, as applicable. CMS would extract pricing data for the set of reference countries specified in § 513.310(b)(6) that have strength data and represent an international originator drug. After applying the data checks specified in § 513.410(a)(2), using the remaining data, CMS would identify the data source at the highest level of the hierarchy specified in § 513.310(c)(2) and the remaining international drug pricing information extracted from the selected data source for the GLOBE Model drug would represent the international analogs to the GLOBE Model drug. If a drug is only sold in the U.S. or does not have any international comparators, CMS would not expect that existing data sources for international drug pricing information would contain information that aligns with the GLOBE Model drug's HCPCS Level II code long description. In such cases, CMS would expect to find no available pricing information and would determine that a Method I benchmark was not available at that time.

We note that, for purposes of identifying the per unit Method II GLOBE Model benchmark, the term ''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. If a drug is only sold in the U.S., CMS would expect that a U.S. manufacturer would not identify any applicable international analog and would not submit international drug net pricing data to CMS for such GLOBE Model drug. In such cases, CMS would expect to determine that a Method II benchmark was not available at that time.

*Comment:* A commenter recommended that CMS publish detailed operational guidance specifying how ASP quarterly updates will be synchronized with international pricing data for each applicable calendar quarter. The commenter also stated the proposed existing data source lag of no more than 90 days may not align with the ASP quarter.

*Response:* We appreciate the commenter's view about the need to synchronize GLOBE Model implementation with the ongoing non-model ASP quarterly updates. In § 513.310(c)(1), CMS proposed that available international drug pricing information data sources that CMS would use to identify the per unit Method I GLOBE Model benchmark for a GLOBE Model drug must 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 such updates available to users of the data source. As we stated in II.G.1.a of the GLOBE Model proposed rule (90 FR 60268), based on our assessment of available data sources, CMS determined that the current lag may be up to 90 days. However, based on our experience with existing data sources for international drug pricing information, the lag may be only up to 60 days which we believe is sufficient for purposes of the GLOBE Model.

To align with the ASP processes, CMS proposed to prioritize use of international drug pricing data from the applicable ASP calendar quarter for the first applicable calendar quarter for which the drug is a GLOBE Model drug. When necessary, with certain limitations, the data sources hierarchy specified at § 513.310(c)(2) would allow for use of international drug pricing information for a period prior to the applicable ASP calendar quarter for the first applicable calendar quarter for which the drug is a GLOBE Model drug. We expect that CMS will be able to apply the proposed approach for using existing data sources in a timely manner and that quarterly Medicare Part B drug pricing files, including GLOBE Model coinsurance percentages, would be available prior to the start of an applicable calendar quarter in manner that aligns with CMS's existing processes and timing for quarterly Medicare Part B drug pricing files. However, after consideration of the comments received, as further discussed in section II.G.2.a. of this final rule, we are adding new § 513.410(c)(5) to address situations where the organization that maintains the data source that was selected in accordance with § 513.310(c)(2) makes updates to the international drug pricing information for international analogs for a GLOBE Model drug available to users within 90 days from the end of the calendar quarter for which drug pricing information is compiled. In such cases, as determined by CMS, CMS would use the updated international drug pricing information as available to identify the per unit Method I GLOBE Model benchmark amount for purposes of determining the per unit GLOBE Model rebate amount for such GLOBE Model drug, and for purposes of calculating the GLOBE Model beneficiary coinsurance adjustment as set forth in § 513.210(b).

Through GLOBE Model monitoring activities, CMS will assess the availability of international drug pricing information that is available through existing data sources and would take steps to address issues related to availability of data as necessary to support consistent and accurate testing of the Method I benchmark approach.

*Final Decision:* CMS is finalizing § 513.310(c)(1) with the following non-substantive technical modifications:

- To correct a numbering error appearing in the proposed regulatory text, subparagraphs (iv) through (vi) are renumbered as (iii) through (v);
- Within renumbered § 513.310(c)(1)(ii) and (iii), the redundant phrase ''across countries with the data source'' is removed from each subparagraph;
- In § 513.310(c)(1), the phrase ''for a reference country'' is removed for clarity; Typographical errors in § 513.310(c)(1)(ii)(D) and renumbered § 513.310(c)(1)(iv) are corrected;
- In § 513.310(c)(1)(i), the words ''and the U.S.'' are inserted to clarify the data source that CMS would use, if available, to calculate average U.S. price as set forth in § 513.410(d);
- In § 513.310(c)(1)(ii), ''sources'' is revised to read as ''source'', the phrase ''as determined by CMS'' is relocated to the end of this provision, and the words ''across countries within that data source'' are inserted in conjunction with removing such wording from subparagraphs § 513.310(c)(1)(ii)(A) through (D);
- In § 513.310(c)(1)(ii)(D), the wording is reorganized and revised to align with terms defined at § 513.20 and read as ''Regulatory approval pathway that at a minimum distinguishes international originator drugs, international generic drugs, international biosimilar biological products, and U.S. originator drugs'';
- In § 513.310(c)(1), we removed the words ''HCPCS Level II'' and inserted ''billing and payment'' for consistency;
- In § 513.310(c)(1)(iv), the wording is reorganized to read ''The data source must have mechanisms in place to maintain, update, validate, and correct, if necessary, the international drug pricing information in the data source on at least a quarterly basis;''
- In § 513.310(c)(1)(v) the words ''The data source must be'' is added for clarity on what must be maintained; and
- In § 513.310(c)(1)(ii)(A), the word ''product'' was removed to align § 513.310(c)(1)(ii)(A) with terminology in § 513.610(b)(1)(ii)(B)(*1*) for nonproprietary name.

After considering the comments received, CMS is also finalizing § 513.310(c)(1) with modifications to align the data source requirements in renumbered § 513.310(c)(1)(iii) with the data sources hierarchy in § 513.310(c)(2). Specifically, § 513.310(c)(1)(iii) is modified as follows:

- Paragraph § 513.310(c)(1)(iii) is updated to read as ''The data source must contain one of the following categories of international drug pricing information;''
- Paragraphs § 513.310(c)(1)(iii)(A), (C), (E) and (F) are consolidated into new paragraphs § 513.310(c)(1)(iii)(B) and (C);
- Paragraph § 513.310(c)(1)(iii)(B) is renumbered as § 513.310(c)(1)(iii)(A) and revised to read as: ''Drug-specific sales data that represent actual or calculated prices paid to the manufacturer by wholesalers, distributors, and other purchasers (expressed in U.S. currency) and corresponding volume data, meaning quantity of units (for example, number of items or packages) sold;''
- New paragraph § 513.310(c)(1)(iii)(B) reads as ''Drug-specific pricing data that represent actual or calculated list prices, ex-manufacturer prices, retail prices or other prices paid to the manufacturer by wholesalers, distributors, and other purchasers (expressed in U.S. currency) and corresponding volume data, meaning quantity of units (for example, number of items or packages) sold;'' and
- New paragraph § 513.310(c)(1)(iii)(C) reads as ''Drug-specific pricing data that represent actual or calculated list prices, ex-manufacturer prices, retail prices or other prices paid to the manufacturer by wholesalers, distributors, and other purchasers (expressed in U.S. currency).''

CMS has removed the extraneous words ''developed and'' from the definition of ''U.S. originator drug'', changed ''reference listed drug'' to ''reference listed drugs'', and changed ''Public Health Services'' to ''PHS'' in § 513.20. CMS has changed ''Public Health Services'' to ''PHS'' in the definition of ''reference product'' in § 513.20. CMS has also corrected a drafting error in the definition of ''international originator drug'' and updated ''351(k)'' to ''section 351(a).''

b. 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, in the GLOBE Model proposed rule (90 FR 60268 through 60269), we proposed that CMS would use the following hierarchy that we proposed to codify in § 513.310(c)(2):

- A data source with drug specific sales and volume 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 § 513.310(b);
- Except for extracted data used by CMS to identify the most recent per unit Method I 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 § 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 § 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 noted that this 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 § 513.310(b) (90 FR 60269);
- 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 § 513.310(b); and
- 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 § 513.310(b).

In cases when there is more than one data source meeting the requirements in § 513.310(c)(2) for a GLOBE Model drug, we proposed 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 proposed 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 § 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.

We noted 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 (90 FR 60269). That is, a country-level price for each of the reference countries would not be required and we proposed that CMS would solely use the available information for as many reference countries as possible. Further, we proposed that CMS would not combine data from different data sources to identify international drug pricing information for GLOBE Model drug X across countries.

The following is a summary of the comments received and our responses.

*Comment:* A few commenters questioned the use of international drug pricing information from existing data sources for periods of time prior to CMS's announcement of the GLOBE Model and prior to finalization of the GLOBE Model in a final rule. In contrast, a commenter supported the use of international drug pricing data prior to the announcement of the GLOBE Model as a strategy to minimize manufacturer influence on available data and CMS's ability to identify a Method I benchmark.

*Response:* We thank the commenters for their feedback on the use of international drug pricing information for periods prior to the start of the

GLOBE Model to identify the per unit Method I GLOBE Model benchmark. At § 513.310(c)(2), CMS proposed how CMS would select an existing data source for international drug pricing information for purposes of identifying a per unit Method I GLOBE Model benchmark for a GLOBE Model drug. As discussed in the GLOBE Model proposed rule (90 FR 60269), we proposed to use a hierarchy to prioritize the use of the international drug pricing information from a data source that includes drug-specific sales and volume data that incorporates discounts, rebates, or other price concessions (if available) from the highest number of reference countries for the applicable ASP calendar quarter and, only when such information was not available, CMS would use available international drug pricing information associated with calendar quarters prior to the applicable ASP calendar quarter, with limitations.

Specifically, in § 513.310(c)(2)(ii), we proposed to use international drug pricing information that contains drug specific sales and volume data from no earlier than the most recent ASP calendar quarter beginning on or after April 1, 2025 (that is, the ASP calendar quarter that would align with the first applicable calendar quarter of the model performance period based on the proposed October 1, 2026 model start), and, in § 513.310(c)(2)(iii), we proposed as necessary CMS would use 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.

This aspect of our proposal was included as an essential component of the model to address the need to mitigate the potential effect of manufacturers' limiting the availability of international drug pricing information in existing data sources during the GLOBE Model performance period and minimize the possibility of CMS 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 (90 FR 60268).

CMS does not interpret the use of historical data as reflecting current global market dynamics, nor does CMS believe that international drug pricing information available in existing data sources must do so for purposes of the model test, provided that the data is within a reasonable timeframe for establishing the per unit Method I GLOBE Model benchmark, which would be the time a Part B rebatable drug becomes a GLOBE Model drug, subject to the availability of data. CMS believes that the data specified in the proposed hierarchy would be sufficiently recent for purposes of the GLOBE Model test and would not be outdated even if data from any prior ASP calendar quarter beginning on or after April 1, 2025 would be used because we believe that such information would retain their utility as a reasonable estimate of international drug pricing information.

As we considered commenters' feedback on this topic, we identified that the provisions at § 513.310(c)(2)(iii) and discussed in section II.G.1.b. of the GLOBE Model proposed rule (90 FR 60269) were inadvertently included in the GLOBE Model proposed rule. Shortly before publication of the GLOBE Model proposed rule, CMS determined that it was not feasible to identify per unit Method I GLOBE Model benchmarks based on such extracted data from January 1, 2024 to December 31, 2024, in a document posted on the GLOBE Model website. As such, we are removing this level of hierarchy from the GLOBE Model regulation finalized in this final rule.

With respect to our proposal in § 513.310(c)(2)(ii), we believe it is necessary for the model test to retain the potential use of international drug pricing information that contains drug specific sales and volume data from the most recent ASP calendar quarter beginning on or after April 1, 2025. This approach means that CMS would use international drug pricing data for a calendar quarter prior to the publication of the GLOBE Model proposed and final rules as necessary to minimize manufacturer influence on available data. As previously stated, we believe data beginning on April 1, 2025 or after is sufficiently recent to provide a reasonable estimate of international drug pricing in the event that drug specific sales and volume 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 § 513.310(b) is not available.

With these clarifications and modifications, we believe we are addressing the commenters' concerns about the potential use of international drug pricing information from prior periods to the extent feasible while maintaining a reasonable safeguard against the potential effect of manufacturers limiting the availability of international drug pricing information in existing data sources.

*Comment:* A commenter requested clarification about how CMS will select among multiple data sources when more than one meets the criteria and how data would be combined across data sources.

*Response:* We appreciate the commenter's request for clarification. In section II.G.1.b. of the GLOBE Model proposed rule (90 FR 60268), CMS proposed a process for selecting an existing data source for purposes of identifying the per unit Method I GLOBE Model benchmark for a GLOBE Model drug. That is, for each GLOBE Model drug, only one data source would be used and CMS would not combine data across data sources or make adjustments to account for differences between the data source selected and other available data sources. To identify the data source that CMS would select and use, we proposed using a hierarchy approach that would identify one data source at the highest level of the hierarchy for each GLOBE Model drug as set forth in § 513.310(c)(2). Further, in cases where there is more than one data source meeting the requirements in § 513.310(c)(2) for a GLOBE Model drug, CMS proposed 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.

We also provided a detailed example of how CMS would apply the proposed hierarchy to identify the sole data source that CMS would use for a GLOBE Model drug in the GLOBE Model proposed rule (90 FR 60269). We did not propose to combine multiple sources of international drug pricing information to develop a single Method I benchmark; however, we did discuss such an approach as a potential alternative (90 FR 60269).

During our consideration of comments we received on this topic, we identified a typographical error in section II.G.1.b. of the GLOBE Model proposed rule within the first sentence of the paragraph in the first column that begins with ''In cases when'' (90 FR 60269). The words ''for a reference country'' incorrectly appear. The intended sentence is as follows: In cases where there is more than one data source meeting the requirements in § 513.310(c)(2) for a GLOBE Model drug, 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. Because there is ample discussion of our proposal within the GLOBE Model proposed rule preamble, and the proposed regulatory text reflects our proposal accurately, we believe that the public has had adequate notice and opportunity to comment on our proposal. We received few comments seeking clarification of our approach, demonstrating that the error in the GLOBE Model proposed rule was not substantive. To clarify this policy, we are finalizing § 513.310(c)(1) with a modification to remove the words ''for a reference country'' as discussed in section II.G.1.a. of this final rule.

*Final Decision:* After considering the comments received, CMS is finalizing § 513.310(c)(2) with modifications. Specifically, CMS is making the following modifications to § 513.310(c)(2):

- The phrase ''for each GLOBE Model drug for an applicable calendar quarter'' is removed;
- In § 513.310(c)(2)(ii), for clarification, with respect to prior ASP calendar quarter and most recent ASP calendar quarter, ''ASP calendar quarter'' is replaced with ''calendar quarter'';
- The proposed regulatory text (90 FR 60327) at § 513.310(c)(2)(iii) is removed, along with the reference to that provision in § 513.310(c)(2)(ii);
- To align with new §§ 513.310(c)(1)(iii)(B) and 513.310(c)(1)(iii)(C) described in section II.G.1.a. of this final rule, the proposed regulatory text (90 FR 60327) at § 513.310(c)(2)(iv) is removed and new paragraphs § 513.310(c)(2)(iii) and (iv) are added;
- New paragraph § 513.310(c)(2)(iii) reads as ''The data source contains drug-specific pricing data and corresponding volume data for the applicable ASP calendar quarter from at least one country described in paragraph (b) of this section;''
- New paragraph § 513.310(c)(2)(iv) reads as ''The data source does not contain drug-specific pricing data and corresponding volume data for the applicable ASP calendar quarter but contains drug-specific pricing data and corresponding volume data for any prior calendar quarter beginning on or after April 1, 2025 from at least one country described in paragraph (b) of this section. If pricing data and corresponding volume data from a prior calendar quarter are used, CMS uses pricing data and corresponding volume data from the most recent calendar quarter for which both sales data and corresponding volume data are available;'' and
- Paragraph § 513.310(c)(2)(v) is revised to read as ''The data source contains drug-specific pricing data for the applicable ASP calendar quarter from at least one country described in paragraph (b) of this section.''

CMS has also made non-substantive corrections of typographical errors appearing in the regulatory text:

- In § 513.310(c)(2), the reference to § 513.400(b) is corrected to read as § 513.410;
- In paragraphs § 513.310(c)(2)(i) through (v), ''drug specific'' is corrected to read as ''drug-specific;''
- In paragraphs § 513.310(c)(2)(i) and (ii), ''sales and volume data'' is corrected to read as ''sales data and corresponding volume data;'' and
- In § 513.310(c)(3), the words ''its drug'' is corrected to read as ''the drug-specific''.

c. Alternatives Considered for Using Existing Data Sources

In section II.G.1.c. of the GLOBE Model proposed rule (90 FR 60269), we stated that in cases when there is more than one data source meeting the requirements in proposed § 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 § 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 did not propose them and stated that we may reconsider the potential value of these approaches based on feedback from interested parties and further information gathering. We sought comments on these alternatives and how CMS could use the most comprehensive international pricing information available.

In the GLOBE Model proposed rule (90 FR 60269), we also stated that we were 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 welcomed 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.

The following is a summary of the comments received and our responses.

*Comment:* A commenter proposed the use of multiple sources of data to develop a singular benchmark as a strategy to minimize manufacturer influence on data.

*Response:* We thank the commenter for suggesting that we consider combining existing data sources. The commenter did not provide specific steps or methods that CMS could follow to best combine such data sources and use such results for the GLOBE Model or how CMS would refine the proposed hierarchy for potential use of more than one data source. Therefore, we decline to adopt this suggestion.

We note that, in section II.G.1.c. of the GLOBE Model proposed rule (90 FR 60269), CMS discussed two alternatives that we considered in cases when there is more than one data source meeting the requirements in proposed § 513.310(c)(3) for a GLOBE Model drug or in cases when there is more than one data source meeting the requirements and for the same number of countries. 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 continue to decline to adopt them at this time and may reconsider the potential value of these approaches in the future.

d. Voluntary Submission of International Drug Net Pricing Data

As discussed in the GLOBE Model proposed rule (90 FR 60269), 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 proposed 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 § 513.620(b), we proposed 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 that corresponds with an applicable calendar quarter during the model performance period.

For each submission, we proposed that the manufacturer must include ''applicable international analog'' defined in § 513.600 as 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 identified in § 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.[167] We also proposed that manufacturers would use data that (1) represent the price of international originator drugs; (2) have complete package size information; (3) have strength data; and (4) represent a dosage form that could be described by the GLOBE Model drug's HCPCS Level II code long descriptor, including route of administration (if applicable). For example, if the HCPCS Level II code long 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 final rule.

We also proposed 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. We noted, as an 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 (90 FR 60270). We also proposed that submission of data must occur no later than 30 days after the end of the applicable ASP calendar quarter. We also noted, 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 (in advance of the proposed model performance period), 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 (90 FR 60270). In this example, we noted that the manufacturer submitted data would include data for the entire applicable ASP calendar quarter (April 1, 2026 to June 30, 2026). We further noted that our proposal would mean manufacturers would have to establish an effective data agreement no later than July 30, 2026 (based on the proposed model start).

Further, we proposed that CMS would conduct a verification review for validity to determine whether the manufacturer's submission meets the submission requirements proposed in § 513.610, which, as we also proposed, would be 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, we proposed that 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 drug 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 would 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 that reported international drug net prices for applicable international analogs would be, 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). We welcomed 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 final rule.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters expressed concerns about the reliability and transparency of the manufacturer-submitted international net pricing data that CMS would use to calculate the Method II benchmark. Several commenters stated that there are structural limitations associated with manufacturers' ability to submit accurate voluntary international drug net pricing data due to competition laws, confidential reimbursement agreements, out-licensing agreements, government clawback agreements, and managed entry agreements. As an example, a commenter stated that countries in the European Union (EU) and the United Kingdom (UK) limit or

[167] Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug pricing information in the 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.

prohibit the exchange of competitive pricing information between independent companies or disclosure of confidential information related to net prices, rebates and payer-specific discounts even where the originating manufacturer retains an economic interest through royalties. The commenter also stated that foreign prices are often determined through confidential reimbursement arrangements with national health authorities or payers which commonly impose non-disclosure obligations that bind the licensee and preclude sharing of net price information, including with the original manufacturer. Commenters stated that these and other limitations may preclude manufacturers from submitting data for the Method II benchmark and, as a result, make certain manufacturers of GLOBE Model drugs solely subject to the Method I benchmark which would be more punitive.

*Response:* We thank the commenters for sharing their concerns regarding potential obstacles manufacturers may face regarding voluntary submission of international drug net pricing data and the potential impact on the GLOBE Model test if manufacturers would be precluded from submitting net pricing data for a GLOBE Model drug. We appreciate that a manufacturer of a GLOBE Model drug may be subject to legal obligations that may constrain their ability to obtain or disclose certain drug pricing information. CMS disagrees that legal constraints, methodological limitations, and commercial risks identified by commenters render the voluntary submission of international drug net pricing data legally impermissible, methodologically unreliable, or commercially untenable. For the GLOBE Model, manufacturer submission of international drug net pricing data is voluntary. Manufacturers are not required to submit this data; the submission option exists to give manufacturers the opportunity to provide international drug net pricing data that is an essential component of testing the Method II benchmark approach and may result in a more favorable benchmark calculation. In the GLOBE Model proposed rule, CMS expressly proposed confidentiality protections for submitted data and a verification process using public and external sources. In regards to transparency, we note that CMS proposed to provide each model participant (that is, a manufacturer of the GLOBE Model drug) with a preliminary rebate report and an opportunity to identify potential mathematical errors using the Suggestion of Error process before CMS would provide a rebate report that would serve as the invoice.

CMS recognizes that countries have different health care systems, market structures, contracting frameworks, and other characteristics, which may lead to some differences in how net prices would be calculated by manufacturers and reported to CMS. CMS does not agree, however, that these differences would make international drug net pricing data unusable for purposes of the GLOBE Model. CMS does not agree that foreign confidentiality restrictions, foreign legal constraints, or commercially sensitive arrangements would mean that the model cannot reasonably rely on manufacturer-reported international drug net pricing data or that it would make the use of such data methodologically risky. These comments identify possible limitations on the availability and completeness of data, but they do not suggest or provide evidence that manufacturers would be completely unable to access relevant information; that such information would be erroneous; or that such information cannot be submitted to CMS, given appropriate reasonable assumptions and confidentiality protections. CMS acknowledges that there may be certain exceptional circumstances where a manufacturer would be unable to submit complete international drug net pricing data. However, we do not believe that such factors would prevent manufacturers from submitting international drug net pricing data in accordance with our proposed requirements at 42 CFR part 513 subpart G, primarily because manufacturers of GLOBE Model drugs could apply reasonable assumptions to the extent necessary to gather information and submit the required data.

To address commenters' concern that a manufacturer in some exceptional circumstances could not satisfy the proposed requirements at 42 CFR part 513 subpart G for submitting international drug net pricing data, we are modifying § 513.610(a)(3)(i)(E) to further clarify that a manufacturer's submission must include supporting documentation that explains how each of the basic data elements (as described in § 513.610(b)) and net pricing data elements (as described in § 513.610(c)) contained within the submission were compiled or calculated and any reasonable assumptions that were applied. We are also modifying §§ 513.610(b)(1) and 513.610(c)(2) and adding new §§ 513.610(b)(3) and 513.610(c)(3) to clarify that, if a manufacturer is unable to include certain basic data elements or net pricing data elements as applicable in its submission, the manufacturer must submit supporting documentation, including any reasonable assumptions that were applied, to fully explain why such data element is not included in its submission. For example, to the extent that a manufacturer may not be able to submit sales data for a drug involved in out-licensing agreements, the manufacturer may describe this as a limitation or assumption in the reasonable assumptions submitted by the manufacturer.

In addition, while we are retaining the completeness and validity requirements in § 513.610(a)(3), in § 513.610(a)(4), we are finalizing a modification to our proposal to clarify that CMS would determine that a submission is an applicable submission if the submission is complete (as described in § 513.610(a)(3)(i)), includes the basic data elements as specified in § 513.610(b), includes the net pricing data elements for one of the two options specified in § 513.610(c), and is valid as determined by CMS as set forth in § 513.610(a)(3)(ii). We are also clarifying in §§ 513.420(a) and 513.420(c) that when CMS is unable to identify an available across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit within available manufacturer-submitted international drug net pricing data for the applicable calendar quarter for a GLOBE Model drug as set forth in § 513.130(d)(2)(ii), CMS identifies that the per unit Method II GLOBE Model benchmark is unavailable for such GLOBE Model drug for such applicable calendar quarter.

We believe that, taken together, these modifications clarify how manufacturers may address external limitations that restrict their access to certain information that they would otherwise include in their identification and submission of international drug net pricing data for purposes of the GLOBE Model as set forth in 42 CFR part 513 subpart G, and how CMS would consider applicable submissions.

In deciding to finalize these modifications, we considered the potential impact on per unit Method II GLOBE Model benchmarks and the model test. Without these clarifications, as stated by the commenters, certain manufacturers may view the option to voluntarily submit international drug net pricing data for a GLOBE Model drug to be impractical. To the extent that the modifications we are finalizing in 42 CFR 513 subpart G and § 513.420 would encourage a manufacturer to

submit international drug net pricing data, we believe that these modifications are essential for testing the Method II benchmark within the GLOBE Model test, particularly in cases where there are more than one manufacturer of a GLOBE Model drug because such cases may involve business arrangements that could limit a manufacturer's ability to include certain data within its voluntary submission of international drug net pricing information. We believe that these modifications help clarify how a manufacturer of a GLOBE Model drug may submit international drug pricing data in a manner consistent with the requirements finalized in 42 CFR 513 subpart G even in cases where a manufacturer does not have access to certain net pricing information, for example, a U.S. manufacturer that is a repackager or relabeler that is not involved with sales of the GLOBE Model drug for any reference country.

*Comment:* A commenter recommended that CMS adopt additional verification mechanisms to assess the reasonableness of manufacturers' voluntarily submitted international drug net pricing data that would be used as a data source for the Method II benchmark. The commenter stated that CMS should independently estimate volume-weighted benchmarks using external data sources and compare those estimates against manufacturer-submitted international drug net pricing data. The commenter further suggested that CMS use financial reporting data to approximate net-to-gross ratios and apply such adjustments to ex-manufacturer pricing information from available existing data sources to develop a metric for assessing the accuracy of the manufacturer submitted data before accepting and using such data for the Method II benchmark test.

*Response:* We thank the commenter for their suggestions for how CMS might enhance the verification review for validity of voluntary manufacturer-submitted international drug net pricing data. As described in section II.G.1.d. of the GLOBE Model proposed rule (90 FR 60269), CMS would conduct a review of the data for completeness and validity to determine whether the voluntarily submitted international drug net pricing data is acceptable for use to identify a per unit Method II GLOBE Model benchmark. We stated that, as part of verifying the validity of the data, CMS would 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). We appreciate the commenter's suggestion that in using available data sources to assess the validity of manufacturer submitted international drug pricing data CMS should calculate a volume-weighted average. We agree and intend to do so as one approach for assessing the validity of a submission pursuant to § 513.610(a)(3)(ii)(B). We believe that the proposed regulatory text is sufficient for this purpose and decline to make modifications to add specificity.

After additional review, we believe that, at this time, CMS does not have access to sufficient data at the GLOBE Model drug level that would be necessary to adopt the commenter's suggestion to use financial reporting data to approximate net-to-gross ratios for all potential GLOBE Model drugs and use such ratio in the verification process. Therefore, we are finalizing our proposed approach without modification. However, CMS may use publicly available manufacturers' financial reporting data as necessary, when available to CMS, to assess the extent to which a manufacturer's submission reflects international drug net pricing in the reference countries as set forth in § 513.610(a)(3)(ii)(B).

*Comment:* A commenter expressed concern that CMS would use significant discretion in determining whether a manufacturer's voluntary submission of international drug net pricing data meets CMS's proposed submission requirements and would qualify to be a data source for a Method II benchmark. The commenter stated that the complexity of establishing international analogs and determining an accurate international benchmark for GLOBE Model drug necessitates a transparent and collaborative approach between CMS and manufacturers.

*Response:* We disagree that significant discretion would have to be used by CMS to determine whether a manufacturer's voluntary submission of international drug net pricing data meets completeness and validity requirements set forth in § 513.610(a)(3) and would be available for purposes of identifying a per unit Method II GLOBE Model benchmark because CMS proposed and is finalizing in this final rule with clarification that manufacturers would submit supporting documentation that explains how each of the data elements was compiled or calculated and any reasonable assumptions that were applied. In addition, we are clarifying when CMS identifies that the per unit Method II GLOBE Model benchmark is unavailable for an applicable calendar quarter in § 513.420(c). While we acknowledge that CMS may use its discretion in performing its review of a submission, we do not believe that substantial discretion would be necessary to determine if a submission is an applicable submission when a manufacturer adheres to the submission requirements. Further, we do not believe that substantial discretion would be necessary to determine the availability of manufacturer-submitted international drug net pricing data for purposes of identifying the per unit Method II GLOBE Model benchmark because CMS would use the applicable submission as set forth in § 513.610(a)(4) submitted by each manufacturer of a GLOBE Model drug as set forth in § 513.310(d)(2) for this determination.

With respect to identifying international analogs, we note that, in § 513.600, CMS proposed that 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. Because manufacturers of Part B rebatable drugs operate in highly competitive markets where competitive intelligence is essential for commercial success, we believe that manufacturers of GLOBE Model drugs would have existing lines of sight on applicable international analogs and would apply such expertise in compiling their submissions. In addition, manufacturers would discuss how international analogs were included or not included in their submissions in the supporting documentation that CMS would review.

As part of model implementation, CMS's Innovation Center typically offers technical support for model participants regarding various aspects of model implementation, such as data reporting. For the GLOBE Model, CMS will offer drug manufacturers technical support through a number of mechanisms, such as education and outreach on topics related to model activities and operations, data submission, access to reports, payment of rebates, and inquiries. Through these supports, manufacturers will have the opportunity to communicate with CMS about their identification of applicable international analogs. We believe these supports will address the commenter's concerns about

the need for a transparent and collaborative approach between CMS and manufacturers with respect to the identification of international analogs for purposes of the Method II benchmark.

*Comment:* A commenter suggested a series of steps that CMS could use for assessing the validity and completeness of the manufacturer submitted international drug net pricing data, and to identify inconsistencies with market dynamics. The suggested steps include assessing exchange rate conversion trends and anomalies, validating GDP and PPP adjustments, comparing prices across multiple data sources where available, identifying outliers, identifying sharp price decreases that revert within short time windows, and detecting abrupt changes in price trends. Another commenter recommended that CMS develop methodologies and enforcement mechanisms to counterbalance or even prevent the manufacturers' manipulation of pricing information and help ensure manufacturers provide their international drug net pricing data in an accurate and timely manner.

*Response:* We thank the commenter for their input on the verification review for validity to determine whether a manufacturer's submission meets the requirements for an applicable submission. As we stated in the GLOBE Model proposed rule (90 FR 60288), as part of verifying the validity of the data, CMS would assess the extent to which a timely and appropriately submitted submission reflects international drug net pricing for the applicable international analogs that were sold in the reference countries during the applicable ASP calendar quarter 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). CMS also provided examples of the validation processes (90 FR 60270), such as those described by the commenter, including, assessing whether (1) the 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, and (2) 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 CMS does not expect manufacturer submitted international drug net pricing data to increase beyond pricing in existing international drug pricing information data sources. Additionally, as discussed in section II.G.1.f. of this final rule, CMS would publish the GDP (PPP) adjuster for manufactures to use, and therefore, would not need to validate the GDP and PPP adjustments as these would be provided to manufacturers, other than to assess that the applicable GDP (PPP) adjuster was applied.

We believe these steps are sufficient to encourage timely and accurate submissions and for CMS to assess the validity and completeness of the manufacturer submitted data, and to identify inconsistencies with market dynamics and are sufficient for purposes of the GLOBE Model. Therefore, we decline to make modifications to add more specificity to the verification process and decline to adopt as codified requirements at this time the commenters suggestion of assessing exchange rate conversion trends and anomalies, identifying outliers, identifying sharp price decreases that revert within short time windows, and detecting abrupt changes in price trends. We intend to apply these types of analyses as CMS determines to be appropriate and, after we gather information through model monitoring activities, may reconsider the potential value of codifying these approaches as requirements in the future.

*Comment:* Commenters raised concerns that manufacturers attempting to comply with the GLOBE Model's Method II data submission requirements could face conflicts with foreign antitrust and competition laws. Commenters noted that EU competition law and the competition laws of individual member states generally prohibit the exchange of competitively sensitive information—including pricing information—between independent companies. Commenters further stated that many foreign countries maintain legal regimes that protect the confidentiality of negotiated net prices as conditions of reimbursement, and that the exchange of such information between licensors and licensees across jurisdictions could constitute a violation of resale price maintenance prohibitions or horizontal information-exchange restrictions under foreign law.

*Response:* CMS acknowledges the commenter's concern regarding potential conflicts between foreign competition law requirements and the voluntary manufacturer submission of international drug net pricing data. CMS provides the following response.

As an initial matter, CMS reiterates that manufacturer submission of international drug net pricing data is entirely voluntary. Manufacturers are not required to submit international drug net pricing data; the submission option exists to provide manufacturers with the opportunity to supply data that may result in an alternative Method II benchmark calculation relative to the Method I benchmark. A manufacturer that determines it cannot lawfully obtain or disclose the required pricing information under applicable foreign law may elect not to submit international drug net pricing data for Method II.

CMS does not have the authority to exempt manufacturers from compliance with foreign competition law, nor does the GLOBE Model require manufacturers to engage in conduct that would violate such laws. CMS expects that manufacturers will exercise independent legal judgment regarding their ability to submit data consistent with applicable legal obligations in all relevant jurisdictions. CMS notes that manufacturers regularly engage in internal reporting, financial disclosure, and regulatory compliance activities that require aggregation of international pricing data—for example, in connection with transfer pricing determinations, financial reporting, and existing government pricing obligations—and CMS expects that similar legal analysis would apply to Method II data submissions.

In light of the barriers to submission of complete data for all reference countries for Method II as asserted by manufacturers, and as discussed in this section II.G.1.d. of this final rule, we are finalizing in this final rule that manufacturers would have an option as part of the voluntary manufacturer submission framework that would allow manufacturers to pursue the voluntary submission of international drug net pricing data even when they are unable able to obtain all required data elements for every international analog. For example, for any data elements of an international product that they are unable to obtain due to out-licensing or co-licensing, manufacturers would submit an explanation as part of the reasonable assumptions, which would be subject to CMS review. We believe this option would mitigate commenters' concerns about foreign antitrust or competition law concerns. CMS also notes that the data agreement at § 513.620 establishes confidentiality obligations that may mitigate some of

the competition law concerns raised by commenters, and as stated in § 513.610(e), the submitted data would not be disclosed in a form which discloses the identity of a specific manufacturer and their international drug 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).

For these reasons, CMS believes the voluntary structure of Method II, combined with the confidentiality protections at § 513.610(e), adequately addresses the competition law concerns raised by commenters without requiring modifications to the model's regulatory text.

*Comment:* Several commenters expressed concerns about the feasibility of testing a benchmark methodology that would be based on voluntary manufacturer-submitted international drug net pricing data. A few commenters stated that CMS should expect that manufacturers will report international drug net prices in ways that are advantageous to their financial circumstances.

*Response:* We thank the commenters for sharing their concerns regarding potential strategic behavior from manufacturers and the feasibility of testing a benchmark based on voluntary manufacturer-submitted international drug net pricing data that could impact the integrity and timeliness of the data and identification of a per unit Method II GLOBE Model benchmark. Prior to identifying the availability of manufacturer-submitted international drug net pricing data that would be used to identify the per unit Method II GLOBE Model benchmark for a GLOBE Model drug for an applicable calendar quarter as set forth in § 513.310(d), CMS would conduct a verification review for validity to determine whether a manufacturer's submission meets certain requirements for voluntary manufacturer-submitted international drug net pricing data as set forth in § 513.610(a)(3) to counterbalance potential manufacturer manipulation of international pricing information and ensure data integrity, completeness and accuracy. As we previously stated in this section of this final rule, we believe our proposal for how CMS would assess the validity and completeness of the manufacturer submitted data is sufficient for purposes of the GLOBE Model. Therefore, we decline to make modifications to add more specificity to the verification process at this time. We also believe our update to §§ 513.610(b) and 513.610(c) to allow manufacturers the option to submit supporting documentation, including any reasonable assumptions that were applied, when manufacturers are unable to include certain basic data elements and net pricing data elements provides an opportunity for manufacturers to submit voluntary manufacturer-submitted international drug pricing when they may otherwise may not, and therefore, increases feasibility of testing a per unit Method II GLOBE Model benchmark. For this reason, we do not believe that further modifications to the proposed provisions are warranted at this time to increase feasibility and integrity of testing a per unit Method II GLOBE Model benchmark.

*Comment:* A few commenters suggested that CMS pursue an alternative method for obtaining data for the Method II benchmark. Commenters recommended that CMS should require that manufacturers report international drug net pricing data instead of allowing manufacturers to voluntarily submit data to ensure that there would be a data source for the Method II benchmark so that this approach could be tested consistently.

*Response:* We thank the commenter for this suggestion. We do not believe that it is necessary to mandate manufacturer reporting of international drug net pricing data as such data is not essential for testing an alternative rebate amount calculation for purposes of the GLOBE Model because the model is also testing the Method I benchmark approach using existing data sources for international drug pricing information, as available. Furthermore, mandating manufacturer reporting of international drug net pricing data would not allow CMS's Innovation Center to learn from testing a voluntary approach. Therefore, at this time, for the GLOBE Model, CMS declines to mandate that manufacturers of GLOBE Model drugs submit international drug net pricing data.

*Comment:* A few commenters expressed concern that, because manufacturers would have limited visibility into the underlying existing data sources and extracted data that CMS would use to identify the per unit Method I GLOBE Model benchmark and because there could be flaws in the how the Method I benchmark is identified, manufacturers would face pressure to submit international drug net pricing data for the Method II benchmark, making this option mandatory rather than voluntary.

*Response:* We disagree that submitting international drug pricing information for purposes of the GLOBE Model would be mandatory for any manufacturer of a GLOBE Model drug; as proposed and as finalized in this final rule, manufacturer submission of international drug net pricing data would be voluntary. CMS proposed mechanisms within the GLOBE Model design to incentivize manufacturers to voluntarily submit international drug pricing information, such as identifying the greater of the per unit Method I GLOBE Model benchmark (if available) and the per unit Method II GLOBE Model benchmark (if available) as the per unit GLOBE Model benchmark for a GLOBE Model drug for an applicable calendar quarter and applying a higher applicable threshold percentage when the per unit Method II GLOBE Model benchmark is greater. Further, to reduce manufacturers' potential concerns with the reasonableness of the per unit Method I GLOBE Model benchmark and to avoid the potential that such international drug pricing information may not represent actual prices, at § 513.410(a)(4)(i)(A), we proposed (and are finalizing in this final rule) 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. These incentives do not change the fact that manufacturer submission of international drug net pricing data would be voluntary.

We also disagree that manufacturers would have limited visibility into existing data sources that CMS could use to determine the per unit Method I GLOBE Model benchmark. As discussed in section II.G.1.a. of the GLOBE Model proposed rule (90 FR 60267) and this final rule, the existing data sources that CMS proposed to potentially use 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. Based on our assessment of such companies' websites, we believe these data sources are routinely accessed by many manufacturers of Part B rebatable drugs, researchers, and others for market assessment and analysis and other purposes. Further, based on a review of the comments we received and the level of detail contained within some of them, we believe that commenters, including potential model participants, in general, already have access to these data sources and would not have limited visibility into the underlying data that CMS may extract and use to calculate a per unit Method I GLOBE Model benchmark.

*Final Decision:* After consideration of the public comments received, CMS is

finalizing § 513.310(d) with non-substantive technical corrections for typographical errors that appeared in the proposed regulatory text and to align wording with §§ 513.420 and 513.610. CMS made modifications so that the term ''international drug net pricing data'' is consistently used and corrected the cross-reference in § 513.310(d)(3) to read ''for purposes of § 513.420.''

In § 513.310(d)(1), ''accepted in accordance with 42 CFR 513.610'' is replaced with ''determined by CMS to be an applicable submission as set forth in § 513.610(a)(4)''. In § 513.310(d)(2)(i), the word ''accepted'' is removed. In § 513.310(d)(2)(ii), ''accepted international drug net pricing information'' is replaced with ''an applicable submission'', the extraneous phrase ''using the accepted international net pricing information identified in paragraph (d)(2)(ii)(A) of this section,'' is removed, and ''presentation level information'' is replaced with ''international drug net pricing data''.

In § 513.310(d)(2)(ii)(B), ''international net pricing and sales data'' is replaced with ''net pricing data elements'' and ''with across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit and sales volume in HCPCS billing units greater than zero'' is added. CMS deleted § 513.310(d)(2)(iii) to remove a step that would be completed under § 513.610.

In § 513.310(d)(3), CMS replaced ''the presentation level information'' with ''such manufacturer-submitted international drug net pricing data.''

In addition, CMS removed the term for ''eligible manufacturer'' from § 513.310(d) and its associated definition in § 513.20 because it was determined that this term is not necessary for the finalized regulation at § 513.310(d).

In new § 513.610(c)(3), CMS added the following: ''If a manufacturer is unable to include certain net pricing data elements in its submission, the manufacturer must submit supporting documentation, including any reasonable assumptions that were applied, to fully explain why such data element is not included.''

e. Criteria and Process for Identifying the Set of Reference Countries

In section II.G.1.e. of the GLOBE Model proposed rule (90 FR 60270), we proposed 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 final rule and the per unit Method II GLOBE Model benchmark as described in section II.G.2.b. of this final rule.

We stated that 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 proposed that CMS would identify a set of reference countries that are non-U.S. Organisation for Economic Co-operation and Development members (that is, non-U.S. OECD-member countries) [168] 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; [169] and (2) an annual real GDP that is at least $400 billion (as measured in U.S. dollars) as estimated and available in the CIA World Factbook,[170] as determined by CMS. We proposed 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, we noted that, at the time the GLOBE Model proposed rule was published, while the CIA online World Factbook was updated daily, the underlying data such as GDP and PPP were reported no more frequently than annually, based on a July 1 mid-point. Therefore, we noted that 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. We also noted that there are other existing sources for GDP per capita data besides the CIA World Factbook, including the World Bank,[171] and the International Monetary Fund.[172] Upon examining these sources, we noted that the GDP data across these sources are highly associated with one another. We proposed using the CIA World Factbook as our source for real GDP per capita and real GDP data as it was issued by a U.S. government agency and includes data for countries that are economically comparable to the U.S.

In the GLOBE Model proposed rule (90 FR 60271), we proposed that, given that the identified set of countries would be economically comparable to the U.S. based on real GDP per capita in 2024 and aggregate real GDP in 2024, 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 proposed to codify the criteria that CMS would use once to identify the set of reference countries for purposes of the GLOBE Model in § 513.310(b). We sought comments on our proposal to use the CIA World Factbook as the data source for real GDP per capita and real GDP data as well as the other data sources we considered.

Following publication of the GLOBE Model proposed rule, on February 4, 2026, the CIA announced that the CIA World Factbook is no longer being published.

To illustrate the potential set of reference countries that would result if the proposed criteria for identifying the set of reference countries were adopted in a final rule establishing the GLOBE Model, we applied the proposed criteria (as set forth in § 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, Czech Republic, Denmark, France, Germany, Ireland, Israel, Italy, Japan, Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom (see Table 5 in the GLOBE Model proposed rule (90 FR 60272)). We noted that 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.

[168] OECD. Members and Partners. Available at: *https://www.oecd.org/en/about/members-partners.html.*

[169] The United States Central Intelligence Agency (CIA). The World Factbook, Country Comparisons-Real GDP per Capita. Information available at: *https://www.cia.gov/the-world-factbook/field/real-gdp-per-capita/country-comparison/.* On February 4, 2026, the CIA announced that the CIA World Factbook is no longer being published.

[170] The United States Central Intelligence Agency (CIA). The World Factbook, Country Comparisons—Real GDP (Purchasing Power Parity). Information available at: *https://www.cia.gov/the-world-factbook/field/real-gdp-purchasing-power-parity/country-comparison/.* On February 4, 2026, the CIA announced that the CIA World Factbook is no longer being published.

[171] The World Bank Group. Data. GDP per capita (current US$). Available at: *https://data.worldbank.org/indicator/NY.GDP.PCAP.CD*

[172] International Monetary Fund. Datasets. Available at: *https://www.imf.org/external/datamapper/datasets/WEO.*

In the GLOBE Model proposed rule (90 FR 60272), we stated our belief 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 previously as well as Chile, Poland, Portugal, and Turkey. We also stated our belief that the 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 also discussed that 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. We noted that 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 G7 countries that include Canada, France, Germany, Italy, Japan, and the United Kingdom, or the G20 countries.[173]

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.[174] [175] 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 stated our belief that these approaches would not 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. We stated our belief 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 saving).

Despite our concerns at the time we developed the GLOBE Model proposed rule about potential negative impacts that could occur if the set of reference countries was not held constant during the 5-year GLOBE Model performance period, we welcomed 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 sought comment on the proposed criteria to select the list of reference countries and whether to revise the list of reference countries. We also welcomed 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.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters provided feedback on the criteria for identifying the set of reference countries. Many commenters suggested that countries that explicitly or implicitly use Quality Adjusted Life Years (QALY) or other standards of comparative- and cost-effectiveness analysis should be excluded for various reasons, including assertions that such methods could effectively import valuation frameworks that assign a lower value to the lives of people with disabilities, chronic illness, rare diseases, cancer, or old age and because CMS is prohibited from using health outcome measures that assign lower value to extending the lives of ill patients compared with healthy individuals. Commenters stated that our proposal is inconsistent with the Affordable Care Act, section 504 of the Rehabilitation Act, Title II of the Americans with Disabilities Act, and Federal nondiscrimination policies, and may cause delays in access to care and innovation. A commenter also stated that populations in the proposed reference countries that use QALYs are different from the U.S. Medicare population.

*Response:* We thank the commenters for their input on the proposed criteria and process for identifying the set of reference countries for the GLOBE Model. Section 1182(e) of the Act states, ''The Patient-Centered Outcomes Research Institute established under section 1181(b)(1) shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended. The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII.''

The GLOBE Model would not adopt the use of QALYs or a similar health outcome measure ''as a threshold'' to determine coverage or reimbursement of GLOBE Model drugs per the plain text of the statute. The GLOBE Model design does not include coverage determinations and does not establish a QALY based reimbursement formula. The use of observed drug pricing data from a set of reference countries would not run afoul of the statute's prohibition. Rather, for purposes of the GLOBE Model, as an input into an alternative rebate amount calculation, foreign prices serve as a proxy for the payment levels at which drug manufacturers are willing to sell their

[173] Non-US members of the G20 are Argentina, Australia, Brazil, Canada, China, France, Germany, India, Indonesia, Italy, Japan, Medico, Russia, Saudi Arabia, South Africa, South Korea, Turkey, and the United Kingdom.

[174] World Health Organization. WHO-Listed Authority (WLA). Available at: *https://www.who.int/initiatives/who-listed-authority-reg-authorities.*

[175] World Health Organization. Intellectual Property and Trade. WHO Response. Available at: *https://www.who.int/health-topics/intellectual-property.*

products, from drug manufacturers' perspectives.

We do not believe it is necessary to exclude countries based on their health valuation methodologies nor do we believe that additional guardrails are necessary to ensure compliance with civil rights protections, given that existing protections, described in more detail below, already are being complied with in full and would continue to be complied with under the GLOBE Model. We also believe that, while a reference country's population may be different than the U.S. Medicare population, using drug pricing data for such country is appropriate as a proxy for the payment levels at which drug manufacturers are willing to sell their products, from drug manufacturers' perspectives, as discussed previously. The GLOBE Model would not incorporate the reference country's legal practices, ethical principles, reimbursement systems, formulary structures, HTA process, or other policies related to health care valuation or access. We do not believe that using international pricing data as one input into the alternative rebate amount calculation is equivalent to adopting the full foreign decision-making framework that may have contributed to that pricing. We also do not believe that using international drug pricing data as an input means that the Medicare program would adopt the broader coverage, reimbursement, or health system features of any reference country—including any differences in investment in innovation or other access-related features that commenters associate with the systems within the proposed set of reference countries. We note that any access-related issues within the proposed set of reference countries reflect a combination of country-specific coverage rules, reimbursement systems, budget constraints, and health system design features within such countries—none of which would be aspects of the GLOBE Model.

CMS notes that existing Federal civil rights protections would continue to apply under the GLOBE Model. Those protections include, among others, section 504 of the Rehabilitation Act of 1973, section 1557 of the Affordable Care Act, and other applicable Federal nondiscrimination requirements. No provision of the GLOBE Model alters, limits, or displaces these protections.

*Comment:* A couple of commenters recommended using a narrower set of reference countries that would have more similar economic and pharmaceutical market sizes to the U.S. These commenters supported using the G7 countries other than the U.S. (Canada, France, Germany, Italy, Japan, and UK) or the countries selected for the GENErating cost Reductions for U.S. (GENEROUS) Model that CMS announced on November 6, 2025, which include the G7 countries other than the U.S. plus Denmark and Switzerland. Commenters also suggested alternative inclusion criteria for identifying the set of reference countries including using one single country and then expanding to other countries, with limitations to exclude countries that use specific reimbursement frameworks. The commenter stated that applying most favored nation pricing based on a single reference country—for example, France—would more faithfully replicate the incentive structure of a most favored nation policy. The commenter believed that while this alternative may not be a perfect proxy, it could help inform policymakers' decisions to expand to other countries. A commenter suggested using an alternative approach such as adding a third criterion for identifying the set of reference countries that would be based on a minimum pharmaceutical market size but stated that this approach may be more administratively burdensome to assess than simply using the G7 country grouping.

*Response:* We thank the commenters for their input on the proposed criteria and process for identifying the set of reference countries for the GLOBE Model. As discussed in the GLOBE Model proposed rule (90 FR 60270 through 60272), we considered several alternatives to identify the set of reference countries, including alternatives that would have a smaller set of reference countries such as those that have more similar economic and pharmaceutical market size to the U.S. We stated our goal 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. (90 FR 60270). We acknowledged that our proposed approach to include countries with a minimum of 60 percent of the U.S. real GDP per capita and $400 billion aggregate real GDP would strike 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 (90 FR 60272). We noted that a higher real GDP per capita threshold could result in a very small set of reference countries and that a lower real GDP per capita threshold could result in a larger set of reference countries which may include countries that would be less similar to the U.S. We believe that these commenters' suggestions would result precisely in the situation that we sought to avoid.

Specifically, we believe that adopting the commenters' suggestions—whether to limit reference countries to G7 nations (excluding the U.S.) plus Denmark and Switzerland, or to begin the model with only a single country—would directly undermine the very outcome the GLOBE Model was designed to prevent: reliance on an insufficiently small set of reference countries that would not support testing and alternative rebate amount calculation using both Method I and Method II benchmark approaches. The proposed alternative rebate amount calculations were explicitly developed to leverage a robust, internationally diverse dataset. For example, a smaller set of reference countries could reduce the appropriateness of removal of pricing information at the dosage form and strength level for a country that falls below 5 percent of the average U.S. price in the Method I benchmark calculation, (2) the application of the GDP (PPP) adjuster to per unit country-level prices in both benchmark calculations, and (3) application of the proposed threshold percentage in the calculation to identify the per unit GLOBE Model benchmark amount. For example, in consideration of the comments received, we estimated that for an illustrative GLOBE Model drug, in general, using a smaller set of reference countries would likely result in a different, higher per unit Method I GLOBE Model benchmark and per unit Method II GLOBE Model benchmark, which would result in a higher per unit GLOBE Model benchmark amount and lower GLOBE Model rebate amount, lowering the amount of GLOBE Model rebates that manufacturers would pay and estimated beneficiary and model savings. Additionally, if the model test was limited to a single reference country, this would increase the probability of a GLOBE Model drug not having a benchmark that CMS could calculate. For these reasons CMS declines to incorporate the commenter's suggestion to use a smaller set of reference countries for the model test.

*Comment:* A commenter suggested that CMS consider including a periodic review mechanism such as every three years to ensure the set of reference countries remains economically comparable.

*Response:* We thank the commenter for their suggestion to consider periodic review in the process to identify the

non-U.S. countries that would be included in the set of reference countries for the GLOBE Model. As discussed in section II.G.1.e. of the GLOBE Model proposed rule (90 FR 60270), we proposed that the identified set of reference countries would remain the same throughout the 5-year GLOBE Model performance period, even if recent information showed that a country would no longer meet the criteria for the set of reference countries during any performance year of the model. CMS also considered alternatives such as adjusting the set of reference countries periodically. CMS is not adopting this approach because we believe it 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 Program (for example, additional administrative costs that would reduce potential savings).

*Comment:* A commenter opposed the proposed process to select a large set of reference countries based on ''economically comparable'' criteria, stating that many of the included countries rely on external reference pricing based on countries that do not meet the proposed GDP-based inclusion criteria.

*Response:* We thank the commenters for their input on the proposed criteria and process for identifying the set of reference countries for the GLOBE Model.

We acknowledge that the proposed criteria for the set of reference countries would include countries that use various methods for drug pricing. For the proposed reference countries that do use external reference pricing, this is not the only element contributing to how pricing is set. Therefore, CMS does not agree that use of external reference pricing should prohibit inclusion of such country. The proposed criteria for inclusion are based on measures of general economic comparability to the U.S. and are not intended to differentiate based on or incorporate a reference country's internal drug pricing system. CMS explicitly addressed the potential for differences between reference countries' drug pricing approaches by including several aspects within the benchmark approaches to accommodate such potential variations in the development of an estimate of pricing realized by the manufacturer. Further, CMS understands the complexity of a country's health care system. Inclusion as a reference country for purposes of the GLOBE Model is not intended to and does not imply perfect similarity with the U.S.

After reviewing the comments we received on this topic, we are not convinced that excluding countries that use external reference pricing would result in a more appropriate set of reference countries than our proposal. For some of these countries, their use of external reference pricing, in part, may contribute to the fact that single source prescription drugs analogous to those sold within the U.S. are three to four times less expensive in these countries.[176] This contributes to potentially avoidable expenditures under the Medicare program, and CMS is authorized under section 1115A of the Act to test an alternative rebate methodology that incorporates the international drug pricing information, regardless of their use of external reference pricing, to reduce program expenditures while preserving or enhancing beneficiary quality of care. As such, we decline to adopt the commenters' suggestions.

*Comment:* A commenter expressed concern that while GDP-based thresholds provide a reasonable starting point for defining economic comparability, it alone is insufficient to account for structural differences in how each reference country manages pharmacy benefits, negotiated drug prices, and delivery of specialty drugs to patients. The commenter recommended that CMS publish a detailed analysis of each reference country's pharmaceutical benefit structure, pricing mechanisms for sole source drugs, the role of intermediaries in price-setting, regulatory approval timelines, patient access restrictions, and distribution cost structures.

*Response:* We thank the commenter for their input. We do not believe that alignment across drug pricing systems among the reference countries is necessary to test an alternative rebate amount calculation. CMS notes that the purpose of the set of reference countries for the GLOBE Model is not to identify perfectly comparable reference countries; rather, the purpose of the set of reference countries for the GLOBE Model is to identify boundaries for the available data that CMS would consider to identify a benchmark to include in an alternative rebate amount calculation tested under the GLOBE Model. Specifically, as explained in section II.G.1.e. of the GLOBE Model proposed rule (90 FR 60270 through 60273), the purpose of identifying the set of reference countries is to identify the scope of international drug pricing information for international analogs to a GLOBE Model drug that would be, if available in existing data sources available to CMS, used to calculate the per unit Method I GLOBE Model benchmark and, if submitted by manufacturers and accepted by CMS, used to calculate the per unit Method II GLOBE Model benchmark.

CMS understands the complexity of a country's health care system. Inclusion as a reference country for purposes of the GLOBE Model is not intended to and does not imply perfect similarity with the U.S. We recognize that GDP-based measures are standard economic practice for cross-country comparisons and, as such, are used to assess economic comparability. Although the commenter identified additional factors that may affect drug pricing within a country, those observations do not show that the approach proposed (or finalized in this final rule) by CMS would be unreasonable for the limited purpose of identifying the set of reference countries for the GLOBE Model. The existence of other variables does not, by itself, mean that CMS has failed to consider an important aspect of the problem. Despite the structural differences commenters note, this does not alter the fact that single source prescription drugs analogous to those sold within the U.S. are three to four times less expensive in economically comparable countries.[177] This contributes to potentially avoidable expenditures under the Medicare program, and CMS is authorized under section 1115A of the Act to test an alternative rebate methodology that incorporates international drug pricing information to reduce program expenditures while preserving or enhancing beneficiary quality of care. After consideration of the commenter's arguments, we disagree that GDP-based criteria alone would be insufficient to determine a set of economically comparable countries for purposes of the GLOBE Model. As such, we decline to adopt the commenter's suggestion.

*Final Decision:* After consideration of the public comments received, CMS is finalizing § 513.310(b) as proposed with minor technical modifications and finalizing § 513.300 with modification to clarify that the definitions of real GDP

[176] RAND Corp. Prescription Drug Prices in the U.S. Are 2.78 Times Those in Other Countries, Feb. 1, 2024). Available at: *https://www.rand.org/news/press/2024/02/01.html.*

[177] RAND Corp. Prescription Drug Prices in the U.S. Are 2.78 Times Those in Other Countries, Feb. 1, 2024). Available at: *https://www.rand.org/news/press/2024/02/01.html.*

per capita and annual real GDP are for purposes of § 513.310(b). In addition, we are also finalizing non-substantive restorative changes throughout the regulatory text to restore the word ''reference'' where it was inadvertently omitted, thereby ensuring that the defined term ''reference country'' is used consistently throughout.

f. Data and Methodology for Identifying the GDP (PPP) Adjuster

In section II.G.1.f. of the GLOBE Model proposed rule (90 FR 60273), we proposed the data sources and calculation CMS would use to identify the GDP (PPP) adjuster, which CMS proposed to codify at § 513.430. Sections II.G.2. and II.G.6. of this final rule discuss the application of the GDP (PPP) adjuster in calculating the per unit GLOBE Model benchmark.

We proposed that, for each country in the set of reference countries, CMS would 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 § 513.20) as determined by CMS. Specifically, at § 513.430(a), we proposed 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, in § 513.430(c) and (d), we proposed to apply the following limitations: (1) the country's real GDP (PPP) per capita and U.S. real GDP (PPP) per capita data must be from the same year; and (2) the real GDP (PPP) per capita used must be for the same year as the data used to calculate the per unit country-level price (as set forth in § 513.410(a)(4)), or the most recent earlier year available; and (3) in cases where the resulting ratio is less than 1.000, the GDP (PPP) adjuster would be set to 1.000.

In Table 5 of the GLOBE Model proposed rule (90 FR 60272), we presented an illustrative GDP (PPP) adjuster using 2024 data from the CIA World Factbook.

We also proposed that, at the beginning of each applicable calendar quarter, 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, as the data source used, in § 513.430(b), we proposed that CMS would use the most recently available information from the CIA World Factbook for each reference country.

On February 4, 2026, the CIA announced that the CIA World Factbook is no longer being published.

The following is a summary of the comments received and our responses.

*Comment:* A couple of commenters stated that the CIA announced that the CIA World Factbook has ended and recommend that CMS identify an alternative data source for GDP information. A commenter recommended that CMS use GDP information published by the World Bank.

*Response:* We thank the commenters for their input. CMS is aware that on February 4, 2026, the CIA announced the sunset of the CIA World Factbook. As noted in the GLOBE Model proposed rule (90 FR 60271), besides the CIA World Factbook, CMS also considered using GDP information from the World Bank or the International Monetary Fund (IMF). Based on our assessment of these two data sources, both data sources provide authoritative, standardized and timely GDP information. In addition, both sources use the International Comparison Program (ICP) data, a global statistical initiative to produce Purchasing Power Parity (PPP) metrics. The World Bank has led the global program coordination of the ICP since 2009.

We compared illustrative per unit Method I GLOBE Model benchmarks using these three potential data sources for the GDP (PPP) adjuster. Our analysis showed there is minimal change on the illustrative per unit Method I GLOBE Model benchmark. Specifically, we estimated that the illustrative per unit Method I GLOBE Model benchmark using the World Bank data for the GDP (PPP) adjuster was, on average, 2.5 percent lower than the corresponding benchmark using the CIA World Factbook. Similarly, using the IMF data for the GDP (PPP) adjuster, the illustrative per unit Method I GLOBE Model benchmark was, on average, 1.8 percent lower compared to the corresponding benchmark using the CIA World Factbook. The estimated percentage difference was 0.7 percent between the illustrative per unit Method I GLOBE Model benchmark using the IMF and the World Bank data. We found qualitatively similar results when comparing our proxy illustrative per unit Method II GLOBE Model benchmark.

To ensure consistency of data sources, given its established history and expertise with the underlying ICP data, and in response to public comment supporting the use of the World Bank data, we believe the World Bank would be the most suitable source for GDP and PPP information for purposes of applying a GDP (PPP) adjuster in the identification GLOBE Model benchmarks. However, to minimize the risk of not having a specified data source for GDP and PPP information, we believe that it is prudent to establish a secondary data source.

Therefore, we are opting to modify the regulatory text to finalize that CMS would use GDP and PPP information from the World Bank as the primary source of GDP and PPP data and the International Monetary Fund as an alternative source if World Bank data are not available. Specifically, CMS would use the World Bank's World Development Indicators (WB WDI)[178] GDP per capita PPP (current international $)(NY.GDP.PCAP.PP.CD) series for the real GPD per capita.[179] If World Bank Development Indicators GDP per capita PPP is not available for a reference country, CMS would use the International Monetary Fund GDP per capita, current prices, purchasing power parity series.[180] We note that the GDP (PPP) adjuster would be used to calculate the per unit country-level price only; as finalized in this final rule, the GDP (PPP) adjuster would not be used to identify the set of reference countries. In Table 5 of this final rule, we present an illustrative GDP (PPP) adjuster using the World Bank data for the set of reference countries set forth in § 513.310(b).

[178] The World Bank Atlas refers to the methodology the World Bank uses to calculate gross national income per capita. The World Bank World Development Indicators refers to a database that contains a collection of current and historical information related to all aspects of development.

[179] World Bank GDP per capita (PPP) series: *https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD.*

[180] International Monetary Fund GDP per capita (PPP) series. *https://www.imf.org/external/datamapper/PPPPC@WEO/OEMDC/ADVEC/WEOWORLD.*

**TABLE 5: ILLUSTRATIVE LIST OF US AND REFERENCE COUNTRIES GDP (PPP) ADJUSTER**

| Countries | GDP (PPP) Adjuster* based on 2024 World Bank Development Indicators GDP |
|---|---|
| United States | 1.000 |
| Canada | 1.328 |
| France | 1.372 |
| Germany | 1.167 |
| Italy | 1.384 |
| Japan | 1.648 |
| United Kingdom | 1.383 |
| Australia | 1.190 |
| South Korea | 1.406 |
| Netherlands | 1.000* |
| Spain | 1.480 |
| Austria | 1.161 |
| Belgium | 1.167 |
| Czech Republic | 1.498 |
| Ireland | 1.000 |
| Norway | 1.000 |
| Sweden | 1.194 |
| Switzerland | 1.000 |
| Denmark | 1.048 |
| Israel | 1.500 |

*Notes: Real GDP and real GDP per capita are based on PPP and are based on World Bank data as set forth in § 513.430. 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 set at 1.000 in cases where the ratio is below 1.0. The GDP (PPP) adjuster is used in the calculation of the per unit Method I GLOBE Model benchmark as set forth in § 513.410 and the per unit Method II GLOBE Model benchmark as set forth in § 513.420.

*Comment:* A few commenters believed GDP-based thresholds are inadequate or not enough to account for differences in income levels and health care systems between the U.S. and the proposed reference countries.

*Response:* We thank the commenters for their input on the inclusion of a GDP (PPP) adjuster. We disagree that, for purposes of the GLOBE Model, the GDP-based thresholds are inadequate or not enough to account for differences in income levels and healthcare systems between the U.S. and a reference country or that CMS must address these differences among reference countries. CMS 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 greater anticipated model savings and beneficiary coinsurance reductions for GLOBE Model beneficiaries. In the GLOBE Model proposed rule (90 FR 60277 and 60279), CMS stated that 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.

CMS understands the complexity of a country's healthcare system and selection as a reference country does not imply perfect similarity with the U.S. GDP-based measures are standard economic practice for cross-country comparisons and as such, are used to compare the economic size, growth, and living standards of countries, often using purchasing power parity to adjust for cost of living differences. Although commenters identify additional factors that may affect prescription drug prices, those observations do not show that the approach taken by CMS is unreasonable for the purpose of accounting for economic differences across countries. The existence of other variables does not, by itself, mean that CMS has failed to consider an important aspect of the problem.

Further, we note that, as discussed in section II.G.3.a. of the GLOBE Model proposed rule (90 FR 60281) and this final rule, CMS proposed to increase the per unit GLOBE Model benchmark by a minimal threshold adjustment.

*Final Decision:* After consideration of the public comments received, CMS is finalizing § 513.430 with modifications as described later in the rule.

- In § 513.430(a), the following is added: For a country, subject to paragraph (b) of this section, CMS calculates the real GDP per capita by dividing the total gross domestic product based on purchasing power parity (PPP) by the total population;
- § 513.430(b) is revised to read as follows: 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 real GDP per capita at the start of the applicable ASP calendar quarter, as determined by CMS, using the total gross domestic product based on purchasing power parity (PPP) and the total population for the same year as estimated and available in the World Bank World Development Indicators GDP per capita PPP (current international) (NY.GDP.PCAP.PP.CD), if available, otherwise as available in the International Monetary Fund GDP per capita, current prices, purchasing power parity series;

- In § 513.430(c), the word ''real'' is added before GDP (PPP) per capita for clarification;
- In § 513.430(c)(2), the word ''unadjusted'' is struck and the phrase ''set forth in § 513.410(a)(4)'' is inserted after ''country-level price,'' in order to align with the finalized regulatory text in § 513.410(a); and
- In § 513.430(d), CMS is making a non-substantive technical modification to rename the paragraph from ''Maximum ratio'' to ''Minimum ratio,'' which more accurately describes the cases where the resulting GDP (PPP) adjuster ratio less than 1.000 is set to 1.000.

2. Methodology To Identify the Per Unit GLOBE Model Benchmark

In the GLOBE Model proposed rule (90 FR 60273), we stated that the proposed GLOBE Model would test alternative calculations to those used by CMS to determine the Medicare Part B drug inflation rebate amount that manufacturers of Part B rebatable drugs owe to the Federal 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 part 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 final rule) while ensuring that beneficiary coinsurance and net Medicare Part B payment would not exceed what they would be absent the model test. In section II.G.2 of the GLOBE Model proposed rule (90 FR 60273 through 60280), we proposed 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 proposed 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) adjusted [181] 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 which data is available according to the hierarchy set forth in § 513.310(c)(2) for the GLOBE Model drug and remains in place for each applicable calendar quarter thereafter until the end of the model performance period, as discussed in section II.G.2.a. of this final rule); or (2) a ''per unit Method II GLOBE Model benchmark'' that would reflect the volume-weighted average of the GDP (PPP) adjusted net price per HCPCS billing unit among a set of reference countries for the applicable ASP calendar quarter based on data calculated and voluntarily reported by manufacturers to CMS on a quarterly basis (this benchmark would only be available and identified by CMS if CMS determines that manufacturer-submitted international drug net pricing data is complete and valid as set forth in § 513.610).

As further described in section II.G.2.a. of this final 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 proposed 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 applicable ASP calendar quarter (or prior calendar quarter, if necessary) that aligns with the first applicable calendar quarter 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 sales data or pricing data and corresponding 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. We proposed that 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 final 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 proposed 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 § 513.610 and described in section II.G.6. of this final rule) and identify the volume-weighted average per unit price as the per unit Method II GLOBE Model benchmark. As set forth in § 513.420, we proposed that 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 final rule) would be calculated by the manufacturer and would be rounded to the third decimal place prior to being submitted to CMS.[182] As discussed in section II.G.6. of this final rule, we proposed that manufacturers would have two data submission options—streamlined and limited—for the international drug net pricing data that would be voluntarily submitted. We refer readers to section II.G.6. of this final rule for additional details on the two manufacturer data submission options.

In § 513.410, we proposed that, prior to model start, 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, if available. These benchmarks would remain in place for applicable calendar quarters that the drug is a GLOBE Model drug

[181] GDP (PPP) means purchasing power parity (PPP)-adjusted per capita gross domestic product (GDP).

[182] When there is more than one manufacturer submission for a GLOBE Model drug for an applicable calendar quarter, CMS calculates 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 final rule.

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, we proposed that 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 that the drug is a GLOBE Model drug until the end of the model. Thus, quarterly for each GLOBE Model drug, after CMS identifies 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), we proposed that 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 (for example, the 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 the GLOBE Model proposed rule (90 FR 60280), we proposed 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, 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's ability to test the model, we believe that 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.

a. Methodology To Identify the Per Unit Method I GLOBE Model Benchmark Using Existing Data Sources

In section II.G.2.a. of the GLOBE Model proposed rule (90 FR 60274) and in § 513.410, we proposed 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 final rule. As discussed in section II.G.1.b. of this final rule, CMS would use available international drug pricing information data sources in accordance with the proposed hierarchy (as set forth in § 513.310(c)) to select the data source used to identify a per unit country-level price for each country that is included in the set of reference countries (as specified in § 513.310(b)).

Specifically, we proposed 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 § 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 the first applicable calendar quarter that the drug is a GLOBE Model drug (or earlier quarter if applicable) for any country that is included in the set of reference countries identified in proposed § 513.310(b). Then, 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 is unavailable for a reference country using the selected data source.

To select a data source at the highest level of the hierarchy as available and identify available international drug pricing information for the GLOBE Model drug, we proposed 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 proposed that CMS would extract and use data that, as determined by CMS, (1) represent the price of a U.S. originator drug (as defined in § 513.20) 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 long descriptor, including route of administration (if applicable); and (4) have strength data.[183] In § 513.20, we proposed to define U.S. originator drug to mean ''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 FD&C Act. U.S. originator drugs are also sometimes called brand name drugs, reference listed drug, or reference products.''

We proposed to only extract and use data for a 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, CMS 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 proposed that CMS would also examine the data source's methods for describing drug products in terms of being sold as a U.S.

[183] Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug pricing information in the 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.

originator drug, international originator drug, or other indicator that would allow CMS to not extract and use international drug pricing information for drug products that are identified as international generic or biosimilar biological products, or U.S. generic or biosimilar biological products (that is, products that are not a single source drug or sole source biological product).

To avoid unintentionally using extracted international drug pricing information for drug products that do not align with the GLOBE Model drug's HCPCS Level II code long descriptor, we proposed that CMS would apply data checks to ensure that the extracted data aligns with the HCPCS Level II code long 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 proposed that CMS would perform additional data checks to identify and discard extracted data when the sales, pricing, or volume data are not greater than zero or the drug product information (for example, product strength or package size) is inconsistent or not verifiable with available product labeling or product approval information. We proposed the exclusion of these records because these records could inappropriately contribute to the calculation of per unit country-level prices.

In addition, we proposed 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 proposed to identify the quantity of drug without counting overfill based on the package labeling or other documentation related to product licensing within a country. We noted that 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 long 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 (as defined in § 513.20). We proposed that, in such cases where we confirm a difference and an appropriate conversion method, CMS would make adjustments in how the pricing, sales and volume data are associated with the HCPCS Level II code long descriptor, as necessary, before calculating the per unit country-level price, such as limiting the number of HCPCS billing units assigned. In § 513.20, we proposed that ''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. 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 cases where CMS would make an adjustment would be uncommon, and, in most cases, the appropriate conversion would be straightforward. We noted that there could be additional cases when adjustments would be necessary if international drug pricing information 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 long 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 code for a GLOBE Model drug, we proposed that CMS would assess whether there are differences in the international drug pricing information attributed to data source coding or country-specific considerations to determine whether the available international drug 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 drug 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 consider 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 per unit country-level prices, could result in a per unit country-level price that would not be a reasonable benchmark, at § 513.410(a)(4)(i)(A), we proposed to remove pricing information at the dosage form and strength level for a country that falls below 5 percent of the average U.S. price. Specifically, prior to calculating the per unit country-level price, we proposed that 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 GLOBE Model drug (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, we proposed 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 as such term is defined in 513.20. 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 the GLOBE Model drug 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 applicable ASP calendar quarter, we believe that using available ASP data from the calendar quarter before the applicable ASP calendar quarter, would be a reasonable alternative and would be suitable for purposes of removing international drug 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 U.S. price). Using available international drug pricing information, we estimated 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 per unit country-level price for a reference country being available. At a 10 percent threshold level, we observed that removing reference country pricing information had several effects: it removed pricing information for a given dosage form and strength that appears consistent with U.S. pricing information, it removed pricing information with significant corresponding sales volume for that dosage form and strength, and in some cases, it removed all pricing data for a dosage form and strength. This resulted in higher country-level prices that approached U.S. pricing in the data source, providing evidence that this approach would not likely produce a reasonable estimate of the pricing realized by manufacturers for the reference countries identified in proposed § 513.310(b). This analysis 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. We noted that 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 a GLOBE Model drug for a country that is included in the set of reference countries, we proposed 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 § 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 previously and in proposed § 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 long descriptor (for example, mg, ml, mcg, etc.), as applicable, using volume and strength information as proposed in § 513.410(a)(3). Note that volume data referred to in these steps includes information about the quantity of drug in the product packaging and, when available, the corresponding volume data, as applicable.

*Step 3:* Adjust the volume data (as proposed in § 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 long 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 § 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 data and corresponding volume data is used, the applicable calculation is as follows (as proposed in § 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 U.S. price as set forth in § 513.410(d).

(2) Using remaining data, CMS sums the adjusted volume data for the presentation levels for the applicable international analog (as defined in § 513.600).

(3) Using remaining data, CMS sums the total sales for all the presentation levels for the applicable international analog (as defined in § 513.600).

(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 long descriptor.

b. If an international drug pricing information data source with pricing data (such as ex-manufacturer or list prices) is used (that is, the data source does not contain available corresponding 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 § 513.410(a)(4)(ii)):

(1) For each extracted 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 long descriptor.

(2) CMS divides the price 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 long 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 § 513.410(d).

(4) Using remaining data, CMS calculates the sum of the price per unit calculated in Step 5b(2) for each 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 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 long descriptor.

*Step 6:* Calculate the per unit GDP (PPP) adjusted country-level price by multiplying the per unit country-level price calculated in Step 5 by the applicable GDP (PPP) adjuster for such country as set forth in § 513.430 (and illustrated in Table 5 in this final rule) 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 proposed 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. For a discussion on use of a data source with pricing data and corresponding volume data, we refer readers to the final decision in this section of this final rule.

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 are, on average, about 422 percent more expensive in the U.S. than in non-U.S. OECD countries.[184] This study did not account for economic differences across markets. We believe that selecting the lowest per unit GDP (PPP)-adjusted country-level price as the per unit Method I GLOBE Model benchmark is an acceptable alternative approach to the rebate amount calculation under the Medicare Part B Drug Inflation Rebate Program. This approach incorporates international drug pricing information for certain single-source drugs and sole-source biological products, and is justified by the fact that the extremely high U.S. prices for these drugs—compared to economically comparable countries—suggest there are potentially avoidable expenditures that could be addressed while preserving or enhancing beneficiaries' quality of care. 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 also believes that using the lowest GDP (PPP) adjusted country-level price when available existing international drug pricing information data sources are used is the most appropriate approach for the GLOBE Model because these data sources may not include pricing information that reflects all price concessions. Calculating an across country average using existing international drug pricing information data sources that contain sales data or pricing data that do not represent actual net prices paid for a GLOBE Model drug in the reference countries (because confidential manufacturer rebates would not likely be accounted for within available existing data sources) or using the *n* lowest country-level price or the average of the *n* lowest GDP (PPP) adjusted country-level prices would be even less likely to estimate the payment levels drug manufacturers are willing to accept for their products, from drug manufacturers' perspectives.

CMS 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. Further, we stated our belief that adjusting a single country-level price using a GDP (PPP) adjuster is reasonable (90 FR 60277). Specifically, given that the proposed reference countries are economically comparable to the U.S. and our proposal to identify the lowest country-level price, we would expect that adjusting for country wealth differences based on GDP (PPP) adjustment would more likely result in an appropriate estimate of international drug pricing information that align with other country-specific dynamics and the payment levels drug manufacturers are willing to accept for their products, from drug manufacturers' perspectives.

We sought 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 sought 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 sought 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 final rule.

The following is a summary of the comments received and our responses.

*Comment:* A few commenters stated that, for new drugs, pricing information for international analogs for the applicable ASP calendar quarter for the first applicable calendar quarter the Part B rebatable drug is a GLOBE Model drug might not be available in existing data sources available to CMS and there would be no Method I benchmark for such GLOBE Model drugs for the remainder of the model test. A commenter suggested that CMS should reassess the availability of international drug pricing information periodically to address the risk of the Method I benchmark being not available.

*Response:* We thank the commenters for sharing their view that there should be a mechanism to ensure that a lack of available international drug pricing information for the applicable ASP calendar quarter for the first applicable calendar quarter the drug is a GLOBE Model drug does not preclude CMS's ability to test a Method I benchmark for such drug. We agree and believe that the commenters' suggestion that in such cases CMS should reassess the availability of international drug pricing information for such drug in existing data sources is reasonable and would enhance the integrity of the model test. Therefore, we are finalizing our proposed process for identification of

[184] Andrew W. Mulcahy, Christopher M. Whaley, Mahlet G. Tebeka, 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.*

the per unit Method I GLOBE Model benchmark in § 513.410 with modifications to establish that CMS would apply the process for identification of the per unit Method I GLOBE Model benchmark for subsequent applicable calendar quarters during the model performance period until a per unit Method I GLOBE Model benchmark is identified. We are retaining that, once identified, the Method I benchmark would remain in place for each applicable calendar quarter thereafter until the end of the model performance period.

Specifically, we are modifying §§ 513.410(a)(1) and 513.410(c) to specify that the identification of available international drug pricing data is subject to the timing specifications in revised § 513.410(c). In § 513.410(c)(2), we are modifying our proposal to specify that, for each Part B rebatable drug that becomes a GLOBE Model drug during the model performance period, CMS would identify the per unit Method I GLOBE Model benchmark for earlier of: (1) the first applicable calendar quarter for which the drug is a GLOBE Model drug; or (2) the first applicable calendar quarter during the model performance period for which CMS identifies a per unit Method I GLOBE Model benchmark for the GLOBE Model drug. In revised § 513.410(c)(3), we are specifying that, subject to new §§ 513.410(c)(4) and 513.410(c)(5), the per unit Method I GLOBE Model benchmark would remain in place for each applicable calendar quarter thereafter until the end of the model performance period. In new § 513.410(c)(4), we are adding that, when the per unit Method I GLOBE Model benchmark for a GLOBE Model drug is identified for an applicable calendar quarter that is not the first applicable calendar quarter for which the drug is a GLOBE Model drug (that is, CMS has identified a per unit Method I GLOBE Model benchmark pursuant to new § 513.410(c)(2)(ii)), for each subsequent calendar quarter, CMS would determine if a per unit Method I GLOBE Model benchmark for that GLOBE Model drug for an earlier applicable calendar quarter is available and, if available, would apply such benchmark for the remaining applicable calendar quarters thereafter until the end of the model performance period. We intend that these modifications will allow CMS to identify a per unit Method I GLOBE Model benchmark for each GLOBE Model drug using international drug pricing information for the earliest applicable calendar quarter, as available, and strengthen the integrity of the model test.

In addition, we are adding new § 513.410(c)(5) to address situations where the organization that maintains the data source that was selected in accordance with § 513.310(c)(2) makes updates to the international drug pricing information for international analogs for a GLOBE Model drug available to users within 90 days from the end of the calendar quarter for which drug pricing information is compiled. In such cases, as determined by CMS, CMS would use the updated international drug pricing information as available to identify the per unit Method I GLOBE Model benchmark amount for purposes of determining the per unit GLOBE Model rebate amount for such GLOBE Model drug, and for purposes of calculating the GLOBE Model beneficiary coinsurance adjustment as set forth in § 513.210(b).

*Comment:* A commenter stated that there is no benefit for Medicare and beneficiaries from Method II submissions, as manufacturers would only submit data if the calculated benchmark is favorable to them and therefore recommended that CMS rely on Method I and implement strategies to prevent gaming. Another commenter supported using only Method I given the limited benefits of encouraging manufacturer voluntary submission of net pricing data.

*Response:* We appreciate the commenters' support to use the per unit Method I GLOBE Model benchmark as a primary benchmark. As we stated in the GLOBE Model proposed rule (90 FR 60245), for the Method I benchmark, CMS 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. CMS appreciates the concern raised by the commenter regarding the potential for manufacturer strategic behavior designed to circumvent the GLOBE Model's rebate obligations. CMS takes these concerns seriously and agrees that the integrity of the international benchmark—and the model's ability to achieve meaningful savings for Medicare beneficiaries—depends on robust safeguards against gaming and evasion.

We note that several features of the GLOBE Model's design provide structural protections against the manipulation scenarios described by commenters. The international benchmark would be derived from publicly available and administratively reported pricing data across multiple comparator countries, reducing the ability of any single manufacturer to materially distort the benchmark through pricing actions in a single foreign market. Nonetheless, CMS acknowledges that no model design is fully immune to strategic behavior, and that the concerns raised by commenters reflect real-world risks that warrant active monitoring and enforcement attention. As such, CMS will monitor for changes in available international drug price information throughout the duration of the GLOBE Model payment period.

*Comment:* A few commenters stated the lowest country-level price may not be representative of pricing across the set of reference countries. Commenters suggested that to ensure robustness and representativeness of the benchmark the per unit Method I GLOBE Model benchmark should be identified using pricing information for more than one country and that there should be a requirement for a minimum number of countries used to identify the benchmark. A commenter suggested that more than one data source could be used to increase the number of country prices that would be used. A commenter cited a study related to drug launches and stated that the study's findings suggest that, based on past patterns, the Method I benchmark for a GLOBE Model drug could be based on pricing information from a very limited number of reference countries and, in some cases, potentially a single reference country. A few commenters suggested that CMS should use an alternative, such as the second lowest, median, or average country-level price or an across country volume-weighted average price (similar to the Method II approach), to identify the Method I benchmark.

*Response:* We thank the commenters for noting that there could be potential alternatives to our proposal to identify the lowest country-level price as the per unit Method I GLOBE Model benchmark.

In response to the suggestion to use pricing information for more than one country, we note that, as proposed in § 513.310(c)(3), if there is more than one data source for a GLOBE Model drug, CMS would select the data source at the highest level of the hierarchy that contains information from the highest number of reference countries. We believe that the $100 million OM Part B spend threshold in the GLOBE Model drug inclusion criteria and the drug exclusions that we are finalizing in this final rule, including the exclusion of orphan-only drugs, reduce the likelihood that newly launched drugs would enter the GLOBE Model without being launched within the finalized set

of reference countries.[185] However, because there could be cases where international drug pricing information would only be available for one reference country, we decline to add a requirement for international drug pricing information for a minimum number of reference countries to be available in order for CMS to identify a Method I benchmark to avoid cases where a per unit GLOBE Model drug benchmark amount would not be identified and CMS would not be able to apply the model test for such applicable calendar quarters which may distort the model evaluation.

In response to the suggestion to use the second lowest, median, or average country-level price or an across country volume-weighted average price instead of the lowest country-level price, we note that these potential alternatives would likely result in a higher Method I benchmark than our proposed approach, which may create greater uncertainty for manufacturers with respect to their decision-making related to voluntarily reporting international drug net pricing data and CMS's ability to test the use of a Method II benchmark. Further, because international drug pricing information available to CMS through existing data sources may overstate actual prices realized (because confidential manufacturer rebates would not likely be accounted for within these available data sources), we do not believe that these alternative approaches for identifying a Method I benchmark would be prudent or essential for the GLOBE Model test.

In response to the suggestion to use international drug pricing information for more than one data source, as discussed in the GLOBE Model proposed rule (90 FR 60269), we note that CMS did not propose to combine data from different data sources to identify international drug pricing information for a GLOBE Model drug across countries because there could be cases where different types of pricing information for a drug from a reference country would be combined. We also stated that CMS may reconsider the potential value of such an approach based on feedback from interested parties and further information gathering. We appreciate the commenters' feedback; however, we remain concerned that combining pricing information across existing data sources could result in unrepresentative benchmarks. Therefore, we continue to believe that our proposed approach is a reasonable balance between concerns about using available international drug pricing information in a manner that would result in a Method I benchmark that is representative of prices for the set of reference countries to the extent feasible and the potential difficulties inherent in combining information extracted from multiple data sources.

After considering the commenters' feedback, based on our analyses and aims of the model test, on balance, we continue to believe that identifying the lowest country-level price as the Method I benchmark is the most appropriate approach for the GLOBE Model test of an alternative Medicare Part B drug inflation rebate amount calculation that would reduce program expenditures while preserving or enhancing quality of care. We further believe that retaining our proposed approach for identifying the per unit Method I GLOBE Model benchmark would not discourage manufacturers from reporting international drug net pricing data (for a Method II benchmark).

*Comment:* Commenters shared mixed views on CMS's proposal to identify the per unit Method I GLOBE Model benchmark once for the first applicable calendar quarter the Part B rebatable drug is a GLOBE Model drug. A few commenters supported CMS's proposal noting the potential for manufacturer behavioral responses that could increase international list prices while not increasing net prices. For example, raising international list prices over time while also increasing international rebates. In contrast, a few commenters stated that, to avoid GLOBE Model rebates, manufacturers may launch international analogs only in reference countries with higher prices, delaying market entry or supply in reference countries with lower prices until after CMS identifies the per unit Method I GLOBE Model benchmark. A few commenters expressed concern that a per unit Method I GLOBE Model benchmark for the first applicable calendar quarter the drug is a GLOBE Model drug may not represent actual prices for the set of reference countries over time, during the remainder of the model performance period. Commenters suggested that the Method I benchmark could be updated to include pricing information that reflects pricing changes, such as higher or lower prices that reflect a more informed perspective on the value of the drug and market changes.

*Response:* As we stated in the GLOBE Model proposed rule (90 FR 60245), for the Method I benchmark, CMS 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. In response to the suggestion that the Method I benchmark could be updated during the 5-year performance period to reflect higher prices, we note that this was an alternative we discussed in the GLOBE Model proposed rule and rejected (90 FR 60274). As evidenced by commenters' feedback, the potential ease with which available international drug pricing information could be potentially manipulated by manufacturers, such as 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 (regardless of whether actual pricing reflects a more informed perspective on the value of the drug and market changes), and given that such behavioral change would impede CMS's ability to test the model, we continue to 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, when feasible) and use that benchmark for the duration of the GLOBE Model.

In response to the suggestion that the Method I benchmark could be updated during the 5-year performance period to reflect lower prices based on a more informed perspective on the value of the drug and market changes, we decline to adopt this modification at this time to avoid increasing the complexity of the Method I benchmark approach which may confound the monitoring and evaluation of this aspect of the model, except, in cases when the per unit Method I GLOBE Model benchmark for a GLOBE Model drug is identified for an applicable calendar quarter that is not the first applicable calendar quarter for which the drug is a GLOBE Model drug as set forth in new § 513.410(c)(4) as discussed in this section of this final rule. CMS will monitor international drug pricing changes during the model performance period and would, if necessary for the integrity of the model test, consider this alternative in future notice and comment rulemaking.

Additionally, we acknowledge commenter's concerns that to avoid GLOBE Model rebates, manufacturers may launch in only reference countries with higher prices or delay market entry

[185] Orphan-only drug means a drug that is designated as a drug for only one or more rare diseases or conditions under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) and for which the only approved indication (or indications) is for one or more such rare diseases or conditions. Refer to § 513.130(c) for the GLOBE Model drug exclusion criteria.

in reference countries with lower prices until after CMS identifies the per unit Method I GLOBE Model benchmark. While these are potential manufacturer responses, our analysis of the illustrative 2024 GLOBE Model Drug HCPCS Level II Codes List (as shown in Table 4 in this final rule) showed that this risk is low as the average time on market since FDA approval for these drugs is 13.5 years, and therefore, if manufacturers were to launch these drugs and biological products in reference countries, they likely would have already done so.

*Comment:* A few commenters stated that transparency is necessary for stakeholders to understand how CMS identified the model benchmarks. Some commenters specifically believed that, because CMS proposes using third-party proprietary existing data sources to identify the per unit Method I GLOBE Model benchmark, CMS should provide full transparency so stakeholders, including manufacturers, would have insight into the data, assumptions, and validation. A few commenters expressed concern that a process without transparency may have errors and would not likely be suitable for future program design. A commenter stated that CMS must develop at least an outline of the procedures CMS will follow to calculate the relevant comparable prices from the comparator nations and allow for public comment on the lowest-cost product or the weighted average prices.

*Response:* We thank these commenters for their feedback. CMS supports transparency to promote fair drug prices. CMS disagrees that it must develop at least an outline of the procedures CMS will follow to calculate the per unit GLOBE Model Method I benchmark. CMS provided the public with sufficient detail and a meaningful opportunity to comment on the process through the GLOBE Model proposed rule (90 FR 60244). In the GLOBE Model proposed rule, we proposed criteria that CMS would use to select an existing data source (90 FR 60266 through 60269 and § 513.310(c)) and a multiple step process that CMS would use to extract and use international drug pricing information from the selected existing data source (90 FR 60274 through 60278 and § 513.410) to identify the per unit Method I GLOBE Model benchmark for a GLOBE Model drug and ensure data quality and transparency. These requirements allow CMS the ability to assess not only the data elements, but also the data collection and processing practices for the data sources and ensure they are appropriate to identify the per unit Method I GLOBE Model benchmark for a GLOBE Model drug. As we do for all CMS Innovation Center models, CMS would create and maintain necessary documentation to support the GLOBE Model test, which may include confidential proprietary information and would not be releasable, and CMS would share nonsensitive model information with stakeholders through the GLOBE Model website, while ensuring the confidentiality of data as appropriate.

We understand that using third-party or proprietary data to inform the GLOBE Model benchmarks would mean that certain data may not be releasable in granular form, although certain data at a higher level, such as monitoring and evaluation findings, would be releasable. We believe that stakeholders would have different interests and information needs regarding specific per unit Method I GLOBE Model benchmarks. For example, Medicare beneficiaries, healthcare providers, researchers and entities interested in impacts of the GLOBE Model on Medicare Part B drug spending may find it sufficient to have access to the GLOBE Model beneficiary coinsurance percentages (which would be based on either a Method I or Method II benchmark) that will be posted quarterly on the GLOBE Model website. We note that, in § 513.710(b)(1)(iv)-(v), CMS proposed to provide GLOBE Model participants (that is, manufacturers of GLOBE Model drugs), among other information, the per unit Method I GLOBE Model benchmark and the per unit Method II GLOBE Model benchmark as part of the GLOBE Model Preliminary Rebate Report for each GLOBE Model drug.

*Comment:* A commenter expressed concerns that data extracted from existing international pricing data do not reflect real-world pricing conditions that could result in over- or under-estimated rebates and payment adjustments. The commenter recommended incorporating validation or sensitivity-testing mechanism and providing greater transparency around data sources and assumptions to improve the reliability of the benchmarks.

*Response:* We thank the commenter for sharing their concern regarding the proposed international drug pricing information that CMS proposed to use to identify the per unit Method I GLOBE Model benchmark. In section II.G.1.a. of the GLOBE Model proposed rule (90 FR 60267), CMS discussed that international drug pricing information in available data sources may be based on prices 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 and that confidential manufacturer rebates would not likely be accounted for within these available data sources. As such, existing sources for international drug pricing information may overstate actual prices realized by manufacturers. In § 513.310(c)(1), we proposed and are finalizing in this final rule criteria for the existing data sources that CMS would use, including that such data sources would 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. As such, we disagree that additional transparency is needed around data sources and data source assumptions.

Additionally, CMS would likely be unable to publicly release certain underlying data elements, as they would include proprietary or confidential commercial information. Even so, CMS believes manufacturers would be able to estimate the per unit GLOBE Model benchmark, as: (1) manufacturers have access to their own international drug pricing information; (2) they likely have access to the data sources described in the GLOBE Model proposed rule (90 FR 60267); (3) detailed steps for how CMS would use available international drug pricing information are outlined in sections II.G.1 through II.G.7 of the GLOBE Model proposed rule (90 FR 60265 through 60299) and this final rule; and (4) GLOBE Model adjusted coinsurance percentages would be published on the GLOBE Model website quarterly, providing insight into the difference between the per unit GLOBE Model benchmark amount and the Medicare payment limit. Also, the per unit Method I GLOBE Model benchmark as identified under § 513.410 and the per unit Method II GLOBE Model benchmark, if available, as identified under § 513.420 will be shared with GLOBE Model participants as part of the GLOBE Model Preliminary Rebate Report for each GLOBE Model drug.

Further in section II.G.2.a of the GLOBE Model proposed rule (90 FR 60274), CMS stated that to 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, CMS proposed to remove pricing information at the dosage form and strength level for a country that falls below 5 percent of the average U.S.

price and considered alternative approaches as discussed in this section of this final rule. As such, we do not believe that additional sensitivity-testing mechanisms or validation of existing data sources would be 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, CMS proposed to establish the per unit Method I GLOBE Model benchmark once at a baseline and use that benchmark for the duration of the GLOBE Model. In this final rule, we are slightly modifying our proposed approach to protect model integrity and address situations when CMS does not identify a per unit Method I GLOBE Model benchmark for the first applicable calendar quarter for which the Part B rebatable drug is a GLOBE Model drug and in cases where the existing data source used makes updates to the international drug pricing information for international analogs for a GLOBE Model drug available to users within 90 days from the end of the calendar quarter for which drug pricing information is compiled. On balance, we continue to believe that data extracted from existing data sources available to CMS would be adequate for purposes of identifying country-level prices and a per unit Method I GLOBE Model benchmark for purposes of the GLOBE Model.

*Final Decision:* After consideration of the public comments received, CMS is finalizing the methodology for identifying the per unit Method I GLOBE Model Benchmark using existing data sources at § 513.410, with modifications to: (1) address situations when CMS does not identify a per unit Method I GLOBE Model benchmark for the first applicable calendar quarter for which the Part B rebatable drug is a GLOBE Model drug; (2) clarify the benchmark calculation steps when pricing data and corresponding volume data are available; and (3) clarify how the average U.S. price is calculated by CMS. These modifications include:

- Revising §§ 513.410(a)(1) and 513.410(c) to specify that the identification of available international drug pricing information is subject to the timing specifications in revised § 513.410(c) and remove extraneous language from § 513.410(a)(1);
- Revising §§ 513.410(a)(2)(i)(A) and 513.410(a)(4)(i) to include ''drug-specific'', ''sales data'', pricing data'' and ''corresponding volume data'' to align with the updates in § 513.310(c);
- Revising § 513.410(a)(4)(i)(B) to update ''paragraph (3) of this section'' to ''paragraph (a)(3) of this section'' for clarity;
- Revising § 513.410(a)(4)(i)(C) to clarify how the average country-level price per unit is calculated when sales data and corresponding volume data are available;
- Revising § 513.410(a)(4)(i)(D) to clarify how the average country-level price per unit is calculated when pricing data and corresponding volume data are available;
- Adding new § 513.410(a)(4)(i)(D)(*1*) to specify that, for each extracted price for a presentation level of the applicable international analogs (as defined in § 513.600), CMS divides the price by the number of HCPCS billing units for the presentation level of the applicable international analogs (as defined in § 513.600) 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 long descriptor. CMS limits the number of HCPCS billing units as described in paragraph (a)(3)(ii) of this section as applicable;
- Adding new § 513.410(a)(4)(i)(D)(*2*) to specify that CMS calculates the sum the products of the price per unit (as calculated in § 513.410(a)(4)(i)(D)*(1)*) and the corresponding converted volume amount (as set forth in § 513.410(a)(3)), and divides that total by the sum determined in § 513.410(a)(4)(i)(B), resulting in an average country-level price per unit, where the unit is the same unit delineated in the HCPCS Level II code long descriptor;
- Revising § 513.410(a)(4)(ii) to update ''ex-manufacturer or list price'' to ''drug-specific pricing data'' and insert ''and the data source does not contain available volume data'' to align with the updates in § 513.310(c);
- Revising § 513.410(a)(4)(ii)(A), to remove ''ex-manufacturer or list'', revise ''in the presentation level by dividing the quantity of drug in the presentation level'' to read ''for the presentation levels of the applicable international analogs (as defined in § 513.600) by dividing the quantity of drug in a presentation level'', and adding the sentence ''CMS limits the number of HCPCS billing units as described in paragraph (a)(3)(ii) of this section as applicable;''
- Revising § 513.410(a)(4)(ii)(B) to update ''ex-manufacturer or list price, as applicable'' to ''price'' to align with the updates in § 513.310(c);
- Revising § 513.410(a)(4)(ii)(D) to update ''ex-manufacturer or list price, as applicable'' to ''price'' to align with the updates in § 513.310(c);
- Revising § 513.410(a)(4)(ii)(E) to update ''ex-manufacturer or list prices that were identified'' to ''prices identified'' to align with the updates in § 513.310(c);
- Revising § 513.410(c)(2) to specify that, 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 earlier of: (1) the first applicable calendar quarter for which the Part B rebatable drug is a GLOBE Model drug; or (2) the first applicable calendar quarter during the model performance period for which CMS identifies a per unit Method I GLOBE Model benchmark for the GLOBE Model drug;
- Adding new § 513.410(c)(3) to specify that, subject to new §§ 513.410(c)(4) and 513.410(c)(5), as applicable, the per unit Method I GLOBE Model benchmark for the GLOBE Model drug remains in place for each applicable calendar quarter thereafter until the end of the model performance period;
- Adding new § 513.410(c)(4) to specify that, when the per unit Method I GLOBE Model benchmark for a GLOBE Model drug is identified pursuant to § 513.410(c)(2)(ii), for each subsequent applicable calendar quarter, CMS will determine a per unit Method I GLOBE Model benchmark for that GLOBE Model drug for the first applicable calendar quarter during the model performance period for which such benchmark is available, and will apply such benchmark for that subsequent applicable calendar quarter and the remaining applicable calendar quarters until the end of the model performance period;
- Adding new § 513.410(c)(5) to specify that, when the data source selected in accordance with § 513.310(c)(2) makes updates to the international drug pricing information for international analogs for a GLOBE Model drug available to users within 90 days from the end of the calendar quarter for which drug pricing information is compiled, CMS uses the updated international drug pricing information as available to identify the per unit Method I GLOBE Model benchmark amount for purposes of determining the per unit GLOBE Model rebate amount for such GLOBE Model drug, and for purposes of calculating the GLOBE Model beneficiary coinsurance adjustment as set forth in § 513.210(b); and
- Revising § 513.410(d)(1) to clarify how CMS calculates the average U.S.

price for a GLOBE Model drug and adding specifications for the calculation at new §§ 513.410(d)(1)(i) and 513.410(d)(1)(ii). Specifically, revised § 513.410(d)(1) clarifies that CMS uses U.S. drug pricing information from the selected data source when available to calculate the volume-weighted average U.S. price per unit. New §§ 513.410(d)(1)(i) and 513.410(d)(1)(ii) clarify the calculation that is used when drug-specific sales data or pricing data and corresponding volume data are available or pricing data are available and the data source does not contain available volume data.

CMS is also finalizing non-substantive modifications to § 513.410 to correct typographical errors in the regulatory text:

- In § 513.410(a)(1), the words ''international'' and ''and the U.S.'' are inserted and ''pricing data'' is replaced with ''pricing information;''
- The provisions within § 513.410(a)(2)(i) are renumbered and in renumbered § 513.410(a)(2)(i)(B), the words ''the GLOBE Model drug's HCPCS Level II code descriptor'' is replaced with ''that product;''
- In § 513.410(a)(2)(i), ''data'' is replaced with ''information;''
- In § 513.410(a)(3), ''HCPCS Code Level II'' is corrected to read as ''HCPCS Level II Code;''
- In § 513.410(a)(3)(i), the extraneous phrase ''for the GLOBE Model drug's HCPCS Level II code descriptor'' is removed;
- In § 513.410(a)(3)(ii)(B), the words ''per therapeutic dose'' and ''per treatment'' are added to reflect the preamble;
- In § 513.410(a)(4), the phrase ''extracted and adjusted in accordance with paragraphs (3)(i) and (3)(ii)'' is revised to read ''extracted, adjusted, and converted in accordance with paragraphs (a)(1) through (3) of this section'' and the extraneous phrase ''for the international drug by country for each country specified in § 513.310(b) for which international drug pricing information is available'' is removed;
- In § 513.410(a)(4)(i)(A) and § 513.410(a)(4)(ii)(C), the phrase ''average price in the U.S.'' is revised to read as ''average U.S. price;''
- In § 513.410(a)(4)(i)(B), the word ''adjusted'' is revised to read ''converted'', the word ''analog'' is revised to read ''analogs'', the word ''specified'' is revised to read ''defined'', and ''paragraph (3)'' is revised to read ''paragraph (a)(3);''
- In § 513.410(a)(4)(i)(D), the phrase ''average price'' is revised to read ''average country-level price;''
- In § 513.410(a)(4)(i)(D)*(2),* ''CMS'' is removed;
- In § 513.410(a)(4)(ii)(C), the phrase ''average price in the U.S.'' is revised to read ''U.S. price;''
- In § 513.410(a)(4)(ii)(D), the phrase ''using remaining data'' and the word ''unit'' are added;
- In § 513.410(d)(1), the words ''of this section'' are added;
- In § 513.410(d)(2), the extraneous phrase ''for the reference country'' is removed and the word ''percentage'' is added following the word ''add-on'' for clarification; and
- Throughout § 513.410 and in the definition of country-level price in § 513.20, ''code descriptor'' is revised to read ''code long descriptor''.

Finally, CMS is finalizing non-substantive modifications to § 513.20 to correct typographical errors in the regulatory text. Specifically, the defined term, ''GLOBE Model adjusted beneficiary coinsurance percentage'' is revised to ''GLOBE Model beneficiary coinsurance percentage.'' CMS has also added the words ''per unit GDP (PPP) adjusted'' and ''reference'' to the definition of ''Method I GLOBE Model Benchmark'' in § 513.20 for clarity and in alignment with the preamble.

b. Methodology for Identifying the Per Unit Method II GLOBE Model Benchmark Using Manufacturer Submitted Data

In section II.G.2.b. of the GLOBE Model proposed rule (90 FR 60278) and § 513.420, we proposed 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.1.d. of this final rule) when such data is available and meets acceptance criteria (as described in section II.G.6. of this final rule), as determined by CMS.

To identify available manufacturer-submitted international drug net pricing data for a GLOBE Model drug, we proposed 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 § 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 proposed 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 long 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 long 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 stated that 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 proposed that manufacturers have the option to submit international drug net pricing data for a GLOBE Model drug and we anticipated the potential situation where CMS would not identify available data, in such cases, we proposed 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, subject to § 513.420(c), when there is one manufacturer submission of international drug net pricing data for a GLOBE Model drug for an applicable calendar quarter, we proposed that the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit data element (as defined in § 513.20 and further discussed in section II.G.6. of this final rule), submitted by the manufacturer, determined to be an applicable submission by CMS as set forth in § 513.610(a)(4), and identified as available manufacturer-submitted international drug net pricing data as set forth in in § 513.310(d), would be identified as the per unit Method II GLOBE Model benchmark. Further, we

proposed that, subject to § 513.420(b), when there is more than one manufacturer submission of international drug net pricing data within available manufacturer-submitted international drug net pricing data for a GLOBE Model drug for an applicable calendar quarter, CMS would 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 available across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit data elements and the volume data elements (in HCPCS billing units).

Specifically, we proposed 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 HCPCS billing units in the applicable submission. The sum of the volume of HCPCS billing units is calculated by summing the volume in HCPCS billing units in the applicable submission.

*Step 2:* CMS sums the amounts calculated in Step 1.

*Step 3:* CMS calculates the total volume by summing the volume in HCPCS 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, in § 513.420(c), we also proposed that when a manufacturer submission for an applicable ASP calendar quarter 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 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 accepted in accordance with § 513.610 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 proposed reference countries listed in Table 5 in the GLOBE Model proposed rule (90 FR 60272), the U.S. originator prices are between 339 and 703 percent higher than international originator drugs.[186] We expect that the per unit Method II GLOBE Model benchmark would tend to be higher than the lowest per unit 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 final rule. Our goal is to encourage manufacturers to report international drug net pricing data (that is reflective of the actual transaction prices internationally) for applicable international analogs that align with a GLOBE Model drug to CMS for purposes of the GLOBE Model to enhance the model test and inform CMS's model monitoring and evaluation activities. We welcomed 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 also welcomed 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.

The following is a summary of the comments received and our responses.

*Comment:* A commenter recommends that Method II be simplified to allow for a one-time annual submission without losing the fixed stability of the benchmark, which would reduce administrative burden.

*Response:* We thank the commenter for their feedback. Given the GLOBE Model's limited duration and the voluntary nature for manufacturer-submitted international net drug pricing data, we do not believe the administrative effort would be significant. Further, as other commenters have expressed in other comments, it is important for CMS to monitor and assess the impacts of the model, including potential strategic behavior from manufacturers. Providing one-time annual submission would limit CMS's ability to clearly understand the impacts of the model. We believe the GLOBE Model currently balances the goals of the test with the limited administrative burden for manufacturers, and for this reason we decline to allow for a one-time annual update of the per unit Method II GLOBE Model benchmark.

*Comment:* A commenter encouraged CMS to reconsider the Method II requirement that all manufacturers of a GLOBE Model drug must submit voluntary manufacturer-reported international drug net pricing data for an applicable calendar quarter and such information must be accepted by CMS. The commenter questioned whether this approach would constrain the model evaluation by limiting the use of the Method II benchmark methodology and CMS's ability to meaningfully compare outcomes under both benchmark methodologies.

*Response:* We thank the commenter for their feedback. Because all manufacturers of a GLOBE Model drug would be responsible for model rebates, if any, we believe it is important to have all manufacturers of a GLOBE Model drug submit voluntary manufacturer-reported international drug net pricing data as a condition for identifying a per unit Method II benchmark for an applicable calendar quarter. We note that, in contrast to this commenter's

[186] 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.*

suggestion, as previously discussed in this final rule, other commenters suggested that CMS require manufacturer-reporting of international drug net pricing data to address potential gaming. As we gain experience under the model, we may revisit this topic for future consideration.

We note that, as discussed in section II.G.6. of this final rule, CMS is finalizing the provisions related to voluntary manufacturer submission of basic data elements and net pricing data elements with modifications to allow manufacturers to submit as part of reasonable assumptions an explanation for why a manufacturer is not able to include certain data elements when calculating the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit. To the extent that these modification may result in cases where CMS would be unable to identify an available across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit within an applicable submission, we are updating § 513.420(c) to address such cases.

*Final Decision:* After considering the comments received, CMS is finalizing § 513.420 with the following non-substantive modifications:

- In the introductory text of § 513.420, the reference is corrected to cite § 513.310(d) and the reference to § 513.610(a) is corrected to cite § 513.610(a)(4);
- In § 513.420(a), for clarity, the words ''within each applicable submission'' are replaced with ''using available manufacturer-submitted international drug net pricing data for the applicable ASP calendar quarter (as identified by CMS in accordance with § 513.310(d));''
- In § 513.420(b)(2)(i), for the clarity, the following sentence is added: ''The sum of the volume of HCPCS billing units is calculated by summing the volume in HCPCS billing units in the applicable submission;''
- In § 513.420(b)(2)(i), for clarity, the word ''HCPCS'' is added so that the phrase reads ''volume in HCPCS billing units;''
- In § 513.420(b)(2)(iii), for clarity, the words ''volume in HCPCS'' are added so that the phrase reads ''volume in HCPCS billing units;'' and
- Paragraph § 513.420(c) is revised to read as ''When CMS determines that manufacturer-submitted international drug net pricing data for an applicable calendar quarter (as set forth in § 513.20) is not available for purposes of § 513.420 as set forth in § 513.310(d)(3) or CMS is unable to identify an available across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit as set forth in paragraph (a) of this section, CMS identifies that the per unit Method II GLOBE Model benchmark is unavailable for such 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 § 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 per unit GDP (PPP) adjusted country-level price for the GLOBE Model drug using available data sources that meet the requirements in proposed § 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 per unit 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 per unit 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 GDP (PPP) 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.

Similarly, we 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 amount 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 estimated 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 GDP (PPP) adjustment 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 amount 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 proposed 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 opted to propose a test for two alternative rebate amount 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 amount 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 amount 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 amount 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 amount calculations. We welcomed comments on the alternatives we considered and our proposed approach for identifying a per unit GLOBE Model benchmark using two alternative calculations.

The following is a summary of the comments received and our responses.

*Comment:* A commenter suggested that CMS take a more directive approach, such as directly engaging with reference country health authorities to obtain verified transaction prices.

*Response:* We thank the commenter for this suggestion. As we stated in the GLOBE Model proposed rule (90 FR 60279), we recognize that there could be alternative ways to identify a benchmark. At this time, we believe that this suggested alternative would be administratively complex and would require substantial start up efforts that make this alternative not feasible for a limited model design beginning on January 1, 2027. We may consider this suggestion in the future for the GLOBE Model if warranted and for other CMS Innovation Center model design alternatives.

*Comment:* A commenter suggested that CMS should not test Method II and rely instead on Method I benchmarks due to the potential strategic behavior from manufacturers.

*Response:* We thank the commenter for this suggestion. As we stated in the GLOBE Model proposed rule (90 FR 60245), the intent of the GLOBE Model is to test an innovative, alternative benchmark for Medicare Part B drug 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. CMS proposed to include two approaches for identifying a benchmark amount for the alternative rebate amount 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 alternative rebate amount calculation. We recognize that there could be alternative ways to identify a benchmark. We proposed that one approach (Method I) would use existing data sources for 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 (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. At this time, we continue to believe that testing both of these approaches in combination would best inform our understanding of innovative alternative benchmarks for Medicare Part B drug inflation rebate amounts for GLOBE Model drugs using international drug pricing information that reflects prices paid in a set of economically comparable countries.

As applicable, we have addressed other comments related to the alternatives we considered for identifying the per unit Method I GLOBE Model benchmark and per unit Method II GLOBE Model benchmark for a GLOBE Model drug in sections II.G.1., II.G.2.a., and II.G.2.b. of this final rule.

3. Methodology for Identifying the per Unit GLOBE Model Benchmark Amount for an Applicable Calendar Quarter

In section II.G.3. of the GLOBE Model proposed rule (90 FR 60280), we proposed 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 § 513.400, we proposed that, quarterly for each GLOBE Model drug, after CMS identifies the ''per unit Method I GLOBE Model benchmark'' as set forth in § 513.410, as available, and the ''per unit Method II GLOBE Model benchmark'' as set forth in § 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 § 513.400(b)(3), we proposed 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 proposed 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 § 513.400(d) and discussed in section II.G.3.a. of this final 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 as specified under section 1847A(b) of the Act for the applicable calendar quarter (as discussed in section II.G.3.b. of this final 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 § 513.20, we proposed that ''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. In general, the Medicare Part B payment limit would be equal to the ''specified amount'' (as defined at 42 CFR 427.302(b)). As noted in section I.B.1.a. of this final rule, for most HCPCS Level II codes, the add-on percentage is 6 percent, 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 (as defined under section 1847A(b)(8)(B)(iii) of the Act), 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 final rule.

As discussed in section II.G.2. of this final 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 proposed 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 § 513.510, as discussed in section II.G.4. of this final 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 an 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, the per unit GLOBE Model rebate amount, as proposed in § 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.

We addressed comments we received on the applicable threshold percentage and add-on percentage amount in the sections that follow. We received no comments on the remainder of our proposal for identifying the per unit GLOBE Model benchmark amount for an applicable calendar quarter.

*Final Decision:* After consideration of the public comments received, CMS is finalizing § 513.400(a) as proposed and §§ 513.400(b) and 513.400(c) with non-substantive modifications to correct typographical errors in the proposed regulatory text. Specifically, in §§ 513.400(b) and 513.400(c), the phrase ''of this section'' is added for clarification.

In addition, CMS is finalizing the definition of ''add-on percentage amount'' in § 513.20 with a modification to remove the extraneous phrase ''the drug or biological product's average sales price, expressed as a percentage of the average sales price or wholesale acquisition cost'' and replaced with ''the amount determined in accordance with section 1847A(b)(4) of the Act'' for clarity. CMS is also finalizing a non-substantive, technical modification to the regulatory text by relocating the definition for ''per unit GLOBE Model benchmark amount'' from § 513.200 to § 513.20 and have updated the definition to mean the amount calculated in accordance with § 513.400.

a. Applicable Threshold Percentage

In § 513.400(c)(1), we proposed 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, we proposed that 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 final 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 amount 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 stated our belief that applying a consistent threshold to the benchmarks that were identified using the same method and data sources would be 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 final 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 proposed 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, such as a de minimis amount of up to 2 percent, based on our review of variation among international drug pricing information for a given drug over time and 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. CMS also proposed mechanisms within the GLOBE Model design to incentivize manufacturers to voluntarily submit international drug net pricing data, such as applying a higher applicable threshold percentage when the per unit GLOBE Model benchmark is based on a per unit Method II GLOBE Model benchmark. In § 513.400(d), we proposed 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 amount calculations, or reference countries. We also considered that no adjustment would be necessary. As noted previously, 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 (the per unit volume weighted GDP (PPP) adjusted manufacturer reported net price), might not provide sufficient incentive for manufacturers to voluntarily submit international drug pricing information for testing the Method II alternative rebate amount calculation. Without sufficient incentive, the model test of the Method II benchmark could be limited or unsuccessfully implemented.

We welcomed comments on our proposal for the applicable threshold percentage and alternatives that may help advance the aims of the model test.

The following is a summary of the comments received and our responses.

*Comment:* A commenter stated that the proposed applicable threshold percentage, 102 percent for Method I and 105 percent for Method II, are not sufficient to account for differences between average sales price (ASP) and foreign prices, and suggested that CMS increase these amounts to account for Federally mandated discounts that are not included in manufacturers' ASP data. Another commenter stated that CMS's proposal to further adjust benchmarks after adjusting for relative gross domestic product acknowledges that rebates could be based on international prices that are not appropriate comparators.

*Response:* We thank the commenters for their input on the proposed applicable threshold percentage. CMS proposed to increase the per unit GLOBE Model benchmark that is based on a per unit Method I GLOBE Model benchmark by an applicable threshold percentage to allow for a modest *de minimis* increase over the international benchmark (2 percent) and a slightly higher applicable threshold percentage (5 percent) when the per unit GLOBE Model benchmark is based on a per unit Method II GLOBE Model benchmark as an incentive for manufacturer voluntary submission of international drug net pricing data. We disagree with the interpretation that allowing for a modest increase over the Method I or Method II benchmark means that such benchmarks are not appropriate comparators for purposes of the GLOBE Model test.

With respect to the observation that the proposed applicable threshold percentage would not be sufficient to account for differences between a GLOBE Model drug's ASP and foreign prices, we note addressing such difference is not the intent of CMS's proposal to include the applicable threshold percentage within the calculation to identify the per unit GLOBE Model benchmark amount. We also note that if such interpretation were to be the intent of CMS's proposal the impact would be to obscure the results of the alternative rebate amount calculation and would likely result in marginal, if any, model rebates.

*Final Decision:* After considering the comments received, CMS is finalizing the applicable threshold percentage as proposed in § 513.400(d).

b. Add-On Percentage Amount

In § 513.400(c)(2), we proposed 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 appliable 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 not increasing the per unit GLOBE Model benchmark by the dollar value of the add-on 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 (which, in general, is equal to 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 alternative rebate amount calculation including an add-on amount while the other part in the comparison would not.

We sought comments on our proposed methodology for identifying the per unit GLOBE Model benchmark amount and our rationale for this approach. We also sought 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 sought 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.

The following is a summary of the comment received and our response.

*Comment:* A commenter expressed concern that including the add-on amount would continue the incentive for providers to choose the highest cost drug to administer to their patient. The commenter suggested an alternative where the GLOBE Model benchmark calculation would not include the add-on amount, which the commenter stated could increase savings.

*Response:* As discussed in section II.G.3.b. of the GLOBE Model proposed rule (90 FR 60281), we proposed to add the add-on percentage amount when calculating the per unit GLOBE Model benchmark amount to avoid overstating the GLOBE Model rebate amount that manufacturers would owe and unintentionally distorting the model test. We believe that consistent treatment of the add-on amount is essential to maintain the focus of the model test on an alternative rebate amount calculation. If an add-on percentage amount were not included, the model test would be confounded by a reduction of the GLOBE Model benchmark amount in a manner that would not likely reflect international drug net pricing in the reference countries.

*Final Decision:* After consideration of the public comments received, CMS is finalizing the proposal to include an add-on percentage amount in the calculation of the per unit GLOBE Model benchmark amount, as set forth in § 513.400(c)(2), with non-substantive modifications to correct typographical errors that appeared in the proposed regulatory text. Specifically, in § 513.400(c)(2), the phrase ''add-on percentage'' is revised to read as ''the add-on percentage'' and the citation ''section 1847A(b)'' is revised to read as ''section 1847A(b)(1)(B).''

4. Methodology for Calculating the GLOBE Model Rebate Amount

In section II.G.4. of the GLOBE Model proposed rule (90 FR 60283), we proposed how CMS would calculate the per unit GLOBE Model rebate amount and the incremental per unit GLOBE Model rebate amount due. We also proposed 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, and 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 as defined in § 513.20.

a. Methodology for Calculation of the Per Unit GLOBE Model Rebate Amount and the Incremental Per Unit GLOBE Model Rebate Amount

In section II.G.4.a. of the GLOBE Model proposed rule (90 FR 60283), we proposed 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 amount 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 amount calculation, for a GLOBE Model drug for an applicable calendar quarter, we proposed 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 final 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 proposed that the per unit GLOBE Model rebate amount would be set at $0.

We stated our intent to design the GLOBE Model in a manner that ensures OM 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 proposed 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 Medicare Part B drug inflation

rebate amount, if any, for the applicable calendar quarter.

We also proposed 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 final rule.

We proposed to codify these calculations in § 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 Medicare Part B drug inflation rebate amount calculated as set forth in 42 CFR 427.302.

We welcomed comments 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.

The following is a summary of the comments received and our responses.

*Comment:* A few commenters supported CMS's proposal to use an incremental rebate approach noting that this approach would be clear and support severability. A commenter stated that the incremental rebate approach would protect the model against anomalously low rebates but is contingent on accurate international drug pricing data.

*Response:* We appreciate the commenters' support for the incremental rebate proposal. We acknowledge this approach would serve as a safeguard for beneficiaries and the Medicare program and that access to international drug pricing data that accurately estimates drug pricing is a key component of the model.

*Comment:* A commenter recommended that CMS publish detailed operational guidance specifying: (1) how the frozen Method I benchmark would be reconciled against dynamic quarterly ASP updates over the five-year performance period; and (2) the process for handling ASP restatements and corrections in GLOBE Model rebate amount calculations and reconciliation.

*Response:* The purpose of the GLOBE Model is to test an alternative payment methodology to the Medicare Part B Drug Inflation Rebate Program's rebate amount calculation that is based on the greater of a per unit Method I GLOBE Model benchmark or a per unit Method II GLOBE Model benchmark. Method I is not intended to reflect global market dynamics and therefore, we disagree that we need to reconcile the Method I benchmark against a dynamic quarterly ASP update. We note, however, that for certain calculations the Medicare Part B Drug Inflation Rebate Program uses the specified amount which may reflect ASP updates. The GLOBE Model is designed to also use the specified amount in certain calculations and would align with ASP updates, such as in situations where there are ASP restatements and corrections. Therefore, with respect to handling ASP reinstatements and corrections in the GLOBE Model rebate amount calculations and reconciliation, CMS would use the most recent data, as applicable, for the calendar quarter, for purposes of determining the specified amount at the time the per unit GLOBE Model rebate amount is calculated by CMS.

As discussed in II.G.1.d. and II.G.6. of the GLOBE Model proposed rule (90 FR 60269; 90 FR 60287) and this final rule, manufacturers have an option as discussed in II.G.1.d. and II.G.6., of the GLOBE Model proposed rule (90 FR 60269; 90 FR 60287) and this final rule to voluntarily submit international net pricing data for an applicable ASP calendar quarter, which could encompass global market dynamics. CMS would then use the greater of the per unit Method I GLOBE Model benchmark or the per unit Method II GLOBE Model benchmark to identify the per unit GLOBE Model benchmark amount for an applicable calendar quarter, using available information as determined by CMS as set forth in § 513.400(b), which may include corrections and restatements of manufacturer-submitted international drug net pricing information as set forth in § 513.610(d)(1), as well as updated international drug pricing information made available by the selected data source within 90 days from the end of the calendar quarter for which drug pricing information is compiled as set forth in § 513.410(c)(5).

*Final Decision:* After consideration of the public comments received, CMS is finalizing § 513.510 as proposed.

b. Identification of the Total Number of GLOBE Model Billing Units

In section II.G.4.b. of the GLOBE Model proposed rule (90 FR 60283), we discussed how the total number of GLOBE Model billing units for a GLOBE Model drug for an applicable calendar quarter would be identified for the 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 proposed, in § 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 OM Part B made separate payment. We proposed 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 OM Part B 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's 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 OM Part B made separate payment.

The following is a summary of the comments received and our responses.

*Comment:* A commenter stated that additional work is needed to ensure 340B units are identified and excluded accurately and consistently across all GLOBE Model drugs. Specifically, the commenter stated that CMS should require providers to use a claims modifier to identify both 340B and non-340B units to increase transparency in the exclusion process.

*Response:* We thank the commenter for their input on the process for identifying 340B units for purposes of the GLOBE Model. To identify the total number of GLOBE Model billing units, CMS proposed to start with the total number of billing units that are identified in accordance with 42 CFR 427.303(b). This starting point ensures that the GLOBE Model and Medicare Part B Drug Inflation Rebate Program will identify 340B units in the same manner and through a single process. Under the CY 2024 OPPS/ASC Final Rule (CMS–1786–FC, 88 FR 81791 through 81792), beginning on January 1, 2025, CMS required all 340B covered entities that submit claims for separately payable Part B drugs and biologicals to report the 340B modifier ''TB'' on claims for drugs acquired through the 340B Program so that CMS can exclude 340B units from the Medicare Part B Drug Inflation Rebate Program. This approach ensures that CMS and manufacturers can address any issues related to 340B units and the Medicare Part B Drug Inflation Rebate Program independent of the GLOBE Model. To the extent that through the Medicare Part B Drug Inflation Rebate Program, the total number of billing units that are identified in accordance with 42 CFR 427.303(b) are revised for an applicable calendar quarter, the GLOBE Model would incorporate such revision through reconciliation activities set forth in § 513.710(d).

*Comment:* A commenter stated that the GLOBE Model rebate should only apply to sales exceeding the $100 million threshold to ensure that small drug markets are protected.

*Response:* We thank the commenter for their input and interpret the comment to be a suggestion that CMS calculate the GLOBE Model rebate after excluding $100 million in OM spending. We appreciate that such an approach may substantially reduce the total GLOBE Model rebate for a manufacturer. However, this suggested approach would substantially limit the scope of the model test and CMS's ability to evaluate the potential impact of the model.

*Final Decision:* After consideration of the public comments we received, we are finalizing § 513.520 with non-substantive modifications to correct typographical errors that appeared in the proposed regulatory text. In § 513.520(b), the phase ''made separate payment'' is updated to ''made separate payment under the model.'' In § 513.520(c), ''equal'' is revised to read as ''equals'' and ''rebate'' is revised to read as ''applicable calendar,'' and the cross-reference is corrected to read ''paragraph (b) of this section.''

c. 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 section II.G.4.c. of the GLOBE Model proposed rule (90 FR 60283) and in § 513.500, we proposed how CMS would calculate the total GLOBE Model rebate amount and the incremental GLOBE Model rebate amount for a GLOBE Model drug for an applicable calendar quarter. To clearly identify the alternative rebate amount calculation 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, an incremental per unit 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 final 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 final rule.

We proposed 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 product of the per unit GLOBE Model rebate amount as calculated pursuant to § 513.510(a) and the total number of GLOBE Model billing units (as identified as set forth in § 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 proposed to also 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 § 513.500(b), we proposed 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 § 513.510(b) and the ''total number of GLOBE Model billing units'' (as identified as set forth in § 513.520).

*Final Decision:* We received no comments on this proposal and therefore are finalizing §§ 513.500(a), 513.500(b), and 513.500(c) with non-substantive modifications for editorial accuracy.

We also refer readers to Table 6 in this final rule where we present 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 calendar quarter based on average estimates of a per unit Method I and Method II GLOBE Model benchmarks [187]

[187] This estimate is not based on international net pricing information, but it is calculated based on the volume-weighted average across countries using IQVIA MIDAS® data and GDP (PPP) adjusted. As described in this final rule, IQVIA national audits and IQVIA MIDAS® reflect local industry standard

Continued

using international drug pricing information that was available to CMS for purposes of the GLOBE Model proposed rule. The illustration incorporates the GLOBE Model drug inclusion and exclusion criteria set forth in § 513.130 and other provisions finalized in this final rule. The illustrative per unit specified amount, illustrative per unit add-on percentage amount, estimated per unit inflation-adjusted payment amount, and estimated per unit Medicare Part B drug 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 benchmarks for Method I and Method II are based on international pricing information that was available to CMS following the process described in sections II.G.1. to II.G.3. of this final 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 GLOBE Model benchmark amount ($12.237) 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 per unit add-on percentage of the Medicare Part B payment limit ($8.830*(1.02) + $3.230). The illustrative per unit GLOBE Model rebate amount for Method I is the greater of $44.905 or $0.000, where $44.905 is the difference between the illustrative per unit specified amount and the illustrative per unit GLOBE Model benchmark amount ($57.146 − $12.24) and $0.000 is the difference between the illustrative per unit specified amount and the estimated per unit Inflation-Adjusted rebate amount ($57.146 − $57.146). 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 ($44.905 − $0.000). We follow a similar process to calculate the illustrative Method II per unit GLOBE Model rebate amount using 105 percent as the threshold percentage.

**TABLE 6: ILLUSTRATIVE INCREMENTAL PER UNIT GLOBE MODEL REBATE AMOUNT AND COINSURANCE REDUCTION FOR AN ILLUSTRATIVE GLOBE MODEL DRUG: METHOD I AND METHOD II BENCHMARKS**

| Method | Illustrative Per Unit Specified Amount[a] | Illustrative Per Unit Add-on Percentage Amount of the Medicare Part B Payment Limit[a] | Estimated Per Unit Inflation-Adjusted Payment Amount[a] | Estimated Per Unit Medicare 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 GLOBE Model Coinsurance Percentage[b] | Illustrative GLOBE Model Per Unit Adjusted Coinsurance Amount[b] |
|---|---|---|---|---|---|---|---|---|---|---|
| Method I | $57.146 | $3.230 | $57.146 | $0.000 | $8.830 | $12.237 | $44.905 | $44.905 | 4.282% | $2.447 |
| Method II | $57.146 | $3.230 | $57.146 | $0.000 | $16.510 | $20.566 | $36.577 | $36.577 | 7.197% | $4.113 |

Notes: [a] This table provides highly simplified per unit estimates for an illustrative GLOBE Model drug for an illustrative applicable calendar quarter using data from 2024 for Method I and Method II as described in this final rule. 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.) and GDP (PPP) adjusters used are based on the World Bank World Development Indicators GDP per capita PPP. [b] The illustrative coinsurance percentage is calculated as 20 percent of the illustrative per unit GLOBE Model benchmark amount divided by the illustrative per unit specified amount. For example, for Method I, the illustrative coinsurance percentage of 4.282 percent is calculated as: 0.20*($12.237)/($57.146). The illustrative per unit adjusted coinsurance amount of $2.447 is the product of the illustrative coinsurance percentage and the illustrative per unit specified amount, rounded to 3 decimal places. For example, the illustrative per unit adjusted coinsurance amount for Method I of $2.447 is the result of multiplying 0.04282 by $57.146.

d. 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 maintained under section 506E of the FD&C Act 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, we proposed, in § 513.500(d), to reduce the incremental GLOBE Model rebate amount, if any, for such GLOBE Model drug for such applicable calendar quarter using the methodology specified in proposed § 513.500(d). 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, we proposed 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). The ''applicable percent reduction'' in the proposed 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 noted that this approach would maintain the

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.

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 proposed 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, we proposed to apply a reduction of the incremental GLOBE Model rebate amount as determined under § 513.500(d)(2) to all the NDCs under the relevant billing and payment code as specified in 42 CFR 427.401(c). As discussed in section II.G.8. of this final 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 proposed to apply, for purposes of the GLOBE Model, the same applicable percentage reduction as used under the Medicare Part B Drug Inflation Rebate Program.

The following is a summary of the comments received and our responses.

*Comment:* A couple of commenters expressed support for reducing GLOBE Model rebate amounts when there is a shortage but also expressed concern that a reduction would not mitigate the underlying risk for shortages. A couple of commenters stated that CMS's proposal to reduce GLOBE Model rebates for plasma-derived products in the event of a shortage is insufficient and does not address concerns that the GLOBE Model could lead to supply chain disruptions.

*Response:* We thank the commenters for their feedback on the proposed reduction in the incremental GLOBE Model rebate amount for a GLOBE Model drug that is currently in shortage. We acknowledge the commenters' concern that a reduction would not mitigate the underlying risk for shortage. Based on the comments we received, we are not persuaded that an alternative approach for reducing the incremental GLOBE Model rebate amount would be more appropriate or warranted for the GLOBE Model test and any such approach would not be within the scope of the GLOBE Model test. Therefore, we are not modifying our proposal. We note that, as discussed in section II.B.5. of this final rule, we are finalizing at § 513.130(c)(1)(vi) that plasma-derived products are excluded from the GLOBE Model.

*Comment:* A commenter stated the FDA's drug shortage list does not reflect the full scope of shortages that health care providers face at any given time, due to how the FDA collects information and the lag in its reporting. The commenter suggested that CMS work with the FDA to update its processes to ensure that any drug facing a shortage is appropriately and timely included in FDA's drug shortage list.

*Response:* We thank the commenter for sharing feedback on our proposal. FDA maintains public, up-to-date lists of finished drugs and biological products that FDA has determined to be in shortage in the United States.[188] For purposes of the GLOBE Model, to maintain consistency with the Medicare Part B Drug Inflation Rebate Program, we believe that using a shortage list maintained by the FDA under section 506E of the FD&C Act would be adequate to identify GLOBE Model drugs in shortage. The FDA has a robust and established process to identify drug shortages. Since the enactment of the Food and Drug Administration Safety and Innovation Act in 2012, manufacturers have been required to notify FDA of certain discontinuances and interruptions in manufacturing, and FDA works closely with manufacturers to obtain drug supply information. As we proposed, CMS will collaborate with the FDA to review FDA's shortage lists and determine whether the number of drugs or length of time on a shortage list changes over time. To the extent that CMS identifies an issue through regular monitoring that would require a change to the GLOBE Model, CMS could take necessary action to make such a change. In addition, to the extent that health care providers may experience local changes in availability of GLOBE Model drugs, such health care providers would be able to inform CMS through the GLOBE Model helpdesk.

*Final Decision:* After consideration of the public comments received, CMS is finalizing § 513.500(d) as proposed. CMS is revising the description of this provision in the preamble for technical accuracy. CMS has also corrected a non-substantive typographical error in § 513.500(d)(1): the reference for equation 1 has been corrected to state ''paragraph (d)(1)'' instead of ''paragraph (c)(1).''

(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. As discussed in section II.B.1. of this final rule, we proposed to exclude Part B rebatable biosimilar biological products from the definition of GLOBE Model drugs. We proposed that, if after notice and comment that proposal is not finalized, 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, we proposed that to the extent that CMS finalizes a definition of GLOBE Model drugs that were to include Part B rebatable 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 § 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

[188] See *https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages* and *https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-regulated-products-current-shortages.*

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.

In the GLOBE Model proposed rule (90 FR 60286), we noted 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.

The following is a summary of the comments received and our responses.

*Comment:* A couple of commenters expressed support for reducing GLOBE Model rebate amounts when there is a severe supply chain disruption for GLOBE Model drugs that are biosimilar biological products but also expressed support for excluding Part B rebatable biosimilar biological products from the GLOBE Model which would make this provision unnecessary.

*Response:* We thank the commenter for sharing their support for the proposed reduction of the incremental GLOBE Model rebate amount for GLOBE Model drugs that are biosimilar biological products when there is a supply chain disruption. In section II.G.4.d.(2) of the GLOBE Model proposed rule (90 FR 60286), CMS noted that if our proposal to exclude Part B rebatable biosimilar biological products from the GLOBE Model is finalized, our proposal for reduction of the incremental GLOBE Model rebate amount for GLOBE Model drugs that are biosimilar biological products when there is a supply chain disruption would not be necessary and we would not include such provision in such final rule. Because CMS is finalizing the inclusion of sole source biological products and therefore Part B rebatable biosimilar biological products are not included in the GLOBE Model as discussed in section II.B. of this final rule, our proposal is not necessary. Therefore, we are modifying § 513.500(e) to remove the proposed regulatory text at § 513.500(e) and instead read as ''Reserved'' and modifying § 513.500(f) to read in part as ''paragraphs (a) through (d)'' to remove reference to paragraph (e).

*Final Decision:* After consideration of the public comments received, CMS is finalizing § 513.500 with modifications to remove the proposed regulatory text at § 513.500(e) and insert ''Reserved.'' CMS is also modifying § 513.500(f) to read in part as ''paragraphs (a) through (d)'' to remove reference to § 513.500(e) and removing the definition of severe supply chain disruption from § 513.20.

5. Payment Responsibilities

As discussed in section II.E. of the GLOBE Model proposed rule (90 FR 60287), we proposed 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 proposed 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 proposed 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 final rule. As discussed in section II.G.8. of this final rule, we proposed 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 proposed 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's 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 sought 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.

The following is a summary of the comments received and our responses.

*Comment:* A commenter urged CMS not to impose additional administrative burdens on pharmacies, pharmacists, or pharmacy personnel related to payment, reconciliation, reimbursement, reporting, or distribution.

*Response:* As discussed in section II.G.8. of this final rule, CMS is finalizing an incremental invoicing approach for GLOBE Model rebate reports, invoicing, payment, Suggestion of Error, and reconciliation processes, which will involve only manufacturers of GLOBE Model drugs (and their designees, if applicable) and CMS (and its contractors, as applicable). Pharmacies and other health care providers and suppliers will not be involved in these processes. For additional information regarding our responses to administrative burdens, we refer readers to section II.G.8. of this final rule.

*Final Decision:* After consideration of the public comments received, CMS is finalizing § 513.530 as proposed, without modification.

6. Reporting Requirements and Process for Voluntary Manufacturer-Provided Data

As discussed in section II.G.2.b. of this final rule, 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 proposed in § 513.610(a)(3)(i) that the data must include all the basic data elements (as set forth in § 513.610(b) and described in section II.G.6. of this final rule) required for each ''applicable international analog'' as defined in § 513.600 that corresponds to a GLOBE Model drug. As discussed in section II.G.1.d., we proposed that an applicable international analog means a non-US analog whose scientific or nonproprietary name, dosage form, and route of administration (if applicable) aligns with a GLOBE Model drug and that is 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 § 513.610(c)) required under one of the two options manufacturers can select to submit net pricing data (as described in section II.G.6.b. of this final rule). We further proposed in § 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 considered an applicable submission and would not be used by CMS for purposes of identifying a per unit Method II GLOBE Model benchmark.

In addition, we proposed that complete data submissions would be assessed by CMS for validity. 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 proposed that CMS may choose to request additional supporting information and/or data from the manufacturer who submitted the data to inform CMS's 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.

*Final Decision:* CMS is finalizing non-substantive technical modifications to § 513.610(a)(3)(ii)(C)(*1*) and new § 513.610(a)(3)(ii)(C)(*2*) for clarity and alignment with the preamble in the GLOBE Model proposed rule (90 FR 60287 through 60288). Specifically, § 513.610(a)(3)(ii)(C)(*1*) is updated to clarify manufacturer submission of additional supporting information or data or both must be submitted to CMS within 5 business days after the date of CMS's request for additional supporting information or data or both. Section 513.610(a)(3)(ii)(C)(*2*) is added to state failure to respond within 5 business days will result in CMS being unable to confirm the validity of the submission.

a. Basic Data Requirements

Under an effectuated GLOBE Model data agreement, manufacturers may make submissions for one or more GLOBE Model drugs for any applicable ASP calendar quarter that corresponds with an applicable calendar quarter during the model performance period. 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, we proposed that the manufacturer would include all applicable international analogs as defined in § 513.600. We also proposed 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 § 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, we proposed to calculate the number of ''HCPCS billing units'' (as defined in § 513.20) in the applicable international analog, by dividing the quantity of drug in the package by the ''HCPCS dosage'' (which means, as defined in § 513.20, the quantity of drug represented in one HCPCS billing unit).

In § 513.610(b), we proposed 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, scientific or nonproprietary name, and HCPCS Level II code. We also proposed that the basic data elements provided by the manufacturer would contain a list of every applicable international analog (as defined in § 513.600) that was sold in one or more reference countries during the applicable ASP calendar quarter. The following list is the required basic data elements that also include presentation level information. We proposed that a complete submission must include all of the following data elements for all of the applicable international analogs (as defined in § 513.600) by reference country:

- Scientific or nonproprietary name.
- Brand name (all variations in international drug names).
- Names of manufacturers, marketers, or licensees.
- Non-U.S. country regulatory approval status [189] (international originator drug or international non-originator drug).
- Dosage form and route of administration (if applicable).
- Strength or concentration.
- 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 (CMS published data which are the quantity of drug represented in one HCPCS billing unit).
- Number of HCPCS billing units.

We proposed 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 correspond to a GLOBE Model drug. We proposed that, if there are missing data elements, the submission would be considered incomplete 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

[189] As defined at proposed § 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 other. Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug pricing information in the 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.

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**

**Basic Data Elements are:**

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:

**Country A**

i.e. all applicable international analogs in the reference country

e.g. brand name

| Applicable International Analog | Scientific or Non-proprietary name (s) | Drug Name (s) | Manufacturer(s), marketer (s), licensee(s) | Regulatory Approval Status | Dosage Form and Route of Administration | Strength | HCPCS Dosage | HCPCS Billing Units | Volume per item | Package Type | Number of items per package |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Analog 1 | | | | | | | | | | | |
| Analog 2 | | | | | | | | | | | |
| Analog … | | | | | | | | | | | |
| Analog n | | | | | | | | | | | |

**Country B**

**Country …**

**Country n**

Note: This is an illustrative example for structure of the basic data elements for each reference country and the applicable international analogs. The specific format for how manufacturers would submit the data is further discussed in section II.G.6.d. of this final rule.

In addition, we proposed that if, for any of the basic data elements, third-party individuals and organizations were used to gather, analyze, or submit the data, the manufacturer must specify their use of third party data with respect to each of the type of activity (gather, analyze, or submit the data) engaged in by the third party, and the identity of the third-party individual or organization.

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. We sought 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 sought comments on whether additional basic data elements should be required or if any of the proposed data elements presents significant data collection, analysis, or submission challenges.

*Final Decision:* Although we did not receive comments on the basic data elements identified in § 513.610, CMS is modifying § 513.610 to address comments discussed in subsequent sections of this final rule. For details on those modifications, see section II.G.6.f. of this final rule. CMS has also made the following non-substantive technical corrections to the regulatory text to correct typographical drafting errors:

- Section 513.610 is renamed as ''Submission and verification of international drug net pricing data;''
- In § 513.610(a)(2), the phrase ''identified in § 513.310'' is replaced with ''specified in § 513.310(b)'' for clarification;
- In § 513.610(a)(3), ''acceptability'' is replaced with ''completeness and validity;''
- In § 513.610(a)(3)(i)(B), the citation ''(d)(2)'' is inserted for clarification;
- In § 513.610(b)(1)(i), ''scientific or'' is added for clarification;
- In § 513.610(b)(1)(ii)(B)(*6*), ''or concentration'' was added to align with terminology in § 513.310(c);
- In § 513.610(b)(1)(ii)(B)(*11*)(*i*), ''the number of'' is added for clarification; and
- In § 513.600, CMS corrected a typographical error in the definition of non-U.S. country regulatory approval status by replacing ''drug's'' with ''analog's.''

b. Options for Submission of Net Pricing Data Elements

As discussed in section II.G.6.b. of the GLOBE Model proposed rule (90 FR 60289), when manufacturers choose to submit voluntary international drug net pricing, we proposed that a two-step process would be used: (1) submission of basic data elements as previously described; and (2) submission of international drug net pricing data from one of the two options proposed in § 513.610(c). For submission of international drug net pricing data, we proposed that manufacturers can choose between these 2 options to submit: streamlined or limited. In both options, we proposed that manufacturers would provide the required volume-weighted average GDP (PPP) adjusted net pricing per HCPCS billing unit for the applicable international analogs for all

reference countries the applicable international analogs were sold in for the applicable ASP calendar quarter (that is, the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit). The difference between the two options is the level of aggregation allowed for the submission of gross sales, net sales, and sales volume that was used by the manufacturer to calculate the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit. In the streamlined option, we proposed that manufacturers would report net pricing data for each applicable international analog in each reference country by net price level. In the limited option, we proposed that manufacturers would report net prices aggregated at the reference country level.

We also proposed, in § 513.610(a)(3)(i), that manufacturers who elect to submit international drug net pricing data must submit all of the net pricing data elements required for one of the two options described later in section, in addition to the basic data elements set forth in § 513.610(b). We proposed the required net pricing data elements in § 513.610(c)(2)(i) for the streamlined option and § 513.610(c)(2)(ii) for the limited option, and discussed our proposal in the GLOBE Model proposed rule (90 FR 60289 through 60295). We proposed that manufacturers would select which option to follow but must select one option. We also proposed that, for each GLOBE Model drug, manufacturers must report net pricing data elements for all the applicable international analogs that are sold in the set of reference countries, using one of the two available options. Additionally, we proposed that 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.

The following is a summary of the comments received and our response.

*Comment:* Commenters recommended that CMS ensure that the assumptions used by manufacturers when reporting international net sales and pricing data are consistent, transparent, and verifiable to support reliable benchmark calculations.

*Response:* We thank the commenters for their feedback. CMS agrees that consistency, transparency, and verifiability of reported data are important to support reliable benchmark calculations. We also interpret assumptions to mean reasonable assumptions manufacturers would use when reporting international drug net pricing data.

As proposed in the GLOBE Model proposed rule (90 FR 60331 through 60333), the voluntary manufacturer data submissions would include supporting documentation explaining how each element of the submission was compiled and calculated, along with any reasonable assumptions underlying the submission. In addition, to the extent that a manufacturer would use third party individuals and organizations to gather, analyze, or submit the data, the manufacturer would specify their use of third party data with respect to each of the type of activity (gather, analyze, or submit the data) engaged in by the third party and the identity of the third-party individual or organization. As an example of a reasonable assumption that may be appropriate, CMS noted in the GLOBE Model proposed rule that expected clawbacks and other types of price concessions subject to delayed reporting may be estimated based on historical data, as this information may not be available to manufacturers in time to be included in a submission due no later than 30 days after the end of the applicable ASP calendar quarter.

CMS sought comment on the reasonable assumptions manufacturers may make when reporting average gross-to-net ratio and net sales data. However, we did not receive any specific comments on this topic. Accordingly, CMS continues to believe that the use of historical data for expected clawbacks and other price concessions with delayed reporting could represent a reasonable assumption that supports consistent and transparent reporting of international drug net pricing data.

In addition, as proposed in § 513.610, CMS would verify the voluntary manufacturer-provided data submission for completeness, including confirming the net pricing data elements and supporting documentation—including documentation of reasonable assumptions—are present. CMS proposed to utilize all available data sources and information to assess the extent to which the submission reflects international drug net pricing in the reference countries, and to request additional supporting materials from manufacturers, as needed, prior to completing its validation assessment. We believe these verification and validation mechanisms are well-suited to ensuring that reasonable assumptions used by manufacturers are appropriate and that benchmark calculations are reliable.

*Final Decision:* While the comments received on topics discussed in this section did not require substantive modifications to § 513.610, CMS is modifying § 513.610 to address comments discussed in other subsections of section II.G.6. of this final rule. Additionally, while CMS proposed that a manufacturer must select the streamlined or limited net pricing data option for the duration of the model performance period, this language was inadvertently left out of the regulation text. CMS did not receive comments on this proposal and, as such, CMS is finalizing the following additions to § 513.610(c)(2) to reference new § 513.610(c)(3) (as discussed in section II.G.1.d. of this final rule): ''Subject to paragraph (c)(3) of this section'' and ''A manufacturer must select one of the net pricing data submission options for the duration of the model performance period.''

(1) Streamlined Option

Under the streamlined option, we proposed 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 proposed to define in § 513.600 that ''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. We proposed to define ''purchaser'' in § 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 concession,'' we proposed the following definition in § 513.600—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 include 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 proposed to define in § 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 proposed that ''net price level'' as defined at § 513.600 would, with respect to sales of applicable international analogs, mean 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 proposed the submission would 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 proposed 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. We proposed that we would expect the manufacturer to obtain data for every transaction that is made directly to healthcare 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 in the GLOBE Model proposed rule (90 FR 60291) that is also repeated here in the final rule, we provided an illustrative example of a voluntary submission of net pricing data by the manufacturer of a fictitious GLOBE Model drug. 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 an applicable submission would include 3 gross and net sales amounts with the corresponding volumes. This logic is repeated for the other reference countries with applicable international analogs to GLOBE Model drug I. In the accompanying narrative (90 FR 60290), we explained that because a 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 would be 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. ILLUSTRATIVE 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 | | | | | |
| | 3 | 1 | 178.00000 | 90.00000 | 40 | | | | | |
| | | 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 the manufacturer by adding for a reference country the products of the net sales amounts in U.S. dollars multiplied by the corresponding sales volume and then dividing by the sum of the sales 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 the manufacturer 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 sales volume in HCPCS units and then dividing by the sum of the sales volume in HCPCS units (this includes all net price levels for all applicable international analogs in all reference countries). This table is for illustrative purposes only and does not contain the following required data elements: Gross sales for every sale involving an applicable international analog aggregated at the net price level, in U.S. dollars, rounded to 5 decimal places; net sales for every sale involving an applicable international analog aggregated at the net price level, in U.S. dollars, rounded to 5 decimal places; and exchange rate data source. We refer readers to §513.610(c) for the net pricing data elements required.

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In addition, under the streamlined option, we proposed that manufacturers would provide one average net-to-gross ratio for each GLOBE Model drug per reference country. For the purposes of the streamlined option, we proposed to define the ''average net-to-gross ratio'' to mean, 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 applicable international analogs in the same reference country. We also proposed that the average net-to-gross ratio would 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 the GLOBE Model proposed rule (90 FR 60291) and this final rule. In that example, in Reference Country A, the sum of all net sales amounts for all applicable international analogs is 1044.00000 and the sum of all gross sale amounts for the same set of applicable international analogs is 1900.00000. Thus, the average net-to-gross ratio would be the sum of 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 proposed that 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 proposed to define in § 513.600 that ''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 sales volumes in HCPCS billing units. In addition, we proposed that the 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 for a reference country must also be rounded to 5 decimal places.

As illustrated in the GLOBE Model proposed rule (90 FR 60291), using 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 final 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 proposed 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 would be 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 proposed to define, at § 513.20, the ''across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit'' to mean the volume-weighted average for all reference countries of GDP (PPP) adjusted net prices, where the weights are the sales 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 proposed that the across volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit would be reported and rounded to 3 decimal places.

We proposed that the GDP-adjustment would be based on purchasing power parity (PPP) and that manufacturers must use the GDP (PPP) adjuster from CMS that aligns with the applicable ASP calendar quarter. We proposed that 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, in § 513.430, we proposed to use the most recent estimate 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 § 513.20) as determined by CMS. We note that, as discussed in section II.G.1.f. of this final rule, in response to comments related to the discontinuation of the CIA World Factbook, CMS would use the World Bank WDI GDP (PPP) if available, otherwise the IMF GDP (PPP) to calculate the GDP (PPP) adjuster for each country for each calendar quarter as finalized at § 513.430.

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 GDP (PPP) adjuster. As a summary, after manufacturers have identified applicable international analogs as defined in § 513.600, for a GLOBE Model drug for an applicable ASP calendar quarter, manufacturers would use the following steps to identify the 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 net pricing data without both sales and volume data that are greater than zero.

*Step 2:* By reference country, convert the volume data to the unit of measurement delineated in the GLOBE Model drug's HCPCS Level II code long 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 proposed that manufacturers would calculate the number of HCPCS billing units in the applicable international analog as defined in § 513.600 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.

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. The manufacturer applies the same exchange rate identified as set forth in § 513.610(c)(2)(i)(A)(*3*) to all net pricing data in a reference country for the applicable ASP calendar quarter.

*Step 7:* By reference country, calculate the volume-weighted net price as follows:

a. Multiply the net sales, in U.S. dollars, by the sales volume in HCPCS billing unit for each applicable international analog and net price level.

b. Sum together the products 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 volume-weighted net price per HCPCS billing unit per reference country. Round the 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 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 amounts calculated in Step 8a by the sum calculated 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 calculated in Step 8b and divide by the sums in Step 7c. (the total volume sold in HCPCS billing units for all applicable international analogs in all reference countries), resulting in 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.

Round the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit to 3 decimal places.

We proposed that manufacturers would submit information on how each of the elements of the submission were compiled and computed and consistent with ASP reporting, any reasonable assumptions that were made during this process. We also proposed that manufacturers would 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 elements and the identity of the third party, or if the manufacturer made any reasonable assumptions to determine the average net-to-gross 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 otherwise 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 sought comments on reasonable assumptions manufacturers may make during their reporting of average net-to-gross ratio and net pricing data elements such as how they account for clawbacks and other price concessions that may have delayed reporting to the manufacturer.

We also recognized 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 proposed in § 513.610(a)(2) that any allocation and calculations be done in a manner consistent with the GAAP, IFRS, or other internationally recognized accounting approaches.[190] We sought feedback on whether there are other accounting approaches that CMS should consider. The following is a summary of the comments received and our responses.

*Comment:* A few commenters raised concerns that, because manufacturers are not required to disclose net prices and may choose whether to voluntarily disclose such prices, CMS should consider establishing minimum data requirements to ensure that reference prices reflect actual net transaction prices rather than list prices. A commenter suggested CMS provide guidance on acceptable methodologies for calculating net-to-gross ratios and for handling delayed price concessions. Commenters also expressed concern that voluntary reporting could lead to incomplete or inconsistent data and may create incentives for strategic reporting behavior—whereby manufacturers report in ways that are advantageous to their financial circumstances—thereby reducing the reliability of Method II benchmarks.

*Response:* CMS thanks the commenters for their feedback. CMS believes that the combination of basic data elements, net price data elements, and a review of supporting documentation, including reasonable assumptions—as set forth in § 513.610—provides a set of minimum data requirements that would be sufficient for CMS to assess reported net prices.

Additionally, CMS has defined in § 513.600 the net sales amount and volume-weighted net price as the amount of money owed by the purchaser exclusive of price concessions. As proposed in § 513.600, price concessions would include volume discounts, prompt pay discounts, cash discounts, free goods, chargebacks, rebates, and other price concessions that lower that amount realized by the manufacturer. Accordingly, CMS expects that reported net prices will reflect actual net transaction prices rather than list prices.

As part of the validation framework proposed in § 513.610(a)(3)(ii), CMS will utilize all available data sources and information to assess the extent to which a submission reflects international drug net pricing in the reference countries and may request additional supporting information or data or both before completing its validation assessment. Under § 513.610(d)(2), manufacturers are also required to attest to and certify the completeness and accuracy of their submissions. CMS believes these requirements, taken together, establish the minimum standards necessary to ensure that submitted information reflects actual net prices rather than list prices.

Regarding guidance on methodologies for calculating net-to-gross ratios, CMS believes it has provided sufficient guidance in the GLOBE Model proposed rule. In section II.G.6. of the GLOBE Model proposed rule, CMS provided illustrative examples for both the limited option (Table 7) and the streamlined option (Table 8), along with step-by-step instructions for calculating each of the net pricing data elements. In addition, § 513.610(a)(2) requires that manufacturers ensure all allocations and calculations are performed in a manner consistent with the generally accepted accounting principles (GAAP), international financial reporting standards (IFRS), or other internationally recognized accounting approaches. As manufacturers regularly prepare financial reports and estimations, CMS believes these accounting principles, standards, and approaches are familiar to manufacturers and provide a well-established foundation for consistent reporting. However, in considering the comments received, CMS identified that the proposed definition of average net-to-gross ratio could be updated to clarify the calculation by a manufacturer and more closely reflect the illustrative examples and details provided in the GLOBE Model proposed rule and has updated this definition in § 513.600 in this final rule.

CMS also recognizes that certain price concessions may be subject to delayed reporting. As discussed in section II.G.6. of the GLOBE Model proposed rule (90 FR 60293), manufacturers may, as part of their reasonable assumptions, use historical data to account for expected clawbacks and other price concessions that may have delayed reporting to the manufacturer and would not be available in time to be included in a data submission due no later than 30 days after the end of the applicable ASP calendar quarter.

Finally, CMS relies on manufacturers providing an accurate and complete submission when submitting their own data. However, if a submission is found to not meet the applicable submission requirements in § 513.610(a)(4), CMS will not use the submission for purposes of identifying available information for purposes of identifying a per unit Method II GLOBE Model benchmark as set forth in § 513.310(d)(3). CMS believes that the established minimum data requirements and applicable submission standards reduce the potential for incomplete or inconsistent data, mitigate incentives for strategic reporting behavior, and support the reliability of Method II benchmarks.

*Final Decision:* While responding to the comments received did not require edits to the regulatory text in § 513.610(c)(2)(i), CMS is finalizing § 513.610(c)(2)(i) as proposed, with a technical modification in the regulatory text for clarity. Specifically, in § 513.610(c)(2)(i)(A)(*5*), CMS has corrected a drafting error by replacing ''GDP (PPP) adjustment'' with ''GDP (PPP) adjuster.'' CMS did receive comments related to manufacturer's overall ability to submit international drug net pricing data and has addressed

[190] Sean Ross, *GAAP vs. IFRS: Key Differences Explained* (Apr. 18, 2025), Available at *https://www.investopedia.com/ask/answers/011315/what-difference-between-gaap-and-ifrs.asp* (Last accessed August 27, 2025).

these comments in section II.G.6.f. of this final rule.

In § 513.600, to clarify, CMS is updating the definition of average net-to-gross ratio to read as: ''*Average net-to-gross ratio* means, for a reference country, the sum of net sales for the set of applicable international analogs in the reference country divided by the sum of gross sales for the same set of applicable international analogs in the same reference country.'' CMS is also updating the definition of volume-weighted net price to read as: ''*Volume-weighted net price* means, exclusive of any price concessions, the volume-weighted average net price in U.S. dollars for a reference country where the weights are sales volume in HCPCS billing units. The volume-weighted net price for a reference country is obtained by the manufacturer by adding the products of the net sales amounts in U.S. dollars multiplied by the corresponding sales volume in HCPCS billing units for the set of applicable international analogs in the reference country and then dividing by the sum of the sales volume in HCPCS billing units for the same set of applicable international analogs in the same reference country.'' For clarification, CMS also added the phrase ''of an applicable international analog'' to the definitions of gross sales amount and net sales amount.

In § 513.20, CMS is updating the definition for across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit for clarity and to align with the preamble and remove the phrase ''from international drug net pricing data from an applicable submission.'' The updated definition reads as: ''*Across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit* means the volume-weighted average GDP (PPP) adjusted net prices in U.S dollars for all reference countries, where the weights are the sales volume in HCPCS billing units for each reference country. The across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit is obtained by the manufacturer by adding for all applicable international analogs in 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 sales volume in HCPCS billing units and then dividing by the sum of the sales volume in HCPCS billing units for all applicable international analogs in all reference countries.''

(2) Limited Option

Under the limited option, we proposed that manufacturers would be required to submit a set of data elements that are aggregated at higher levels than CMS proposed under the streamlined option. For all the applicable international analogs to a corresponding GLOBE Model drug, as defined in § 513.600, and for each reference country, we proposed that manufacturers would 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 that are an aggregate of all the applicable international analogs and net price levels. For the purposes of the limited option, we proposed to use the same definition as for the streamlined option for ''gross sales amount'' and ''net sales amount'' as defined in § 513.600. Manufacturers must also report what the local currency is (for example, euro, yen, etc.). We also proposed the total gross sales and total net sales would 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.

In the GLOBE Model proposed rule (90 FR 60293), we stated that 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 healthcare entities, distributors, wholesalers, or other international purchasers. In addition, we proposed that manufacturers would be required 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 proposed to define the ''average net-to-gross ratio'' for the limited option to be the same as for 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 proposed that manufacturers would round the average net-to-gross ratio to 5 decimal places.

We also proposed that manufacturers would report, for each country, the volume-weighted net price across all applicable international analogs corresponding to a GLOBE Model drug, as defined in § 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 final rule. For the limited option, we also proposed to define the ''volume-weighted net price'' the same as for 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 § 513.600. The volume-weighted net price per reference country must be rounded to 5 decimal places.

In addition, we proposed 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 § 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 § 513.20. 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 proposed that the GDP adjustment would be based on purchasing power parity (PPP) and that manufacturers must use the GDP (PPP) adjuster from CMS that aligns with the applicable ASP calendar quarter. We proposed that 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, in § 513.430, we proposed to use the most recent estimate 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 § 513.20) as determined by CMS. We would publish this GDP (PPP) adjuster at the beginning of each applicable calendar quarter. We note that, as discussed in section II.G.1.f. of this final rule, in response to comments related to the discontinuation of the CIA World Factbook, CMS would use the World Bank WDI GDP (PPP) if available, otherwise the IMF GDP (PPP) to calculate the GDP (PPP) adjuster for each country for each calendar quarter as finalized at § 513.430. The across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit would represent the volume-weighted average net price per HCPCS billing unit of the applicable international analogs corresponding to a GLOBE Model drug across all reference countries where the applicable international analogs are sold and would include an adjustment using GDP (PPP).

Table 8 in the GLOBE Model proposed rule (90 FR 60294) and this final rule illustrate the net pricing data elements that would be required for GLOBE Model Drug I for the limited option. In this illustration, 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 sales 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 are shown.

**TABLE 8: ILLUSTRATIVE TABLE SHOWING NET PRICE DATA ELEMENTS REQUIRED UNDER THE LIMITED OPTION FOR ILLUSTRATIVE GLOBE MODEL DRUG "I"**

| Reference Country | Total Gross Sales Amount (Local currency) | Total Net Sales Amount (Local currency) | Total Sales Volume | 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) |
|---|---|---|---|---|---|---|---|---|
| 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 the manufacturer by adding for a reference country the products of the net sales amounts in U.S. dollars for the set of applicable international analogs in the reference country multiplied by the corresponding sales volume and then dividing by the sum of the sales volume for the same set of applicable international analogs in the same reference country. The across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit is obtained by the manufacturer by adding for all applicable international analogs in 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 sales volume in HCPCS billing units and then dividing by the sum of the sales volume in HCPCS billing units for all applicable international analogs in all reference countries. This table is for illustrative purposes only and does not contain the following required data elements: Total gross sales amount for each reference country in U.S. dollars, rounded to 5 decimal places; total net sales amount for each reference country in U.S. dollars, rounded to 5 decimal places; and exchange rate data source. We refer readers to §513.610(c) for the net pricing data elements required.

In the GLOBE Model proposed rule (90 FR 60294), we provided a summary of our proposal as follows. After manufacturers have identified applicable international analogs sold that correspond to a GLOBE Model drug for an applicable ASP calendar quarter, we proposed that 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 long 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

proposed that manufacturers would calculate the number of HCPCS billing units in the applicable international analog as defined in § 513.600 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. The total 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. The total 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, 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. The manufacturer applies the same exchange rate identified as set forth in § 513.610(c)(2)(ii)(A)(4) to all net pricing data in a reference country for the applicable ASP calendar quarter.

*Step 7:* By reference country, calculate the volume-weighted net price.

a. Multiply the net sales, in U.S. dollars, by the sales volume in HCPCS billing unit for each applicable international analog.

b. Sum together the products determined in Step 7a.

c. Sum together the sales volume in HCPCS billing units for all applicable international analogs in the reference country.

a. Divide the sum determined in Step 7b by the sum determined in Step 7c, resulting in the volume-weighted average net price per HCPCS billing unit for the 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 volume-weighted net price calculated in Step 7d by the applicable GDP (PPP) adjuster for the applicable ASP calendar quarter (to be published by CMS in a supplemental document).

b. Per reference country, multiply the amounts calculated in Step 8a by the sum calculated in Step 7c (total sales volume in HCPCS billing unit for all applicable international analogs for the reference country).

c. Sum together the amounts in Step 8b and divide by the sum of the sums from Step 7c (total sales volume in HCPCS 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. We note that the results of the simplified calculations shown in Step 8 are equivalent to adding for all applicable international analogs in 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 sales volume in HCPCS billing units and then dividing by the sum of the sales volume in HCPCS billing units for all applicable international analogs in all reference countries as stated in the definition of across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit in § 513.20.

The following is a summary of the comments received and our responses.

*Comment:* A commenter suggested that the methodology for calculating method II benchmarks should incorporate standardized net price reporting across dosage forms and strength.

*Response:* We thank the commenter for this suggestion. In § 513.20, we proposed and are finalizing that ''HCPCS billing units'' are the standardized measurement quantities 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. CMS believes that this is the most robust and appropriate method for converting information about international drug products to a level that permits comparison with OM Part B data for a GLOBE Model Drug, aligns with the way Part B rebatable drugs are identified as set forth in 42 CFR 427.101(a)(1), is consistent with Method I benchmark calculations, and provides a consistent and necessary methodology for using international drug pricing information for purposes of the GLOBE Model.

*Final Decision:* CMS did not receive any comments specific to the limited option and is therefore finalizing § 513.610(c)(2)(ii) as proposed, with two technical modifications to the regulatory text. First, in § 513.610(c)(2)(ii)(A), CMS added the words ''and for every sale involving an applicable international analog aggregated at the reference country level.'' Second, in § 513.610(c)(2)(ii)(A)(*3*), CMS added the words ''rounded to 5 decimal places for each reference country.'' These additions correct drafting errors in the GLOBE Model proposed rule; the omitted language appears in both the preamble and the corresponding regulatory text for the limited option in this final rule. In § 513.610(c)(2)(ii)(A)(*7*), CMS has corrected a drafting error by replacing ''GDP (PPP) adjustment'' with ''GDP (PPP) adjuster.'' CMS did receive comments related to manufacturers' overall ability to submit net pricing data and has addressed these comments in section II.G.6.f. of this final rule.

c. Exchange Rate Considerations

In section II.G.8.c. of the GLOBE Model proposed rule (90 FR 60295), for both options for submitting net pricing data elements, we proposed 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 we proposed 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 proposed that manufacturers would use either the World Bank Atlas (for a conversion method in lieu of a straight exchange

rate),[191] IMF exchange rates data,[192] the Federal Reserve Bank foreign exchange rates,[193] or exchange rates from country-specific sources to identify the average exchange rate. We proposed that, if the data source chosen uses an exchange rate frequency that is less than annual (for example, daily, weekly, monthly, quarterly), manufacturer will calculate an exchange rate for the currency conversion which corresponds to an average exchange rate of the chosen frequency for the applicable ASP calendar quarter during which international sales occurred. We also proposed that manufacturers would use the same exchange rate for currency conversion for all applicable international analogs, as defined in § 513.600, in a reference country. In other words, all net pricing data in a reference country for an applicable ASP calendar quarter would be calculated by the manufacturer using the same exchange rate. We also proposed that, once an exchange rate data source is identified, the manufacturer would continue 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 would be reported with each voluntary submission. We stated that this approach is necessary so that a manufacturer's submitted international net pricing data for a GLOBE Model drug would be in a consistent format and CMS would be able to combine the data appropriately for purposes of testing an alternative rebate amount calculation methodology. We sought 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.

*Final Decision:* CMS did not receive any comments relating to the exchange rate considerations and is therefore finalizing § 513.610(c)(2)(i)(A)(*3*)(*i*) and § 513.610(c)(2)(ii)(A)(*4*)(*i*) with non-substantial modification to align the language in these sections such that they read as: ''The exchange rate 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.'' CMS is also revising § 513.610(c)(2)(i)(A)(*3*)(*iv*) and § 513.610(c)(2)(ii)(A)(*4*)(*iv*) to state ''The manufacturer reports which exchange rate data source was used and continues to use this exchange rate data source for subsequent submissions'' for clarity and alignment with the preamble.

CMS also received a comment regarding the validity and completeness of manufacturer-submitted international drug net pricing data, including concerns about market dynamic inconsistencies, exchange rate conversions, and anomalies. CMS has addressed this comment in section II.G.1.d. of this final rule.

d. Attestation and Submission

As we stated in the GLOBE Model proposed rule (90 FR 60295), while manufacturer reporting would be voluntary, submitted data must meet completeness, and validity standards in proposed § 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 Model benchmark for a GLOBE Model drug for an applicable calendar quarter, as discussed in section II.G.2.b. of this final rule. In § 513.610(a)(1), we proposed that if the manufacturer is electing to submit international drug net pricing data, the data must be received by CMS within 30 calendar days after the end of the applicable ASP calendar quarter for which the manufacturer is making the submission and the data that is contained within the submission must correspond to the applicable ASP calendar quarter. In addition, we proposed that an authorized representative, on behalf of the manufacturer, must provide an attestation that each submission is accurate and complete to the best of the manufacturer's knowledge, is prepared in full compliance with the requirements specified under § 513.610 (including, but not limited to the requirements for basic data elements and net pricing data elements, either the streamlined or limited option), and that the authorized representative has the authority to make such attestation on behalf of the manufacturer. We also proposed that the authorized representatives for the manufacturer must provide contact information and attest as such. We proposed, in § 513.600, that ''authorized representative'' would mean 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. We proposed that an authorized representative must specify if they are a third-party organization that is submitting data on behalf of the manufacturer.

We proposed that a data submission would not be considered complete if it does not include all attestation requirements in § 513.610(d)(2), such as contact information of the authorized representative, whether a third-party organization is submitting on behalf of the manufacturer, and the attestation itself. We also stated that the submission would also be considered incomplete if the required basic data elements defined in § 513.610(b) and the required net pricing data elements in the selected streamlined or limited option, as defined in § 513.610(c) as applicable, 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 § 513.610(f), we also proposed that the attestation and data submission process would occur through a CMS designated system. We proposed that authorized representatives would access the CMS Health Plan and Management System (HPMS), which is currently used for Manufacturer Discount Program reporting, reporting for the Negotiation Program, and for the Medicare Part B Drug Inflation Rebate Program. We stated that 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. We stated that, while we intend to designate HPMS, we may designate a different CMS system for submission, if necessary.

In § 513.610(e), we proposed that CMS would maintain the confidentiality of information submitted to the extent permitted by law and in accordance with applicable privacy and security requirements. We also proposed that, pursuant to an effectuated GLOBE Model data agreement, CMS would not disclose manufacturer-submitted international drug net pricing information in a form which discloses the identity of a specific manufacturer

[191] *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).

[192] *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)* (Last accessed Sept. 24, 2025).

[193] *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).

and their international drug net pricing and sales data except as CMS determines to be necessary to carry out §§ 513.210 and 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 proposed that 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. We further proposed that once the manufacturer chooses to voluntarily submit international drug 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 in the reference countries specified in § 513.310(b) for the applicable ASP calendar quarter. We stated that this approach is necessary so that a manufacturer's submitted international drug net pricing data per GLOBE Model drug would be in a consistent format and that CMS would be able to combine the data appropriately for purposes of testing an alternative rebate amount calculation methodology. We also proposed in § 513.620(a)(3)(iii) that if a manufacturer chooses to no longer submit voluntary international drug net pricing data after the data agreement is effective and CMS has determined sales of the applicable international analogs have occurred in the reference countries specified in § 513.310(b) for the applicable ASP calendar quarter, CMS may terminate the data agreement. The manufacturer may also elect to terminate the data agreement.

If the data agreement has been terminated, as discussed in section II.G.4. of this final rule, the per unit Method I GLOBE Model benchmark would be used for the GLOBE Model drug for the remainder of the model duration.

The following is a summary of the comments received and our responses.

*Comment:* A few commenters expressed concern about how CMS will maintain the confidentiality of net pricing data submitted under Method II. Commenters stated that release of such information could cause significant harm to protected privacy and business interests. Some commenters also raised concerns that CMS has not provided assurances regarding whether submitted data could be used for other governmental purposes or disclosed beyond the model, including to other agencies or through public processes. A commenter further stated that if net prices were to become visible to foreign countries, it could lead to downward price spirals and exacerbate the practice of foreign ''free riding.''

*Response:* We thank commenters for raising these concerns. In § 513.610(e), CMS proposed to maintain 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, governing the computation of GLOBE Model beneficiary coinsurance percentage, the adjusted Medicare payment for the GLOBE Model, and GLOBE Model rebate. As such, these net prices would not be disclosed to foreign countries. CMS believes these protections are sufficient to support the submission and use of Method II data for purposes of the model.

*Comment:* Several commenters stated that CMS has not articulated adequate data-use limitations or non-disclosure commitments for manufacturer-submitted international drug net pricing data under Method II. Commenters stated that the existing confidentiality provision at § 513.610(e) provides only that CMS will maintain confidentiality ''to the extent permitted by law,'' which commenters characterized as insufficient given the sensitivity of the data. Commenters raised specific concerns about: (1) whether submitted data could be shared with other HHS components, other Federal agencies, or Congress; (2) whether the data would be protected from disclosure under the Freedom of Information Act (FOIA); (3) whether net pricing data could be disclosed to foreign governments, potentially triggering downward price spirals in reference countries; and (4) whether the data could be used by CMS for purposes beyond the GLOBE Model, including other CMS Innovation Center models, the Negotiation Program, or enforcement proceedings.

*Response:* CMS acknowledges the heightened sensitivity of international drug net pricing data and the importance of providing manufacturers with clear, specific assurances regarding data protection. CMS provides the following clarifications.

First, manufacturer-submitted international drug net pricing data under § 513.610 are not releasable to the public unless authorized by law. CMS will review records responsive to any FOIA request on a case-by-case basis in accordance with FOIA, including 5 U.S.C. 552(a)(8), and other applicable law.

Second, under the GLOBE Model data agreement at § 513.620, CMS will not disclose manufacturer-submitted international drug net pricing data in a form that identifies a specific manufacturer or its drug-specific international net pricing and sales data, except as CMS determines necessary to carry out §§ 513.210 and 513.500 (governing the GLOBE Model rebate amount calculation, beneficiary coinsurance, and adjusted Medicare payment). This protection applies to all downstream uses within CMS.

Third, CMS will not share manufacturer-specific international drug net pricing data with foreign governments, international organizations, or any non-U.S. entity.

Fourth, with respect to inter-agency sharing, CMS will not disclose manufacturer-submitted international drug net pricing data to other Federal agencies—including the Department of Justice, the Federal Trade Commission, or the Office of the U.S. Trade Representative—for purposes other than carrying out the GLOBE Model, unless requested in the course of a law enforcement action or investigation or as necessary for HHS program integrity functions.

Fifth, manufacturer-submitted international drug net pricing data will be used for purposes of the GLOBE Model—specifically, for the identification of per unit Method II benchmarks, rebate calculations, verification and compliance reviews, and model evaluation.

CMS believes these commitments, together with the data agreement requirements at § 513.620 and the confidentiality provision at § 513.610(e), provide manufacturers with adequate assurance regarding data protection under the GLOBE Model.

*Final Decision:* CMS made a non-substantive modification to correct a typographical error in the numbering of the attestation requirements under § 513.610(d) from § 513.610(d)(1) to § 513.610(d)(2). Additionally, after

consideration of the public comments received, CMS is finalizing the attestation requirements at § 513.610(d)(2) and the submission platform and security requirements at § 513.610(f) as proposed, with minor technical modifications.

CMS is also finalizing the confidentiality and data protection requirements at § 513.610(e) with non-substantive terminology modifications. Specifically, CMS added the word ''drug'' to the phrases ''manufacturer-submitted international net pricing information'' and ''international net pricing and sales data'' to align § 513.610(e) with the terminology used throughout this final rule.

CMS is also finalizing § 513.620 with the following minor technical modifications for clarity:

- In § 513.620(a)(1), revising ''of paragraphs (b) in'' to read as '' in paragraph (b) of'';
- Renumbering § 513.620(a)(3)(iii) to § 513.620(a)(3)(ii);
- Adding the phrase ''and as specified in the applicable executed data agreement'' to § 513.620(a)(2);
- Splitting § 513.620(a)(3)(i) into § 513.620(a)(3)(i)(A) and § 513.620(a)(3)(i)(B);
- Updating § 513.620(a)(3)(i) to read ''If a manufacturer elects to voluntarily submit manufacturer's international drug net pricing data, the manufacturer;''
- Renumbering proposed regulatory text § 513.620(a)(3)(ii) to § 513.620(a)(3)(i)(B);
- Adding the words ''any of'' to § 513.620(a)(3)(i)(B);
- Updating § 513.620(a)(2) to read as ''CMS uses applicable submissions, determined in accordance with paragraph (b) of this section, § 513.610(b) and § 513.610(c), and as specified in the applicable executed data agreement, to identify the per unit Method II GLOBE Model benchmark, subject to § 513.310(d) and § 513.420 for the applicable ASP calendar quarter corresponding to the submission.''; and
- Updating the first sentence in § 513.620(a)(3)(ii) to read as ''After the data agreement specified in paragraph (b) of this section is effective, if a manufacturer chooses to no longer submit voluntary international drug net pricing data for GLOBE Model drug(s) for which the manufacturer has submitted voluntary international drug net pricing data and CMS has determined sales of applicable international analogs to such GLOBE Model drug(s) have occurred in the reference countries specified in § 513.310(b) for the applicable ASP calendar quarter, CMS may terminate the data agreement for all GLOBE Model drugs of the manufacturer.''

e. Corrections and Resubmissions

In the GLOBE Model proposed rule (90 FR 60296), we stated that we recognize errors may occur during a manufacturer's submission of international drug net pricing data. We proposed, in § 513.610(d)(1), to allow corrections of an applicable submission within 30 calendar days of the submission deadline. For example, if a manufacturer submits international drug 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 proposed to limit the timeframe for submission of corrected international drug net pricing data to CMS for an applicable ASP calendar quarter to 30 calendar 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 in which the GLOBE Model beneficiary coinsurance adjustment would apply. We stated that 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 calendar days for manufacturers to submit corrected international net pricing data to CMS would provide 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, while avoiding the operational complexity of continuously revising Method II benchmarks from different quarters, which may change quarterly based on manufacturer submissions. We note that our calculation of the Method II benchmark is more operationally complex compared to the Method I benchmark, which in most circumstances is calculated once for the duration of the model.

We also proposed that if CMS chooses to request additional supporting information and/or data from the manufacturer who submitted the data to inform CMS's assessment of the validity of the submission, the manufacturer would have to respond by submitting such information and/or data within 5 business days of such request.

The following is a summary of the comments received and our responses.

*Comment:* A commenter suggested CMS develop a manufacturer submission portal with validation to provide real-time validation of submissions, reduce errors, and enable faster corrections within the 30 calendar days window for manufactures to submit corrected international net pricing data.

*Response:* We thank the commenter for their suggestion to have a manufacturer submission portal with validation to reduce errors and allow faster corrections. As the voluntary submission of international drug net pricing data is based on manufacturer's gross and net sales information, CMS relies on manufacturers providing an accurate and complete submission when submitting their own data. As such, we would be unable to determine a complete and valid submission without having reviewed all submitted data and therefore, we do not intend to include a comprehensive real time validation process within the manufacturer submission portal. As proposed in § 513.610(f), CMS intends to use the HPMS for manufacturer submission of voluntary international drug net pricing data. This system is currently used for Manufacturer Discount Program reporting, reporting for the Negotiation Program, and for the Medicare Part B Drug Inflation Rebate Program. Therefore, we expect that most manufacturers of Part B rebatable drugs would have familiarity with HPMS, which would reduce submissions errors. CMS intends to allow submission of all the required data elements set forth in § 513.610(b) and § 513.610(c), as deemed feasible, in the HPMS system to also reduce submission errors related to missing data elements. To the extent feasible, CMS intends that HPMS would facilitate some automated data validation checks, such as missing required data elements and incorrect data formats, that would enable manufacturer corrections during the submission process. As we further develop the submission portal, we will provide manufacturers with technical instructions for data submission. We may revisit this topic for future consideration as we explore use of HPMS and should we designate a different manufacturer submission portal.

*Final Decision:* After consideration of the public comments received, CMS is

finalizing § 513.610(d)(1) as proposed, without modification.

f. Alternatives Considered

As discussed in section II.G.8.f. of the GLOBE Model proposed rule (90 FR 60296), we considered offering a more comprehensive option for manufacturers to report net pricing data elements. Under this potential option that we considered, in addition to the data elements noted in the streamlined and limited options, manufacturers would be 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, we considered that 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 such submission, manufacturers would also submit an across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit 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 stated that we decided not to offer this option due to concerns of manufacturer and CMS reporting burden.

We stated that we also considered offering an option that would allow 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 would 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 stated that we decided against including this option because our ability to verify this information would be limited. In addition, we stated that 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 stated that we decided against the policy of CMS calculating values because we believe that the manufacturer 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 stated that we did not believe it was necessary. We sought feedback on these policies.

In addition, we stated that we considered providing manufacturers the set of applicable international analogs for which they must submit the international net pricing data. However, we stated our belief 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 a Method II GLOBE Model benchmark. However, we stated that 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 stated our belief that 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 sought 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.

In addition, we stated that 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 stated that 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 stated that 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 stated our belief 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 our proposed approach. We stated that 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 sell directly and which ones to be sold by other entities to reduce the manufacturer's GLOBE Model rebate liability. We stated that 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, in formulating our proposed approach and assessing the alternatives described previously. We sought 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 stated that 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. After considering these alternatives, we stated our belief that allowing maximum flexibility would lead to significant data standardization issues that may pose a challenge in testing an alternative rebate amount 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 stated our belief that our proposed 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 submissions, balances the need for flexibility and data standardization.

In addition, we stated that 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 stated that 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. We stated that we balanced the timing needed to calculate the GLOBE Model beneficiary coinsurance percentage and manufacturers' process and timelines for data gathering and believe that manufacturers would be able to make reasonable assumptions of nets sales based on historical data. Therefore, we stated our belief that requiring initial data submission to occur within 30 calendar 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.

Further, we stated that we also considered allowing manufacturers up to 1 year after initial data submission to correct data and account for any delayed price concessions such as clawbacks. For this alternative, 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, although manufacturers are only required to report multiple net pricing data elements, including those that reflect the effects of price concessions, manufacturers are also required to report an average net-to-gross ratio, 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 in developing these reported values. We sought 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 reporting timelines proposed for attestation, and if there are other types of reasonable assumptions manufacturers may make to meet the proposed submission requirements.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters stated that manufacturers may be held financially responsible under the model's international benchmarking approach for prices they do not set or influence. Commenters stated this may particularly harm U.S.-only licensees and small biotechnology firms that do not commercialize products in reference countries or that have out-licensed foreign rights to unaffiliated third parties. Commenters also stated that manufacturers that have out-licensed or co-licensed their products may be disadvantaged, as they are legally restricted from gathering information about the international analog, resulting in their products' benchmarks defaulting to Method I.

Commenters explained that foreign licensees independently establish pricing, discounts, and rebates and may not share transaction-level net pricing data due to confidentiality agreements or the absence of contractual audit rights. A commenter further stated that Federal antitrust laws prohibit industry participants from sharing confidential pricing information. Commenters argued that applying Method II reporting requirements to manufacturers without global pricing control could impose financial liability without corresponding authority over foreign pricing decisions and urged CMS to establish exemptions, safe harbors, or alternative reporting pathways for affected manufacturers to not sell, distribute, or market products outside the U.S.

*Response:* We emphasize that the submission of international net pricing information is voluntary without any punitive element. If the manufacturer chooses to submit voluntarily, in § 513.610(a)(3)(i) and in the preamble of the GLOBE Model proposed rule, we proposed that, in part, a complete manufacturer's voluntary submission of international drug net pricing data would include supporting documentation that explains how each of the elements of the submission were compiled or calculated and any reasonable assumptions that were applied. In the preamble of the GLOBE Model proposed rule (90 FR 60293), examples of information to submit for reasonable assumptions include how the manufacturer determined the average net-to-gross ratio.

One of the alternatives we considered for Method II and outlined in the GLOBE Model proposed rule was to allow 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. We also recognize the complexities inherent in international pharmaceutical markets including diverse relationships between U.S. and international entities responsible for product marketing and distribution and acknowledge commenters recommendations to establish, exemptions, safe harbors, or alternative reporting pathways for manufacturers that are unable to share transaction-level pricing data for applicable international analogs in certain reference countries due to contractual arrangements. CMS appreciates commenters' recommendations for exemptions or alternative treatment where a manufacturer does not control or influence pricing in certain reference countries due to bona fide out-licensing or similar arrangements. Rather than establishing a categorical exemption, CMS is finalizing an approach that permits manufacturers to document such circumstances as part of their reasonable assumptions when submitting Method II data.

As such, we are updating the basic data elements and net pricing data elements requirements to allow manufacturers to submit as part of reasonable assumptions an explanation for why a manufacturer is not able to include certain data elements when calculating the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit. An example of a reasonable assumption is if the manufacturer has an out-licensing or co-licensing agreement in which they do not control pricing in certain reference countries. CMS will verify a manufacturer's submission for completeness as proposed in § 513.610(a)(3), which includes reviewing the submission for supporting

documentation for reasonable assumptions that were applied. As such, we believe this updated approach does not cause harm to small biotechnology firms that do not commercialize products in certain reference countries.

We disagree that this model conflicts with Federal antitrust laws and note that commenters have not identified a legally cognizable harm within the U.S. that would give rise to antitrust liability domestically. However, we acknowledge commenters' concerns and believe that this updated approach to submitting Method II data alleviates those concerns.

Additionally, we also believe this updated approach does not cause manufacturers that out-license or co-license in certain reference countries to default to Method I, as our analysis after implementing the finalized GLOBE Model drug inclusion and exclusion criteria in § 513.130 suggests manufacturers are likely able to voluntarily report some pricing information such as the across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit that would be sufficient for CMS to assess the validity and completeness. We also believe that such information, if deemed applicable by CMS, is also sufficient for CMS to use to identify a per unit Method II GLOBE Model benchmark. Therefore, we believe manufacturers can report under Method II, if desired. Finally, we note that the alternative calculation for the rebate amount under the Medicare Part B Drug Inflation Rebate Program does not hinge on whether manufacturers of GLOBE Model drugs control foreign prices. As stated in section II.G.1.a. of this final rule, the prices that are used in the benchmark are a proxy for the payment levels drug manufacturers accept in economically comparable countries for similar drugs and demonstrate potentially avoidable expenditures for Medicare beneficiaries that use GLOBE Model drugs because the GLOBE Model drugs are priced significantly higher in the U.S.

*Comment:* A commenter recommended that CMS develop guidance on acceptable methodologies for manufacturers' calculation of net-to-gross ratios and delayed price concessions to encourage manufacturers to submit international drug net pricing data for the Method II benchmark.

*Response:* We thank the commenter for their suggestion. Beyond what we have already discussed in this section of this final rule, we decline to develop further guidance for how manufacturers must compile and calculate international drug net pricing data at this time. As we gain experience with manufacturer-submitted international drug net pricing data, we may reconsider this topic.

*Final Decision:* After consideration of the public comments received, CMS is finalizing the provisions at § 513.610(a), § 513.610(b), and § 513.610(c) with modifications to update the requirements related to: scope of submission; verification of manufacturer submission; applicable submission; basic data requirements; and net pricing data elements requirements. These modifications are intended to allow manufacturers to submit an explanation for why certain basic data elements or net pricing data elements are not included as part of reasonable assumptions in the submission. CMS is also finalizing the definitions in § 513.600 not previously mentioned as finalized in section II.6.a through II.6.e of this final rule, such as, authorized representative, applicable international analog, net price level, price concession, and purchaser as proposed with a minor non-substantive modifications to the definition of applicable international analog and price concession for clarity. For applicable international analog, the phrase ''specified in § 513.310(b)'' is added after reference countries and grammatical corrections are applied to reflect a singular subject. For price concession, the definition for free goods was reformatted to reflect formatting of the other price concessions listed within the definition of price concession.

7. GLOBE Model Beneficiary Coinsurance Adjustment and Adjusted Medicare Payment for GLOBE Model Drugs

As part of the GLOBE Model design, in § 513.210, we proposed 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 OPPS, beneficiary coinsurance does not exceed the inpatient deductible amount). 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 proposed 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. We proposed 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 § 513.400(c)(4) as determined by CMS. 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 proposed 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.

We also proposed that, if the payment amount does not exceed the per unit GLOBE Model benchmark amount, 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.

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 an applicable calendar quarter, we proposed 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 OM Part B payment amount for separately payable units of the GLOBE Model drug furnished to GLOBE Model beneficiaries during the applicable calendar quarter. (90 FR 60266)

We proposed that 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. We also proposed that CMS's 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 of this final rule, the illustrative payment amount of $57.146 exceeds the illustrative per unit GLOBE Model benchmark amount of $12.237. In this case, the illustrative GLOBE Model beneficiary coinsurance is $2.447, calculated by multiplying the per unit GLOBE Model benchmark amount by 0.20. The illustrative GLOBE Model beneficiary coinsurance percentage is 4.282 percent, which is the result of dividing $2.447 by the illustrative payment amount of $57.146. Based on the finalized GLOBE Model drug inclusion and exclusion criteria in § 513.130 and using illustrative 2024 data for drugs identified in Table 4, calculations for the Method I benchmark estimated that, for 94 percent of the illustrative GLOBE Model drugs, the beneficiaries who would be eligible for the model would see an illustrative GLOBE Model coinsurance percentage between 2 and 12 percent.

In conjunction with testing an alternative calculation for beneficiary coinsurance, we proposed 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 under 42 CFR 419.41(e). That is, when the GLOBE Model beneficiary coinsurance adjustment applies, we proposed 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 × $100) = $90.

We note that claims for any Part B rebatable drug that is excluded from the GLOBE Model for an applicable calendar quarter, is not separately payable, or is not eligible for the inflation-adjusted beneficiary coinsurance as defined at 42 CFR 427.200 would not be subject to the GLOBE Model beneficiary coinsurance percentage and payment adjustment.

We sought comments on our proposed approach for testing an alternative calculation for beneficiary 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 GLOBE Model performance period.

The following is a summary of the comments received and our responses.

*Comment:* A commenter supports the proposed reduction in beneficiary coinsurance paired with corresponding adjustments to physician reimbursement to maintain the full Medicare Part B allowable payment.

*Response:* We thank the commenter for their support for the proposed approach for GLOBE Model beneficiary coinsurance adjustment and adjusted payment for GLOBE Model.

*Comment:* A commenter expressed concern that the GLOBE Model will not significantly reduce Medicare beneficiary out-of-pocket costs because patient cost-sharing is tied to list prices instead of net prices.

*Response:* We thank the commenter for sharing their concern that the out-of-pocket costs may not be reduced significantly under the proposed GLOBE Model beneficiary coinsurance adjustment for GLOBE Model drugs. We disagree that Medicare beneficiary out-of-pocket costs will not be significantly reduced. In section IV.D.1. of this final rule, specifically in Table 14, CMS presents the estimated out-of-pocket savings to Medicare beneficiaries based on reduced premiums and coinsurance rates from the GLOBE Model totaling $177 million.

To maintain alignment with how beneficiary coinsurance is adjusted in accordance with section 1847A(i) of the Act and 42 CFR part 427 subpart C while testing an alternative rebate amount calculation, we believe that the GLOBE Model beneficiary coinsurance adjustment and adjusted Medicare payment for GLOBE Model drugs are essential components of the GLOBE Model and are finalizing their inclusion in the GLOBE Model. In § 513.210(b), we are clarifying that GLOBE Model beneficiary coinsurance would only apply to claims when 42 CFR 410.152(m), 42 CFR 419.41(e), and 42 CFR 489.30(b)(6) as applicable would apply.

*Comment:* A few commenters sought clarification regarding the process that providers will use for calculating and collecting beneficiary coinsurance amounts when the beneficiary has supplemental coverage. Commenters also expressed concern about collecting incorrect beneficiary coinsurance amounts and how the model will ensure GLOBE Model rebate dollars are returned to patients. Commenters also sought clarification on how they or CMS would identify GLOBE Model eligible beneficiaries and GLOBE Model drugs. A commenter urged CMS to ensure that the GLOBE Model Eligible Beneficiary List is made available to all hospitals that bill for Medicare Part B drugs, as there is no other mechanism outlined by CMS for hospitals to identify which of their OM patients are included in the GLOBE Model, and which are not. The commenter stated that, absent access to this list or any other way to identify GLOBE Model beneficiaries, hospitals could be at risk of collecting the incorrect beneficiary coinsurance amounts.

*Response:* We thank the commenters for their feedback on the proposed GLOBE Model beneficiary coinsurance adjustment and adjusted Medicare payment for GLOBE Model drugs. We believe that healthcare providers serve patients who have a variety of health insurance coverage with varying cost-sharing requirements for different services, including those with supplemental coverage and those who are furnished drugs that could be GLOBE Model drugs. Due to these variations, healthcare providers routinely adopt processes for collecting amounts associated with patient financial responsibility either upfront or after claims are processed. Upfront collection is more likely to result in situations where a refund is necessary as compared to collecting cost-sharing after the insurer has processed the claim and notified the healthcare provider of the patient's financial responsibility.

Beneficiary coinsurance reduction under the Medicare Part B Drug Inflation Rebate Program began on April 1, 2023. Since that time, health care providers have been responsible for collecting applicable coinsurance which

may be less than the typical 20 percent for Part B rebatable drugs and have existing methods and processes to comply with applicable Medicare participation requirements related to accurate collection of amounts from beneficiaries. We believe that these existing methods and processes will be sufficient for healthcare providers who furnish a GLOBE Model drug to a GLOBE Model eligible beneficiary to accurately determine the amount of coinsurance to collect from a beneficiary. For example, Medicare participating providers may routinely wait for the Medicare Explanation of Benefits, and a response from any supplemental insurer, before determining the amount that a beneficiary owes the provider.

In section II.C. of the GLOBE Model proposed rule, CMS proposed that, prior to the model start and periodically thereafter, but no more frequently than weekly, CMS would identify eligible OM beneficiaries 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. In section II.F. of the GLOBE Model proposed rule, CMS proposed that after CMS finalizes a rule establishing the GLOBE Model, no later than 30 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. Further, as discussed in section II.B. of this final rule, CMS will make available the GLOBE Model Drug List along with the applicable GLOBE Model coinsurance percentage on the GLOBE Model website quarterly, in advance of the calendar quarter. CMS believes that this information is adequate for providers to identify potential GLOBE Model beneficiaries. In addition, CMS intends to provide technical documents such as FAQs and factsheets that providers may share with their beneficiaries, for example, including, but not limited to an overview of the GLOBE Model and what the cost-sharing reductions mean for beneficiaries.

We appreciate the commenters' concern about collecting incorrect beneficiary coinsurance amounts. After reviewing the comments received, to mitigate this potential risk and to minimize potential administrative burden on providers and suppliers, we are modifying § 513.210 by adding new paragraph (b)(4) to clarify that the applicable GLOBE Model beneficiary coinsurance adjustment is determined solely by CMS and administrative and judicial review is precluded consistent with sections 1847A(i)(8)(D) and (E) of the Act and section 1115A(d)(2) of the Act. CMS will update its claims processing systems such that the applicability of the GLOBE Model beneficiary coinsurance adjustment will be determined as part of claims processing on the date a claim is processed.

*Comment:* A commenter stated that the mark-ups that 340B hospitals charge on Part B medications exceed the total price of those drugs in wealthy European countries and that these markups inflate insurance premiums and increase patients' coinsurance spending. The commenter suggests reforms are needed to ensure transparency and eliminate abuse of the 340B Program in order to improve affordability and access.

*Response:* We thank the commenter for sharing their concerns regarding the 340B Program. We refer the commenter to section II.N.2. of the GLOBE Model proposed rule for a discussion of the potential interactions of the GLOBE Model with the 340B Program; proposed reforms to the 340B Program are outside the scope of this final rule.

*Final Decision:* After consideration of the public comments received, CMS is finalizing § 513.210 with modifications to clarify that GLOBE Model beneficiary coinsurance would only apply to claims when 42 CFR 410.152(m), 42 CFR 419.41(e), and 42 CFR 489.30(b)(6) as applicable would apply. CMS is also adding new paragraph § 513.210(b)(4) to clarify that the applicable GLOBE Model beneficiary coinsurance adjustment is determined solely by CMS and administrative and judicial review is precluded consistent with sections 1847A(i)(8) of the Act and section 1115A(d)(2) of the Act. Sections 1847A(i)(8)(D) and (E) of the Act preclude administrative or judicial review of the computation of coinsurance and amounts paid related to the Medicare Part B Drug Inflation Rebate Program, respectively. Absence of such language elsewhere does not mean other parts of the GLOBE Model are not precluded from administrative and judicial review consistent with section 1847A(i)(8) of the Act and section 1115A(d)(2) of the Act.

CMS is finalizing paragraphs (a), (c), and (d) in § 513.210 as proposed, without modification. CMS is also finalizing the definitions in § 513.200 with a technical modification to remove the definition of ''per unit GLOBE Model benchmark amount.'' In its place, CMS is finalizing § 513.210(b) with a modification to clarify that the per unit GLOBE Model benchmark amount is set forth in § 513.400(c)(4) and to include regulatory text for ensuring 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 as proposed at 90 FR 60266 but omitted from the proposed regulatory text.

Specifically, CMS made the following changes:

- In paragraph § 513.210(b), ''GLOBE Model drugs'' is revised to read as ''a GLOBE Model drug'' and the matter after ''CMS'' is replaced with ''uses the following steps:'';
- Paragraphs § 513.210(b)(1) and (2) are renumbered as paragraphs § 513.210(b)(2) and (3) respectively.
- New paragraph § 513.210(b)(1) is added and reads as ''CMS identifies the lesser of the per unit GLOBE Model benchmark amount as set forth in § 513.400(c)(4) and the inflation-adjusted payment amount for the applicable calendar quarter determined under 42 CFR 427.302(g) as determined by CMS.'';
- The first sentence of renumbered § 513.210(b)(2) is updated to read as ''If the payment amount as set forth in 42 CFR 427.201(b)(3) exceeds the amount identified in paragraph (b)(1) of this section, the GLOBE Model beneficiary coinsurance adjustment applies and the GLOBE Model beneficiary coinsurance is calculated by multiplying the amount identified in paragraph (b)(1) of this section by 0.20.''; and
- Renumbered § 513.210(b)(3) is updated to read as ''If the payment amount as set forth in 42 CFR 427.201(b)(3) does not exceed the amount identified in paragraph (b)(1) of this section, the adjustment to the beneficiary coinsurance set forth in paragraph (b)(2) 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.''8. GLOBE Model Rebates Reports, Invoicing, and Reconciliation

In section II.G.8. of the GLOBE Model proposed rule (90 FR 60299) and in proposed 42 CFR 513 subpart H, we presented two alternative approaches for how CMS would invoice manufacturers for GLOBE Model rebates. We stated that, after considering future comments on the GLOBE Model proposed rule, CMS intends to adopt one of these approaches, or a similar approach that emerges from CMS's consideration of comments and further analysis of the alternatives and establish corresponding regulatory text. Hence, although the GLOBE Model proposed rule included two options for invoicing

processes in subpart H, CMS only described one option within the regulatory text (90 FR 60333). We stated that CMS only intends to include one option in a final rule that would establish the GLOBE Model.

As discussed in the GLOBE Model proposed rule, one option we considered is called the ''combined'' approach. Under a combined approach, we proposed that, 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 final rule. Because there would be a single combined report and rebate amount due, we proposed 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 final 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.

We stated that 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. We also stated that, for CMS, the increased operational complexity of combining data from the Medicare Part B Drug 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.

Also as discussed in the GLOBE Model proposed rule, another option we considered is called the ''incremental'' approach. Under the incremental approach, we proposed that 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 § 513.500(b). Under this two-stage process, we proposed that 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 § 513.710 and further discussed in section II.G.8.b. of this final rule. In § 513.710(b), we proposed 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 as set forth in § 513.710(c).

Consistent with our proposed timing of invoicing activities, the GLOBE Model Preliminary Rebate Report would reflect any revisions identified through the Suggestion of Error (SOE) 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 § 513.720, we proposed a separate SOE process such that a manufacturer would submit its SOE 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 that would be 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. We stated that the incremental approach, using a two-step reporting and invoicing process and separate SOE 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. We stated that, 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, and 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 estimated 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 2 months.

At § 513.20, we proposed, that ''date of receipt'' would have the same meaning as set forth in 42 CFR 427.500. We proposed that this term would be applicable to both options.

We sought comment 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's systems, operations, and financial resources.

The following is a summary of the comments received and our responses.

*Comment:* A commenter stated that current billing payment statements under the Medicare Part B Drug Inflation Rebate Program are inadequate for the level of detail required for the GLOBE Model, noting that they contain little more than an NDC code, number of units dispensed, and an amount owed. The commenter recommended that CMS work with affected manufacturers to develop a billing statement that would provide sufficient information to ensure that claims and rebate data are accurate (including the identification of 340B claims) and that any data derived from the GLOBE Model to support future claims of efficacy can be validated.

*Response:* We thank the commenter for their input. We believe that the data proposed to be provided in the Preliminary GLOBE Model Rebate Reports are sufficient for manufacturers to review the Preliminary GLOBE Model

Rebate Report for a Suggestion of Error. Thus, we interpret the commenter's feedback as seeking clarification on the level of information that will be made available for GLOBE Model Rebate Reports, including how rebatable units for purposes of the GLOBE Model will be identified.

As discussed in section II.G.8.b. of this final rule, CMS is finalizing an incremental invoicing approach. We are finalizing under § 513.710(b)(1), the GLOBE Model Preliminary Rebate Report for an applicable calendar quarter, under an incremental invoicing approach, would include the following information:

- 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 under § 513.520;
- The total number of billing units as determined under 42 CFR 427.303;
- The per unit Method I GLOBE Model benchmark as identified under § 513.410;
- The per unit Method II GLOBE Model benchmark, if available, as identified under § 513.420;
- The per unit GLOBE Model benchmark amount as set forth in § 513.400;
- The per unit GLOBE Model rebate amount as set forth in § 513.510(a) ;
- The incremental per unit GLOBE Model rebate amount as set forth in § 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 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 under § 513.510(a) for the GLOBE Model drug for the applicable calendar quarter, as set forth in § 513.510(a)(1)(i);
- The total GLOBE Model rebate amount as set forth in § 513.500(a);
- The incremental GLOBE Model rebate amount as determined in § 513.500(b);
- Any applied reductions as determined under 42 CFR 513 subpart F;
- The proportion of manufacturer-reported ASP units, if applicable;
- The reduced incremental GLOBE Model rebate amount, if applicable;
- The incremental GLOBE Model rebate amount or reduced incremental GLOBE Model rebate amount due, if any; and
- Other data elements as determined by CMS.

The subsequent GLOBE Model Rebate Report, as set forth in § 513.710(c), would also include the information listed above, as well as any revisions resulting from CMS's review of a Suggestion of Error as set forth under § 513.720, if applicable, and any CMS-determined recalculations pursuant to § 513.720(d)(2). We note that the above-mentioned information includes two provisions that were not shown in the proposed regulatory text but were discussed conceptually in the GLOBE Model proposed rule preamble (90 FR 60301). These provisions are (1) the amount, if any, by which the specified amount exceeds the per unit GLOBE Model rebate amount and (2) the incremental GLOBE Model rebate amount or reduced incremental GLOBE Model rebate amount due, if any (incremental GLOBE Model rebate owed). The inclusion of these provisions are technical modifications to the regulatory text to align with the preamble of the GLOBE Model proposed rule and also to provide clarification that the rebate report will include the incremental amount owed by the manufacturer. We are also including an additional provision at § 513.710(b)(1)(xviii) to allow CMS to add other data elements to the GLOBE Model rebate reports, as determined by CMS, as necessary to support model operations. We believe that this level of detail will be sufficient for manufacturers to identify any potential mathematical errors.

Accurate identification of rebatable billing units is a priority for CMS. Under the Medicare Part B Drug Inflation Rebate Program, CMS provides guidance on how CMS identifies the number of billing units sold during the rebate quarter and to assist manufacturers' understanding of how billing units are identified.

For the GLOBE Model, the CMS Innovation Center will work closely with the Medicare Part B Drug Inflation Rebate Program and will use the total number of billing units as determined in accordance with 42 CFR 427.303(b) as the starting point for identifying the total number of GLOBE Model billing units as set forth under § 513.520. The total number of billing units determined under 42 CFR 427.303(b) excludes the following: (1) billing units acquired under the 340B Program, as identified under 42 CFR 427.303(b)(1); (2) billing units with a rebate under section 1927 of the Act, as identified under 42 CFR 427.303(b)(2); (3) billing units that are packaged into the payment amount for an item or service and are not separately payable, as identified under 42 CFR 427.303(b)(3); (4) billing units when a drug is no longer a Part B rebatable drug, as identified under 42 CFR 427.303(b)(4); and (5) billing units subject to discarded drug refunds, as identified under 42 CFR 427.303(b)(5). Any future changes to the determination of total number of billing units under 42 CFR 427.303 would carry over to the GLOBE Model.

From the total number of billing units determined under 42 CFR 427.303(b), CMS will identify the billing units for which, on the date of service: (1) the beneficiary was identified by CMS as a GLOBE Model eligible beneficiary, and (2) OM Part B made separate payment under the model.

To implement the GLOBE Model, CMS is modifying the OM Part B claims processing systems. These modifications will enable real-time identification of claims for GLOBE Model drugs furnished to GLOBE Model eligible beneficiaries that were processed using the GLOBE Model claims processing instructions. These instructions will be issued prior to the start of the model and will implement the GLOBE Model beneficiary coinsurance percentage and adjusted Medicare payment amount. Information for interested parties, including beneficiaries and healthcare providers, will be made available on the GLOBE Model website.

By capturing GLOBE Model claims in real time, CMS believes it will accurately calculate the total GLOBE Model billing units, the total GLOBE Model rebate amount, the incremental GLOBE Model rebate amount due, and other applicable calculations. Throughout the GLOBE Model payment period, the CMS Innovation Center will maintain a help desk which manufactures can email to request assistance with their inquiries.

*Comment:* Two commenters raised concerns regarding pharmacy involvement in the GLOBE Model rebate process. A commenter requested clarification on whether pharmacies would have any role in the rebate invoicing, payment, or reconciliation process under the GLOBE Model, or whether that process would be exclusively between manufacturers and CMS. A second commenter urged CMS not to impose additional administrative burdens or unfunded mandates on pharmacies, pharmacists, or pharmacy personnel related to payment, reconciliation, reimbursement, reporting, or distribution.

*Response:* The GLOBE Model Rebate Reports, invoicing, payment, Suggestion

of Error, and reconciliation processes, as set forth in 42 CFR 513 subpart H, will involve only manufacturers of GLOBE Model drugs (and their designees, if applicable) and CMS (and its contractors, as applicable). Pharmacies and other healthcare providers and suppliers will not be involved in these processes.

As discussed in section II.B. of this final rule, Medicare Part B providers and suppliers who furnish GLOBE Model drugs to OM beneficiaries in the model cohort will not be GLOBE Model participants. These providers and suppliers will continue to buy and bill for GLOBE Model drugs as usual and receive separate payment under Medicare Part B, as applicable. Additionally, as with the Medicare Part B Drug Inflation Rebate Program, when the GLOBE Model beneficiary coinsurance adjustment for GLOBE Model Drugs applies, 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, the Medicare payment amount is correspondingly adjusted and 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. Accordingly, the GLOBE Model will not impact OM Part B providers' or suppliers'' payment levels.

To assist providers and suppliers to anticipate when the GLOBE Model beneficiary coinsurance adjustment may apply, CMS will publish the ZIP Codes that constitute the GLOBE Model geographic regions, which would enable providers and suppliers to identify if their OM beneficiaries may have been selected into the model and therefore may qualify for reduced coinsurance. CMS will also publish quarterly the GLOBE Model Drug List with the applicable GLOBE Model beneficiary coinsurance percentage. Providers and suppliers will continue to be informed of the coinsurance amounts owed by their beneficiaries as part of usual Medicare claims processing. CMS does not anticipate that providers and suppliers will require additional support beyond these resources and the usual existing claims process to ensure accurate collection of coinsurance from their beneficiaries. Further, because Medicare Part B payment limits for separately payable drugs are updated quarterly, we believe that providers have established expertise in adjusting their estimates of the coinsurance amounts that beneficiaries would owe and that any additional effort related to the GLOBE Model would be minimal, particularly because providers commonly identify beneficiary coinsurance after all applicable payers have adjudicated a claim. As such, no unfunded mandates will be imposed on pharmacies, pharmacists, or pharmacy personnel as a result of the GLOBE Model rebate process.

For additional information regarding our responses to administrative burdens and unfunded mandates more broadly, we refer readers to section IV. (Final Regulatory Impact Analysis) of this final rule.

*Comment:* A couple of commenters strongly supported the use of the proposed incremental approach (rather than the combined approach) for GLOBE Model rebate amounts reports, invoicing, and reconciliation processes. Key reasons include: the incremental approach preserves the integrity and timeline of the existing Medicare Part B Drug Inflation Rebate Program under the IRA, avoiding unnecessary delays to existing Rebate Reports; the combined approach would delay Preliminary Rebate Reports for all manufacturers by up to 2 months, creating administrative disruption even for manufacturers not subject to GLOBE Model obligations; the incremental approach reinforces the proposed severability policies, ensuring that GLOBE Model operations do not interfere with the IRA's inflation rebate program if the model is challenged or invalidated; and separate reporting timelines reduce the risk of errors and allow for cleaner reconciliation processes. The commenters also expressed their belief that the incremental approach would be operationally more favorable than the combined approach and would provide administrative efficiencies for CMS and manufacturers.

*Response:* We thank the commenters for sharing their support for the incremental approach. After careful consideration of the comments received, CMS agrees with commenters that the incremental approach is the appropriate framework for reporting, reconciling, and invoicing GLOBE Model rebate amounts. We are finalizing the incremental approach in this final rule.

As discussed in section II.G.8. of the GLOBE Model proposed rule (90 FR 60299 through 60302), CMS sought to establish an efficient approach that closely aligns with processes currently used under the Medicare Part B Drug Inflation Rebate Program and would be familiar to manufacturers of Part B rebatable drugs. We agree with commenters that maintaining the established timelines and operational integrity of the Medicare Part B Drug Inflation Rebate Program under the IRA is a paramount concern. The IRA's inflation rebate program represents a significant statutory obligation with established reporting cadences and manufacturer expectations. CMS does not intend for the GLOBE Model to disrupt or supersede the IRA's existing rebate infrastructure. The incremental approach allows GLOBE Model-specific rebate amount calculations and reporting to proceed while preserving the Medicare Part B Drug Inflation Rebate Program's timelines and minimizing operational disruption to the broader manufacturer community.

CMS is persuaded by commenters' concerns that the combined approach would impose administrative burdens on manufacturers that have no GLOBE Model obligations. Delaying Preliminary Rebate Reports by up to 2 months for all manufacturers—including those not participating in or subject to the GLOBE Model—could lead to disproportionate operational consequence. The incremental approach appropriately limits the administrative impact of the GLOBE Model to those manufacturers with actual GLOBE Model rebate obligations, consistent with CMS's general commitment to minimizing unnecessary regulatory burden.

CMS also agrees with commenters that separate reporting timelines reduce the risk of errors and facilitate cleaner reconciliation processes. Combining GLOBE Model and IRA inflation rebate reporting into a single, integrated process introduces complexity that could increase the likelihood of calculation errors, data discrepancies, and reconciliation disputes. The incremental approach allows each rebate amount calculation to be independently verified and reconciled, improving accuracy and reducing administrative burden for both manufacturers and CMS.

Based on the comments received, CMS is finalizing the incremental invoicing approach at § 513.710. CMS believes that this approach supports the efficient testing and evaluation of the GLOBE Model, provides adequate transparency for manufacturers and minimizes adverse impacts on manufacturers and on CMS's systems, operations, and financial resources.

Additionally, CMS is modifying the definition for ''date of receipt'' in § 513.20 to align with the required definition for the incremental approach. For the incremental approach, the date of receipt means the calendar day

following the day on which a report of a GLOBE Model rebate amount (as set forth in § 513.500(a) through (f)) is made available to the manufacturer of a GLOBE Model drug by CMS.

*Final Decision:* After consideration of the comments received, CMS has determined that the incremental invoicing approach will provide sufficient information to ensure the accuracy of claims and rebate data under the GLOBE Model. CMS is finalizing § 513.710 with modification to add the following provisions in § 513.710(b)(1) and adjust the paragraph numbering accordingly:

- 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 § 513.510(a) for the GLOBE Model drug for the applicable calendar quarter as set forth in § 513.510(a)(1)(i);
- The incremental or reduced incremental GLOBE Model rebate amount due, if any; and
- Other data elements as determined by CMS.

CMS is also finalizing the definition of ''*date of receipt*'' in § 513.20 with modification to align with the incremental approach. As finalized, ''*date of receipt*'' means the calendar day following the day on which a report of a GLOBE Model rebate amount (as set forth in § 513.500(a) through (f)) is made available to the manufacturer of a GLOBE Model drug by CMS.

CMS has also made non-substantive modifications to correct typographical errors that appear in the proposed regulatory text for § 513.710(b) and made comporting changes within § 513.710(b). Specifically, CMS has corrected (1) citation in § 513.710(b)(vii) from ''§ 513.520'' to ''§ 513.510(a);'' (2) citation in § 513.710(b)(viii) from ''§ 513.520'' to ''§ 513.510(b);'' (3) citation in § 513.710(b)(xii) from ''§ 513.500'' to ''§ 513.500(a);'' and (4) removed ''as determined'' from § 513.710(b)(x) and § 513.710(b)(xi).

CMS has also made comporting changes to § 513.710(d)(1)(i) to address the additional information finalized in § 513.710(b) and to fix drafting errors. Specifically, in § 513.710(d)(1)(i), ''paragraph (b)(1)(i) through (xiii)'' is updated to ''paragraph (b)(1)(i) through (xviii)'' and ''paragraphs (d)(1)(i)(A) through (K)'' is updated to ''paragraphs (d)(1)(i)(A) through (J).''

CMS has also made technical corrections to § 513.710(c) to address the following drafting errors: (1) an incorrect CFR citation for the SOE; (2) clarification that the GLOBE Model Rebate Report serves as the invoice of a manufacturer's incremental GLOBE Model amount or reduced incremental GLOBE Model rebate amount due; (3) changed ''from paragraph d(2) of this section'' to ''pursuant to paragraph d(2) of this section;'' and (4) a clarification that the manufacturer's incremental GLOBE Model amount or reduced incremental GLOBE Model rebate amount due—not the total rebate amount—is reported as a dollar amount rounded to the nearest cent.

We note that CMS will also provide additional operational guidance, including specific reporting timelines and submission requirements, through sub-regulatory guidance issued in advance of the model's implementation to inform model participants of the manner and process for obtaining reports and submission of a SOE.

a. 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 proposed 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 proposed 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 stated our belief that it would not 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 proposed to waive 42 CFR 427.501 to the extent necessary to include GLOBE Model rebate information within the Rebate Report (and subsequent reports). We proposed 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 proposed 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 § 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 final rule and identified under § 513.410); the per unit Method II GLOBE Model benchmark, if available (as described in section II.G.2.b. of this final rule and identified under § 513.420); the per unit GLOBE Model benchmark amount as set forth in § 513.400; the per unit GLOBE Model rebate amount as set forth in § 513.510(a); the incremental per unit GLOBE Model rebate amount as set forth in § 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 § 513.500(a); the incremental GLOBE Model rebate amount as set forth in § 513.500(b); 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 § 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 42 CFR 427.301(a). We noted that, while we proposed to issue the Preliminary Rebate Reports 2 months 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 proposed several amendments to 42 CFR 427.501(b)(2), (c) and (d). Specifically, we proposed that 42 CFR 427.501(c) would be waived 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 Rebate Report with the total GLOBE Model rebate amount due for a GLOBE Model drug for that applicable calendar quarter. We proposed 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 the GLOBE Model proposed rule (90 FR 60308), under the combined approach, we proposed 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 all Part B rebatable drugs by up to 2 months. We proposed 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. As such, we did not propose a separate SOE process for GLOBE Model information under the combined approach. We proposed that, 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.

*Final Decision:* CMS did not receive comments in support of the combined approach. Having received comments in favor of the incremental approach, CMS is finalizing the incremental approach for rebate reporting and reconciliation, as discussed in sections II.G.8.a. and II.G.8.b. of this final rule.

b. 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 § 513.710 and § 513.720, we proposed regulatory text for GLOBE Model Rebate Reports and reconciliation, including a SOE 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 § 513.710(c), for the GLOBE Model rebate reporting activities, we proposed 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 § 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 § 513.520; the total number of billing units as determined under 42 CFR 427.303; the per unit Method I GLOBE Model benchmark as identified under § 513.410; the per unit Method II GLOBE Model benchmark as identified under § 513.420; the per unit GLOBE Model benchmark amount as set forth in § 513.400; the per unit GLOBE Model rebate amount as set forth in § 513.510(a); the incremental per unit GLOBE Model rebate amount as set forth in § 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 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 § 513.510(a) for the GLOBE Model drug for the applicable calendar quarter as set forth in § 513.510(a)(1)(i); the total GLOBE Model rebate amount as set forth in § 513.500(a); the incremental GLOBE Model rebate amount as determined in § 513.500(b); 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 § 513.710, we proposed 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 would continue to include 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 invoice that is specific to the GLOBE Model for an applicable calendar quarter, we proposed 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 rebate amount. The incremental rebate amount due (and invoiced on the GLOBE Model Rebate Report) would be calculated by multiplying the incremental per unit GLOBE Model rebate amount by the total number of GLOBE Model billing units as proposed under § 513.520 and then applying applicable reductions as

determined under 42 CFR 513 subpart F. 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. We proposed that the GLOBE Model would adopt the reconciliation approach under the Medicare Part B Drug Inflation Rebate Program specified at 42 CFR 427.501(d). That is, we proposed that, within 12 months of the issuance of the GLOBE Model Rebate Report, a report of the reconciled incremental GLOBE Model rebate amount would 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 would conduct a preliminary reconciliation of the incremental GLOBE Model rebate amount as set forth in § 513.710(d). We also proposed that 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 in the GLOBE Model proposed rule (90 FR 60302) and repeated in the final rule (Table 9A), showed 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 9A: ILLUSTRATION OF THE PROPOSED TWO-STEP INVOICING TIMELINE FOR GLOBE MODEL REBATE AMOUNTS: EXAMPLE FOR APPLICABLE CALENDAR QUARTER OCTOBER – DECEMBER 2026[a]**

| 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 § 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 § 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 § 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 § 513.710(d)(1) | Within 12 months of the date of issuance of the GLOBE Model Rebate Report | August 31, 2028 |

Note: To assist readers, this Table 9A is a reprint of Table 9 that appears in the GLOBE Model proposed rule at 90 FR 60302.

We proposed 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 stated our belief 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 and incremental rebate 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 proposed 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.

In § 513.500, we proposed 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 incremental GLOBE Model rebate amount such that the

rebate amount due would reflect such reductions (if applicable). In addition, we proposed 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.

We proposed that, 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.

We received comments in favor of the incremental approach and are finalizing the incremental approach for rebate report and reconciliation. We refer readers to section II.G.8. for comments related to the incremental approach and our responses.

As discussed in section II.A. of this final rule, we are revising the model start date to January 1, 2027, with the first performance year starting April 1, 2027, to provide additional time for implementation and stakeholder readiness. As such, we have updated the information that appeared in Table 9 in the GLOBE Model proposed rule (90 FR 60302) to reflect the model start date and beginning of model performance period as finalized at § 513.1(c).

**TABLE 9B: ILLUSTRATION OF THE INCREMENTAL INVOICING TIMELINE FOR GLOBE MODEL REBATE AMOUNTS: EXAMPLE FOR APPLICABLE CALENDAR QUARTER APRIL – JUNE 2027**

| 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 | November 30, 2028 | GLOBE Model Preliminary Rebate Report (See § 513.710(b) | At least 1 month prior to the issuance of the GLOBE Model Rebate Report | January 31, 2028 |
| Rebate Report (See 42 CFR 427.501(c)) | No later than 6 months after the end of each applicable calendar quarter | December 31, 2028 | GLOBE Model Rebate Report (See § 513.710(c) | No later than 8 months after the end of each applicable calendar quarter | February 29, 2028 |
| 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 | November 30, 2029 | Rebate Report – Preliminary Reconciliation (See § 513.710(d(1)(i) | At least 1 month prior to the issuance of a report with the reconciled rebate amount | January 31, 2029 |
| Rebate Report – Regular Reconciliation (See 42 CFR 427.501(d)(1)) | Within 12 months of the issuance of the Rebate Report | December 31, 2029 | Rebate Report – Regular Reconciliation (See § 513.710(d)(1) | Within 12 months of the date of issuance of the GLOBE Model Rebate Report | February 28, 2029 |

c. Suggestion of Error (SOE) Process Under the Incremental Approach

In § 513.720, we proposed a SOE process for the GLOBE Model such that a manufacturer would submit its SOE to CMS, for CMS's 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. We proposed that CMS would make available a method for a manufacturer to submit a SOE for GLOBE Model reports that would be substantially similar to the method used for the Medicare Part B Drug Inflation Rebate Program. Further, we proposed that CMS would include any revisions to the calculation of the incremental GLOBE Model rebate amount, if determined necessary by CMS based on the manufacturer's SOE, 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 SOE. We noted that the scope of the SOE process set forth in § 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 sought comment on our proposal for a separate SOE process that would be included for the incremental approach if such approach is adopted for the model.

The following is a summary of the comments received and our responses.

*Comment:* Several commenters expressed concern that CMS did not propose any review, reconsideration, or appeal process for manufacturers. Commenters stated that it is important for CMS to provide a process through which manufacturers can seek review of the agency's calculations and rectify errors in identification of GLOBE Model beneficiaries, coinsurance, reimbursement, and rebate calculations.

*Response:* We respectfully disagree with the assertion that CMS did not propose any review, reconsideration, or appeal process for manufacturers. As discussed in section II.G.8. of the GLOBE Model proposed rule (90 FR 60244 through 60254), CMS discussed that the SOE process would be available to GLOBE Model participants who believe there is a mathematical error or errors to be corrected prior to the issuance of the Rebate Report or a subsequent reconciliation of the rebate amount due.

CMS does not believe a more complex review process is necessary, as the GLOBE Model SOE process will mirror the already-established Suggestion of Error process in the Medicare Part B Drug Inflation Rebate Program—a framework that is familiar to manufacturers of Part B rebatable drugs.

In addition, CMS plans to make the following information publicly available on the CMS website for review by providers, beneficiaries, and other interested parties: GLOBE Model geographical ZIP Code areas; the GLOBE Model Drug List; and cost-sharing reduction information. Based on the comments received, CMS also intends to publish technical documents—such as a user-friendly fact sheet or similar resource—that providers can use or share with their beneficiaries regarding, for example, the overview and goals of the GLOBE Model. Furthermore, CMS intends to leverage existing infrastructure, including a model help desk, where providers and manufacturers may submit inquiries.

*Comment:* A commenter opposed the proposed SOE process, noting that a courtesy process is insufficient for a mandatory, high-dollar model. The commenter urged CMS to clarify the methodology—including data used and underlying assumptions—to improve transparency, and to incorporate reconciliation and resolution of errors so that GLOBE Model determinations are contestable, attributable, and correctable, with binding timelines and escalation procedures.

*Response:* We thank the commenter for sharing their concern regarding the proposed SOE process.

As discussed in section II.G.8. of the GLOBE Model proposed rule (90 FR 60244 through 60254), CMS presented its proposed process—including timelines—for manufacturers to submit a SOE when they believe there is a mathematical error or errors to be corrected prior to the finalization of the Rebate Report or a subsequent reconciliation of the rebate amount due. Our timelines for the SOE process mirror the binding timelines in the Medicare Part B Drug Inflation Rebate Program, 42 CFR 427.503(c), which states the manufacturer must submit its Suggestion of Error for the applicable calendar quarter within 10 calendar days from the date of receipt of a Preliminary Rebate Report or a preliminary reconciliation of a rebate amount using the method and process established by CMS.

As stated in section II.G.8. of this final rule, CMS is adopting the incremental invoicing approach. CMS believes this approach supports the efficient testing and evaluation of the GLOBE Model and provides adequate transparency for manufacturers to identify mathematical errors and for CMS to make revisions, if deemed necessary, prior to the issuance of the GLOBE Model Rebate Report—while minimizing adverse impacts on manufacturers and the CMS's systems, operations, and financial resources.

The GLOBE Model's SOE process, as previously stated, mirrors the existing Medicare Part B Drug Inflation Rebate Program's Suggestion of Error process. As such, the GLOBE Model will utilize the established methodology of that program, which is already familiar to manufacturers of Part B rebatable drugs. CMS believes that leveraging this existing framework—rather than developing a more complex separate process—is appropriate given the model's structure and the nature of the calculations involved.

With respect to an escalation procedure, we believe the SOE process is sufficient for manufacturers to escalate to CMS if they believe there is a mathematical error or errors to be corrected. Additionally, we note that administrative and judicial review is precluded consistent with sections 1847A(i)(8) and 1115A(d)(2) of the Act.

*Final Decision:* After careful consideration of the comments received, CMS is finalizing § 513.720 as proposed, without modification, except to correct two drafting errors: (1) an incorrect CFR citation; (2) to change ''total'' to ''incremental'' in paragraph (c); and (3) the removal of the word ''total'' from § 513.720(d). As corrected, § 513.720(d) should reference § 513.710(b) and § 513.710(c)(1), respectively.

*H. Program Compliance Requirements and Enforcement*

1. Enforcement Action

a. Enforcement of GLOBE Model Rebate Amount Payments by Manufacturers

In § 513.740, we proposed that the manufacturer of a GLOBE Model drug would be required to pay the incremental GLOBE Model rebate amount by 11:59 p.m. PT on the 30th calendar day after receipt of the GLOBE Model Rebate Report.

We stated in the GLOBE Model proposed rule (90 FR 60302) that manufacturer payment of GLOBE Model rebate amounts is critical to model test integrity and is necessary to make the OM program whole. Without these payments, there would be limited ability to test potential savings to program expenditures or impacts to quality of care. In circumstances when CMS reduces the coinsurance for GLOBE Model eligible beneficiaries who have received a GLOBE Model drug (that is, when the published payment amount, as set forth in 42 CFR 427.201(b)(3), exceeds the per unit GLOBE Model benchmark amount), we stated that 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. Given the importance of these rebates, we proposed that 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 to effectuate this model test.

Consistent with the Medicare Part B Drug Inflation Rebate Program and the regulations at 42 CFR 427.600, in § 513.800, we proposed that manufacturers of a GLOBE Model drug that have failed to timely pay the incremental GLOBE Model rebate amount, including any reconciled rebate amount, would be subject to a CMP in an amount equal to 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 would be separate from and in addition to any CMP assessed under 42 CFR 427.600.

We further proposed to rely on the general CMP authority in section 1128A of the Act as codified in 42 CFR part 423, subpart T. For instance, 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.'' We stated our belief 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.

In addition, we proposed that, if CMS assesses a CMP for a manufacturer, the manufacturer would be held responsible for paying the incremental GLOBE Model rebate amount, and any related CMP amount imposed on the incremental GLOBE Model rebate. We proposed 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 the incremental GLOBE Model rebate amount, we 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 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 for CMS to pursue CMPs in order to ensure compliance with payments of the incremental GLOBE Model rebate amount, and to effectuate this model test.

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 § 513.800(b).

We also proposed appeals procedures for GLOBE Model rebate amounts at § 513.800, including a manufacturer's right to a hearing following a decision by CMS to impose a CMP. We proposed to codify CMP and appeals procedures for GLOBE Model rebate amounts at 42 CFR 513, subpart I.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters objected to the use of CMPs to enforce GLOBE Model rebate amount payments. Commenters maintained that CMS lacks statutory authority to impose CMPs without Congressional authorization and that CMPs are beyond an agency's administrative powers. A commenter further contended that the CMP structure is disproportionate and lacks procedural protections for manufacturers. Another commenter stated that the CMP structure introduces coercion.

*Response:* We thank commenters for expressing their concerns regarding the use of CMPs to enforce GLOBE Model rebate obligations.

We note section 1115A(b) of the Act grants CMS the authority to test payment and service delivery models, and manufacturer payment of GLOBE Model rebate amounts is critical to the integrity of the model test.

Furthermore, section 1128A of the Act provides CMS with broad authority to impose CMPs in a variety of contexts where program integrity and compliance are at issue. CMS has long relied on CMPs as a standard and legally recognized tool to enforce compliance with Medicare and Medicaid program requirements. The use of CMPs in the GLOBE Model is consistent with this established legal framework and is necessary to ensure that manufacturers fulfill their rebate obligations and that the OM program is made whole, thereby supporting the model's cost-reduction objectives. We note that Congressional authorization for CMPs need not be model-specific; rather, the existing statutory framework under sections 1115A and 1128A of the Act provides a sufficient legal basis for the enforcement mechanisms established in this final rule.

We respectfully disagree with the characterization that CMPs are beyond CMS's administrative powers in this context or introduce coercion. Federal agencies routinely exercise enforcement authority through CMPs when such authority is grounded in statute, and courts have consistently upheld the use of CMPs as a legitimate exercise of administrative power where the statutory basis is clear. As noted previously, the statutory authority under sections 1115A and 1128A of the Act provides the requisite legal foundation for the GLOBE Model's enforcement mechanisms. The CMP structure established in this final rule represents a reasonable and proportionate exercise of that authority, designed to deter non-compliance and protect the integrity of the Medicare program and Federal expenditures by ensuring that manufacturers fulfill their rebate obligations and that the OM program is made whole.

We also believe our proposed CMP structure is proportionate, as it aligns with the CMP structure established under the Medicare Part B Drug Inflation Rebate Program. Accordingly, where the CMS Innovation Center tests a model under section 1115A of the Act that tests an alternative change to the calculation of the rebate amount within that existing statutory framework, CMS believes the existing congressional penalty authority remains applicable to the rebate obligation as tested under the model. Because the GLOBE Model tests an alternative rebate methodology for the otherwise applicable statutory rebate amount for certain drugs tested under the model, use of the existing enforcement mechanism is necessary to effectuate the alternative payment in the same manner that the Medicare Part B Drug Inflation Rebate Program operates. Additionally, we note that a manufacturer retains the right to a hearing following any CMS decision to impose a CMP, and those hearing and appeal rights are set forth in statute under section 1128A of the Act. We believe those standard and established appeal and hearing rights are an adequate procedural protection for manufacturers.

*Final Decision:* After careful consideration of the public comments received, CMS is finalizing § 513.800 with modifications to clarify the CMP structure aligns with the CMP structure established under the Medicare Part B Drug Inflation Rebate Program, by adding the following: ''The provisions of 42 CFR 427.600 regarding the imposition of civil money penalties and their respective appeals also apply with respect to this subchapter to the same extent as they are applicable with respect to part 427, except that, in applying such provisions with respect to this subpart, any reference to 42 CFR 427.301(a) shall be considered a reference to the incremental GLOBE Model rebate amount calculated pursuant to § 513.500.'' As this revised language adequately covers CMP determination, notice, collection, and appeal, CMS has removed the provisions related to determination of the CMP amount, notice of imposition of CMPs, collection of CMPs, and appeal procedures for CMPs in paragraphs § 513.800(b) through (e) and renumbered paragraph § 513.800(f) as paragraph § 513.800(b).

b. Other Enforcement Actions

We proposed that CMS could impose one or more enforcement actions such as CMPs 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 proposed 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 final rule had taken place:

- Suspending or terminating the data agreement with the manufacturer.
- Requiring the manufacturer to provide additional requested information to CMS or its designees through an audit.
- Subjecting the manufacturer to additional monitoring, auditing, or both.

As part of the CMS 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 program integrity interests of the Medicare program. For this reason, CMS will monitor actions of GLOBE Model 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 sought 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.

We received no comments on this proposal.

*Final Decision:* All manufacturers must abide by all existing Federal rules and regulations. Therefore, this language is not subject to finalization of such requirements in regulatory text since the government retains the authority to audit, monitor, request additional information, and terminate a participant in other existing Federal rules and regulations.

*I. Collection of GLOBE Model Rebate Amounts*

1. Systems To Collect GLOBE Model Rebate Amounts

In § 513.740, CMS proposed the deadline and process for payment of incremental GLOBE Model rebate amounts, including the amounts owed by a manufacturer, the consequences of failure to pay an incremental GLOBE Model rebate amount due, and potential refunds to a manufacturer (as articulated similarly in 42 CFR 427.505), applicable to GLOBE Model rebate amounts calculated under the GLOBE Model. In § 513.730, we proposed the process by which manufacturers would access Rebate Reports (which is substantially similar to the process codified in 42 CFR 427.504). We stated that this process would apply to Rebate Reports including GLOBE Model rebate amounts (that is, combined rebate amounts, under the proposed combined invoicing approach described in section II.G.8.a. of the GLOBE Model proposed rule and incremental GLOBE model rebate amounts under the incremental invoicing approach described in section II.G.8.b. of the GLOBE Model proposed rule, as applicable) calculated under the GLOBE Model, including any report of reconciled rebate amounts. In addition, we proposed that the ''date of receipt'' would have the same meaning as set forth in 42 CFR 427.500, that is the date of receipt would be the calendar day following the day on which a report of a GLOBE Model rebate amount (as set forth in § 513.500) is made available to the manufacturer of a GLOBE Model drug by CMS.

We also proposed, in § 513.740(a), that payment of an incremental GLOBE Model rebate amount owed by a manufacturer would be due no later than 11:59 p.m. PT on the 30th calendar day after the date of receipt of information regarding the rebate amount on a GLOBE Model Rebate Report (as set forth in § 513.710) or a report of a reconciled incremental GLOBE Model rebate amount (as set forth in § 513.710(d)). In addition, in § 513.740(c), we proposed that if a reconciled incremental GLOBE Model rebate amount for an applicable calendar quarter as set forth in § 513.710(d) is less than what the manufacturer paid for that applicable calendar quarter, CMS would 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. As further discussed in section II.H. of this final rule, we proposed at § 513.740(b), that failure to pay an incremental GLOBE Model rebate amount due timely and in full may result in an enforcement action as described in 42 CFR 513 subpart I.

As discussed in section II.G.8. of this final rule, CMS is finalizing the incremental invoicing approach in this final rule.

The following is a summary of the comment received on this topic and our response.

*Comment:* A commenter stated that the process of invoicing Preliminary Rebate Reports, Rebate Reports, and reconciliation would create administrative complexity and burden for participants.

*Response:* We thank the commenter for this feedback. We are finalizing a process to access Rebate Reports and pay invoices that is substantially similar to the process codified in 42 CFR 427.504. By leveraging existing reporting and reconciliation infrastructure and processes, we believe this approach will minimize administrative burden on model participants associated with payment of the incremental GLOBE Model rebate amount. Further, we note that the Preliminary Rebate Report process facilitates the SOE process which we believe is an important protection for manufacturers who are model participants and should be retained as part of the GLOBE Model invoicing process.

*Final Decision:* CMS is finalizing § 513.730 as proposed without modification and § 513.740 as proposed, with a technical modification to insert the words ''an incremental GLOBE Model'' in the section heading and correcting typographical errors. Specifically, (1) in § 513.740(a) the phrase ''either of the following'' is added; (2) in § 513.740(b) ''subpart I of this part'' is changed to ''42 CFR part 513 subpart I;'' and in § 513.740(c) ''will initiate'' is changed to ''initiates''. CMS also refers readers to section II.G.8.b. of this final rule for the final decision on finalizing the incremental invoicing approach and the corresponding update to the date of receipt definition at § 513.20.

*J. Quality Measures*

1. General

Consistent with the evaluation provisions of section 1115A(b)(4) of the Act, we proposed utilizing quality measures to monitor and evaluate whether quality of care, including as measured through patient-level outcomes, remains consistent or changes as a result of the alternative Medicare Part B drug inflation rebate amount calculation for GLOBE Model drugs (90 FR 60304). We proposed that payments to manufacturers or providers would not be adjusted based on quality of care. We stated that CMS would consider multiple domains of monitoring as outlined elsewhere in the rule, including but not limited to, out-of-pocket costs, utilization of care, and access to GLOBE Model drugs.

2. Collection of Quality Measures

In § 513.900, we proposed 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 as a means to monitor the GLOBE Model's use of an alternative approach to the calculation of the Medicare Part B drug inflation rebate

amount under the Medicare Part B Drug Inflation Rebate Program. As such, the quality measures in this final rule are not to assess individual provider performance but to assess model performance. As stated in section II.J.1. of this final rule, we proposed that payments to providers would not be adjusted based on quality of care. In the GLOBE Model proposed rule (90 FR 60304), we stated that the GLOBE Model may include, but would not be limited to, 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 healthcare utilization, such as hospitalizations or emergency room visits.

CMS would monitor these measures for all separately payable Part B drugs as well as for the subset of GLOBE Model drugs. This would enable CMS to examine changes among drugs that are specifically targeted by the model as well as broader effects on Medicare Part B and downstream outcomes.

We also stated that CMS may 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 our proposed quality strategy, we 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.

We stated that we do not anticipate the GLOBE Model test of a new payment approach would impact high value prescribing as the payment incentive directly to the prescribers (that is, the Medicare allowed amount and payment to the provider or supplier) would be equivalent between the intervention and control group (generally ASP+6 percent).

We noted that accurate measurement of medication management and medication adherence for Medicare Part B clinician-administered drugs is challenging because dosing schedules are variable, clinical assessment is required, and insurance claims lack sufficient clinical context.[194] To limit additional burden upon beneficiaries, we proposed using existing national surveys wherever possible. If necessary to assess how the GLOBE Model has affected patient quality of care, we proposed that CMS may consider implementing a beneficiary survey. Information obtained through existing national surveys and any beneficiary surveys conducted for purposes of the GLOBE Model may be used to inform CMS' monitoring and evaluation activities and to identify potential unintended consequences, changes in access to care, or other quality concerns associated with the model. CMS may use information from these activities, together with claims data and other available information, to determine whether modifications to model operations, monitoring activities, or other actions are warranted.

We also stated that the proposed GLOBE Model does not test the efficacy of prescription drugs, but rather, it tests the impact of an alternative payment approach. Thus, we did not propose new monitoring of changes to drug-related adverse events. We proposed that 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. We stated that any additional measures, including potential beneficiary surveys, utilized by CMS would not add significant burden to GLOBE Model participants or beneficiaries.

CMS sought comments on the proposed quality measures that CMS would use to monitor potential changes in the quality of care that may result from the alternative approach to the calculation of the rebate amount under the Medicare Part B Drug Inflation Rebate Program.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters emphasized that CMS should ensure its quality monitoring framework captures changes in patient access, treatment continuity, and clinical outcomes—particularly for patients with serious conditions such as cancer, rare diseases, and chronic illnesses. Commenters highlighted specific risks including treatment delays, therapy switching, and disease progression, and urged CMS to employ clinically meaningful measures capable of detecting these potential unintended consequences.

*Response:* We thank commenters for their feedback on the quality monitoring framework. CMS agrees that it is important to assess potential unintended consequences of the GLOBE Model, particularly for patients with serious conditions. The quality monitoring framework includes measures related to patient access, costs, and quality of care—with a specific focus on drug utilization, out-of-pocket costs for Part B drugs, changes in site of care or prescriber, prescribing patterns, continuity of care, and downstream healthcare utilization. These measures are identified to provide CMS with timely insight into whether the model is producing unintended effects on patient care.

In alignment with our quality monitoring strategy, the model's evaluation will assess the GLOBE Model's impact on quality through clinically meaningful measures, including treatment patterns and care delivery (as discussed in section II.P. of this final rule). CMS is committed to using this monitoring and evaluation framework to identify and respond to any adverse impacts on patient access or clinical outcomes throughout the GLOBE Model test period.

*Comment:* Several commenters expressed concern that the proposed quality measurement framework may not fully capture real-world impacts on care delivery and patient experience. Commenters recommended that CMS consider whether additional measures or data sources are needed to assess medication management, patient out-of-pocket costs, total cost of care, changes in site of care, and downstream healthcare utilization. Commenters also raised concerns regarding the model's reliance on claims-based measures and existing survey data, noting that such data sources may lack sufficient clinical context to accurately assess medication adherence, treatment appropriateness, and quality of care. Commenters recommended greater transparency around data sources and suggested that CMS consider whether additional data collection approaches may be needed.

*Response:* We thank commenters for their feedback on the proposed quality

[194] Lam WY, Fresco P. Medication Adherence Measures: An Overview. Biomed Res Int. 2015:217047. *https://pmc.ncbi.nlm.nih.gov/articles/PMC4619779/.*

measurement framework. We recognize the importance of measuring a broad range of factors that may affect beneficiaries under the GLOBE Model, including patient out-of-pocket costs, total cost of care, site of care, and downstream utilization. As part of the model's monitoring and evaluation activities, we plan to assess these considerations on an ongoing basis to the extent feasible, while primarily using claims-based measures and existing national surveys in order to minimize additional administrative burden. Claims-based data are available for both the comparison and intervention groups and support evaluation of changes in utilization, site of care, and other observable indicators of quality.

Specifically, as discussed in sections II.J. and II.P. of the GLOBE Model proposed rule, we will assess beneficiary out-of-pocket spending, including variation by supplemental coverage status, and evaluate whether the model influences drug access, site of care, including potential shifts across outpatient hospital, physician office, and other care settings, and changes in prescribing. We will also examine patterns of medication utilization using available data sources to better understand how the model may impact prescribing patterns and continuity of care.

As stated in the GLOBE Model proposed rule (90 FR 60304), CMS recognizes that claims-based data sources have inherent limitations with respect to assessing certain aspects of care, including medication adherence and treatment appropriateness for Part B clinician-administered drugs, due to variable dosing, the need for clinical context, and limitations in available data. The GLOBE Model quality measures, monitoring activities, and evaluation framework have been designed with these limitations in mind. To the extent feasible, we may assess these domains using claims-based indicators such as treatment continuity, timing and regularity of drug administration, and patterns of treatment initiation, switching, or discontinuation, consistent with these limitations.

To supplement claims-based measures where appropriate, we may also use targeted, voluntary surveys of providers who administer Part B drugs to assess aspects of care not captured in claims data, such as changes in perceived prescribing practices, site of service, and interactions between patient and provider. With respect to patient experience, we will assess whether the GLOBE Model produces any notable changes using existing survey instruments, such as the Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys. If monitoring and evaluation activities indicate that existing data sources are insufficient, CMS may consider deploying targeted survey instruments.

Finally, we are committed to transparency in our monitoring and evaluation approach and will maintain clear documentation of data sources and methodologies. We will continue to assess whether supplemental data sources are needed to support a comprehensive and clinically meaningful evaluation of the GLOBE Model and will consider additional data collection approaches if existing sources prove insufficient.

*Comment:* A few commenters expressed concern that additional quality monitoring activities beyond existing claims sources, including provider surveys or other supplemental data collection, could increase the reporting and administrative burden on providers, health systems and model participants. These commenters recommended that CMS minimize additional data collection requirements and rely on existing data sources where possible.

*Response:* We thank commenters for sharing their concerns regarding the potential administrative burden associated with quality monitoring activities under the GLOBE Model. We are committed to minimizing additional reporting and administrative burden by relying primarily on existing claims-based data sources and limiting the need for new reporting requirements. The GLOBE Model quality, monitoring, and evaluation frameworks have been designed with this principle in mind, leveraging data that is already routinely collected and available for both the comparison and intervention groups through evaluation activities.

Where supplemental data collection is determined to be necessary to support a comprehensive evaluation of the model, we will consider approaches that reduce burden on providers and health systems to the extent feasible, including the use of targeted, voluntary data collection instruments rather than mandatory reporting requirements. CMS will continue to assess whether the existing data infrastructure is sufficient to meet the model's quality, monitoring and evaluation needs and will seek to avoid imposing requirements that go beyond what is necessary to evaluate the GLOBE Model's impact.

*Comment:* Several commenters recommended that CMS adopt safeguards and closely monitor access and quality issues as they emerge during model implementation. These commenters emphasized the importance of identifying negative impacts on care delivery and ensuring that CMS has the capacity to respond promptly if the model notices related access or treatment disruptions over the course of the GLOBE Model test period. Some commenters also requested clarification on how CMS will take action if monitoring identifies adverse effects on patient access or outcomes.

*Response:* We thank commenters for their feedback on access and quality monitoring under the GLOBE Model. We agree that ongoing monitoring of patient access and quality of care throughout the GLOBE Model test period is essential, including the timely identification of potential adverse impacts. The GLOBE Model will include robust ongoing monitoring and evaluation processes, and CMS will use data gathered through these activities to assess whether modifications to model operations, monitoring approaches, or other safeguards may be appropriate, including actions to mitigate identified access or quality concerns during the model performance period.

With respect to commenters' requests for clarification on how CMS will respond to adverse findings, we retain the authority and commitment to act through available mechanisms to address any meaningful negative impacts on beneficiary access or quality in a timely manner. This includes the authority to recommend to the Secretary that CMS initiate proposed rulemaking to modify or terminate the GLOBE Model, as needed.

CMS declines to specify in this final rule the precise model adjustments that would be made in response to any particular monitoring and evaluation findings. The nature and scope of any responsive action will depend on the specific circumstances identified, and we believe that retaining flexibility to tailor our response is essential to effective model oversight. We are committed to transparency in our quality and monitoring activities and will communicate with model participants and other stakeholders, as appropriate, if significant access or quality concerns are identified.

*Final Decision:* After careful consideration of the public comments received, CMS is finalizing the proposed approach to quality measurement and providing clarification regarding the scope of monitoring and evaluation activities, as described in this section of this final rule.

CMS will maintain a quality, monitoring, and evaluation framework for the GLOBE Model that primarily relies on claims-based measures and existing data sources, consistent with the proposed approach. As such, CMS is finalizing § 513.900 with modification to § 513.900(b)(1) to include the words ''including claims-based measures''.

CMS is also clarifying that monitoring will encompass a broad set of domains to assess model performance and identify potential unintended consequences. These domains include, but are not limited to: utilization and prescribing patterns; access to Part B drugs; continuity of care; site of care; and downstream healthcare utilization.

During model implementation, CMS will assess whether supplemental data collection, including targeted and voluntary surveys, may be necessary to capture aspects of care not reflected in existing claims and survey data, while seeking to minimize additional reporting and administrative burden on providers and beneficiaries.

Finally, CMS will conduct ongoing quality and monitoring activities throughout the model performance period. Data gathered through these activities may be used to inform potential modifications to model operations, monitoring approaches, or other safeguards, as appropriate, to address any identified concerns related to patient access, quality of care, or unintended consequences.

*K. Beneficiary Protections*

1. General

In the GLOBE Model proposed rule (90 FR 60304), we stated that 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 considered various options to protect beneficiary access to Medicare Part B drugs during the GLOBE Model test period. One potential option CMS considered was 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, in § 513.910, we proposed setting up a process for collecting complaints from providers and beneficiaries to notify CMS that a particular drug has become harder to source or obtain. We also proposed 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. We noted that a GLOBE Model reporting system could include existing CMS reporting systems such as 1–800-Medicare for beneficiaries. Additionally, we stated that CMS could develop an email inbox for the GLOBE Model to receive reports from providers and beneficiaries. We also stated that 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. In addition, we noted that CMS could consider making beneficiaries aware of the available reporting methods such as sending letters to eligible GLOBE Model beneficiaries with reporting instructions. We sought comment on a potential plan to build a GLOBE Model reporting and monitoring system for stakeholders and any other methods to protect beneficiaries.

The following is a summary of the comments received and our responses.

*Comment:* A few commenters supported CMS's proposal to offer a reporting system for providers and beneficiaries to notify CMS of drug access issues related to the GLOBE Model. A commenter also encouraged CMS to leverage the Medicare Ombudsman and the Office of Program Operations and Local Engagement (OPOLE), 1–800–MEDICARE, and the State Health Insurance Programs (SHIPs) as part of the reporting system for the GLOBE Model.

*Response:* We thank the commenters for their support of our proposal to establish a reporting system for providers and beneficiaries to notify CMS of drug access issues under the GLOBE Model.

We agree with the commenter's suggestion to incorporate existing, well-established Medicare resources into the GLOBE Model reporting framework. Accordingly, CMS will coordinate, to the extent feasible, with the Medicare Ombudsman, OPOLE, and 1–800–MEDICARE as part of monitoring efforts for the GLOBE Model. These resources provide accessible and widely recognized channels through which beneficiaries and providers can raise concerns about drug access issues, and their inclusion will help ensure that CMS receives timely and comprehensive information to monitor and address any access challenges that may arise under the model. The Medicare Ombudsman and OPOLE serve as important resources for beneficiaries experiencing difficulties with their Medicare coverage, including issues related to accessing prescription drugs. By coordinating with the Medicare Ombudsman and OPOLE, CMS will be positioned to identify and respond to systemic drug access concerns in a timely manner. Similarly, 1–800–MEDICARE is a widely recognized and accessible helpline that beneficiaries and providers (on behalf of beneficiaries) already use to report Medicare-related issues, making it natural to incorporate as one facet of the GLOBE Model reporting system.

For beneficiaries, 1–800–MEDICARE will remain the primary point of contact for questions and assistance related to beneficiary inquiries, including inquiries about the GLOBE Model.

With respect to the commenter's recommendation to also include the SHIPs, CMS appreciates this suggestion and notes that SHIPs can report issues and send inquiries directly to OPOLE through existing coordination processes. CMS also notes that SHIPs primarily serve an educational and counseling function by helping beneficiaries understand Medicare coverage options, rather than serving as a formal reporting mechanism for model-related access concerns. CMS will continue to assess the potential role that SHIPs and other stakeholder resources may play in supporting the GLOBE Model's reporting infrastructure and may consider additional reporting channels in future rulemaking or model guidance as the model is implemented and evaluated. CMS believes that coordination with the Medicare Ombudsman, OPOLE, and 1–800–MEDICARE programs provides sufficient existing reporting channels for purposes of the model, and at this time, we do not believe it is necessary to expand the existing reporting infrastructure further. CMS also notes that there are existing reporting vehicles outside of the GLOBE Model for reporting drug supply and procurement issues. For example, the FDA maintains a drug shortage reporting mechanism that is available to healthcare providers and other stakeholders.[195] CMS encourages providers to make use of these existing channels, as appropriate,

[195] Food and Drug Administration. Drug Shortages. Available at: *https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages.*

in addition to the GLOBE Model helpdesk.

*Comment:* A few commenters requested CMS conduct outreach to beneficiaries, including providing beneficiary notices of participation and opportunities for beneficiary engagement. A commenter specifically requested that CMS provide beneficiary notices in the beneficiary's language of choice. Another commenter urged CMS to develop beneficiary education tools that outline how the model operates and what beneficiary protections are available. A commenter also recommended engaging affected communities in developing patient-centered alternatives.

*Response:* We thank the commenters for their feedback regarding beneficiary outreach and education under the GLOBE Model. We appreciate the commenters' interest in ensuring that beneficiaries are informed about the model and have access to resources that explain how it operates and what protections are available to them.

After careful consideration, CMS declines to adopt direct beneficiary notices of inclusion in the model cohort under the GLOBE Model. While CMS can identify beneficiaries who meet the criteria for inclusion in the model cohort, CMS cannot reliably determine prospectively which of those beneficiaries will receive a separately payable GLOBE Model drug during the model performance period. A notice sent to all beneficiaries in the model cohort would therefore reach many beneficiaries who may never receive a GLOBE Model drug or experience a model-related coinsurance effect, while a notice targeted to beneficiaries who have received a GLOBE Model drug would generally rely on claims information available after the relevant service. In addition, beneficiaries are not model participants and are not required to enroll, opt in, consent, take any action, change providers or suppliers, or make an opt-out decision as a result of their inclusion in the model cohort. For these reasons, CMS does not believe that individual beneficiary notices of cohort inclusion are necessary. Beneficiaries retain all existing Medicare rights and protections under the GLOBE Model, and the model does not alter Medicare coverage rules or beneficiaries' ability to choose among Medicare providers and suppliers.

Nevertheless, CMS recognizes the importance of ensuring that beneficiaries and providers have access to clear, accessible information about the model. To support transparency and beneficiary awareness, we will make technical documentation and user-friendly fact sheets available on the GLOBE Model website. These resources will explain how the model operates and may impact beneficiaries, including the circumstances in which beneficiaries may receive reduced coinsurance for GLOBE Model drugs, the beneficiary protections that remain in place, and the CMS resources available for questions or concerns.

To further support beneficiary awareness, CMS will publish on the model website the selected geographic areas with the relevant ZIP Codes associated with the GLOBE Model. CMS will also post the GLOBE Model Drug List and other model information so that beneficiaries and other interested parties can learn about the model and its potential applicability. Beneficiaries may use existing CMS assistance resources, including 1–800–MEDICARE, the Medicare Ombudsman, and OPOLE, or the GLOBE Model helpdesk to obtain information or report concerns.

With respect to the commenter's request that beneficiary notices be provided in the beneficiary's language of choice, CMS appreciates this recommendation and is committed to accessible communication. CMS will develop user-friendly fact sheets and other educational and technical materials for the GLOBE Model website consistent with CMS's existing language access obligations and commitments.

Regarding the request to develop beneficiary education tools that outline how the model operates and what beneficiary protections are available, as noted previously, CMS will develop and post a user-friendly fact sheet and technical documentation on the GLOBE Model website to serve this purpose. These materials will be designed to be clear and accessible to beneficiaries and will outline the model's structure, the potential cost-sharing benefits available, and the protections that remain in place for all Medicare beneficiaries under the model.

Regarding the recommendation to engage affected communities to develop patient-centered alternatives, CMS does not believe that an alternative model design is necessary. The GLOBE Model is designed to directly examine impacts to selected beneficiary populations who use a GLOBE Model drug through reduced coinsurance, which itself represents a meaningful, patient-centered benefit. CMS will continue to monitor the model's impact on beneficiary access and outcomes throughout the model performance period and will consider stakeholder input as part of its ongoing evaluation activities.

*Comment:* A commenter requested adding a reporting mechanism specifically for physicians.

*Response:* We thank the commenter for their feedback regarding the establishment of a physician-specific reporting mechanism under the GLOBE Model. We appreciate the commenter's interest in ensuring that providers have clear and accessible channels through which to raise concerns about drug access (including procurement issues) that may be related to the model.

CMS acknowledges the importance of ensuring that physicians and other providers impacted by the GLOBE Model have meaningful opportunities to report drug access issues as they arise. In response to this comment and as we discussed in the GLOBE Model proposed rule (90 FR 60304), CMS will post on the GLOBE Model website instructions for how to contact the model helpdesk email inbox through which stakeholders, such as providers or beneficiaries, may reach out directly to CMS to report concerns related to drug access issues experienced under the GLOBE Model. CMS encourages providers to utilize this resource as a primary point of contact for questions and concerns, including, but not limited to model-related drug access concerns.

CMS also notes that there are existing reporting vehicles outside of the GLOBE Model through which providers may report drug supply and procurement issues. For example, the FDA maintains a drug shortage reporting mechanism that is available to healthcare providers and other stakeholders on its Drug Shortages website.[196] CMS encourages providers to make use of these existing channels, as appropriate, in addition to the GLOBE Model helpdesk.

To further support providers impacted by the GLOBE Model, CMS plans to post the GLOBE Model Drug List and model geographic areas on the GLOBE Model website. These resources will allow providers to readily identify the drugs included under the model and to monitor any updates to the drug list over time. In addition, CMS will develop and post a FAQ document on the GLOBE Model website. This FAQ will address common questions related to the model. In addition to other drug shortage reporting, providers who encounter procurement issues are encouraged to notify CMS through the model's helpdesk so that CMS can monitor and respond to any access challenges that may arise under the model.

[196] Food and Drug Administration. Drug Shortages. Available at: *https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages.*

CMS believes that these resources—the helpdesk, the GLOBE Model Drug List, a list of model geographic areas, and the FAQs—will collectively provide providers and other stakeholders with the information and reporting channels necessary to support successful model implementation and to ensure that any drug access concerns are identified and addressed in a timely manner.

*Comment:* A couple of commenters opposed CMS's proposal to primarily rely on a reporting system to identify access issues. These commenters specifically request that CMS expand beneficiary protections under the model to include activities before access issues arise. The commenters suggest that CMS specifically include safeguards against access disruptions, increased transparency for patients, and protections for beneficiaries without supplemental coverage. Further, these commenters stated that limiting a reporting system to drug access issues would not capture additional beneficiary complaints relating to the model. Finally, these commenters are concerned that CMS will depend on beneficiary complaints alone to determine whether there are access issues caused by the implementation of the model and encouraged CMS to develop beneficiary educational tools that explain the model and how beneficiaries are protected under it.

*Response:* We thank the commenters for their feedback. Beneficiary protection is of paramount importance to CMS, which is why we proposed to implement a plan for reporting and monitoring that will allow stakeholders to identify potential disruptions to drug access that may result from the GLOBE Model. We solicited feedback on the details surrounding this reporting and monitoring system to ensure we sufficiently learn about and can investigate any potential beneficiary access issues. CMS acknowledges commenters' views that affordability challenges may vary across beneficiary populations and that many beneficiaries have supplemental coverage that may reduce their out-of-pocket liability. However, CMS continues to believe that reducing coinsurance for GLOBE Model drugs may provide meaningful financial benefits for affected beneficiaries and that monitoring beneficiary access remains an important component of the model. We agree that stakeholder responses to the GLOBE Model, including distribution decisions, could in some circumstances affect how certain clinician-administered drugs are sourced or furnished, even though the model does not require alternative distribution arrangements. Accordingly, CMS does not intend to rely solely on beneficiary complaints to identify access issues. In addition to the reporting pathways finalized in this section, CMS will use available model oversight and claims-based monitoring, as feasible and consistent with applicable privacy protections, to assess potential signals of access disruption, including patterns that may be consistent with increased use of alternative distribution arrangements such as white-bagging or brown-bagging. CMS recognizes concerns raised by commenters that increased reliance on such arrangements could create operational challenges for providers and could contribute to delays or disruptions in beneficiary access to clinician-administered therapies, including concerns related to care coordination and patient safety. While CMS is not finalizing specific restrictions on alternative distribution arrangements as part of the GLOBE Model, we will use the reporting and monitoring processes finalized in this section of this final rule to identify potential access disruptions associated with such arrangements. Such monitoring may include review of available Medicare Part B and Part D claims and other operational data for changes in utilization, billing, and site-of-care patterns that may suggest delayed, interrupted, or displaced access to clinician-administered therapies, including access in the office setting. We believe the reporting and monitoring plan, along with the model education activities, will offer sufficient safeguards to protect beneficiaries' access to necessary drugs while also monitoring for any access disruptions that may arise.

We appreciate the recommendation that CMS directly notify beneficiaries of their inclusion in the GLOBE Model. CMS is not finalizing individual beneficiary notices of model-cohort inclusion because, although CMS can identify beneficiaries who meet the cohort eligibility criteria, CMS cannot reliably determine prospectively which beneficiaries will receive a separately payable GLOBE Model drug. A notice to all beneficiaries in the model cohort would be overinclusive, while a notice targeted based on receipt of a GLOBE Model drug would rely on claims information available after the relevant service. In addition, the model does not require beneficiaries to take any action and does not change beneficiary eligibility for Medicare benefits, Medicare coverage rules, or provider choice. CMS will support beneficiary awareness through publicly available educational materials, website information, and existing beneficiary assistance resources. Further, we believe that the regular mechanisms available to beneficiaries to report complaints and get help with Medicare issues—including but not limited to 1–800–MEDICARE and Medicare Beneficiary Ombudsman—can be utilized by beneficiaries to report any other issues that may be related to the GLOBE Model, allowing the model-specific reporting and monitoring system to be primarily focused on access-related issues.

*Final Decision:* After consideration of the public comments received, CMS will enhance model implementation activities. CMS will coordinate with 1–800–MEDICARE, the Medicare Ombudsman, and OPOLE resources for beneficiaries (and providers on behalf of beneficiaries) to report issues potentially related to the GLOBE Model; stakeholders can also utilize the GLOBE Model helpdesk to report issues potentially related to the GLOBE Model. CMS will also supplement these reporting channels with claims-based monitoring to identify potential access disruptions, including those associated with alternative distribution arrangements or shifts in site of care for clinician-administered therapy access. While CMS will not provide individual notices of model-cohort inclusion to beneficiaries, CMS will make accessible technical and educational materials and model information available through CMS channels to support beneficiary and stakeholder awareness. CMS will not impose a beneficiary-notification or outreach requirement or expectation on providers or suppliers. CMS is finalizing § 513.910 as proposed with non-substantive modification to change ''In a form and manner specified by CMS, CMS will establish'' to ''CMS establishes'' for clarity.

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 who would be included in the CMS 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.

In the GLOBE Model proposed rule (90 FR 60304), we stated that CMS 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. We stated that, while CMS acknowledges the GLOBE Model may affect drug access, we believe 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. We stated that 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. We stated our belief that beneficiaries would benefit by being categorized as a GLOBE Model eligible beneficiary due to the potentially reduced coinsurance percentage that would apply for eligible GLOBE Model drugs for GLOBE Model eligible beneficiaries.

We sought comment on the decision not to include a beneficiary opt-out and whether variations of a beneficiary opt-out could be considered.

The following is a summary of the comments received and our responses.

*Comment:* Several commenters expressed concern over beneficiaries' inability to opt out from the model, commenting on a lack of beneficiary choice in model inclusion. Commenters stated that beneficiaries could be exposed to potential adverse effects and experience unintended consequences without having any opportunity to leave the demonstration. A few commenters specifically highlighted the importance of uninterrupted access to appropriate oncology care and noted the potential for included beneficiaries to face reduced access to appropriate therapies if the model impacts how drugs are distributed. A commenter requested CMS establish a consent protocol for beneficiaries. A commenter, however, stated that CMS should not allow beneficiary opt-out to preserve the integrity of the evaluation.

*Response:* We thank commenters for this feedback. Because beneficiaries in selected geographic areas will automatically be assigned to the model cohort as part of the model test, individual beneficiaries will not be able to opt out of the GLOBE Model. However, the model does not limit a beneficiary's ability to choose among Medicare providers and suppliers or the range of services that are available to them. Further, CMS does not believe that beneficiaries will be harmed by their inclusion in the model cohort and, therefore, an opt-out mechanism is not warranted.

*Final Decision:* After consideration of the public comments received, CMS is finalizing our proposal to not include a beneficiary opt-out provision in the GLOBE Model.

*L. 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, we stated in the GLOBE Model proposed rule (90 FR 60305) that CMS intends to monitor for specific potential issues that could arise as part of the GLOBE Model. Specifically, we stated that CMS intends to monitor for major changes in beneficiary access, as viewed through changes in site of care, provider, and other measures (as described in section II.J. of this final rule). We also stated that CMS may also monitor changing pharmaceutical list prices in the U.S. to determine whether any changes to model policies or duration could be necessary in future performance periods. In addition, we stated that CMS may also consider monitoring impacts on drug innovation, R&D, and timing of drugs coming to market in the U.S. We also proposed to collaborate with the FDA to review shortage lists and determine whether the number of drugs or length of time on a shortage list changes over time. We stated that, 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. If CMS determines through regular monitoring that an issue warrants consideration of a change to a model policy or the model duration, CMS will initiate review of potential responsive action within 30 calendar days of that determination. Any resulting modification or termination would occur in accordance with section 1115A(b)(3)(B) of the Act, 42 CFR part 513, and, as necessary, notice-and-comment rulemaking.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters broadly urged CMS to establish robust, proactive monitoring mechanisms to detect and respond to any adverse impacts on patient access to drugs—particularly for oncology, rare disease, and complex therapies. Specific concerns included: manufacturers potentially narrowing drug distribution or reducing supply to the U.S. to avoid GLOBE Model rebates; drugs being withdrawn from the market or becoming unavailable in GLOBE Model-designated ZCTAs; and shifts in utilization from Medicare Part B to Medicare Part D that could increase patient cost-sharing burdens. Commenters recommended that CMS establish clear access monitoring triggers and corrective action protocols, including the ability to remove drugs from the model if access is compromised.

*Response:* CMS appreciates the thoughtful comments submitted by a broad range of stakeholders regarding the importance of protecting patient access to drugs under the GLOBE Model. CMS shares commenters' commitment to ensuring that Medicare beneficiaries continue to receive timely access to clinically necessary therapies throughout the model's operation.

CMS agrees that a robust, proactive monitoring framework is essential to the implementation of the GLOBE Model. CMS recognizes commenters' concerns that access disruptions may contribute to treatment delays, disruptions in care coordination, or other patient safety concerns, particularly for beneficiaries receiving complex clinician-administered therapies. As described in section II.J. of this final rule, CMS intends to conduct continuous monitoring of model performance with a focus on assessing beneficiary access measures.

CMS appreciates commenters' recommendations regarding the monitoring of model effects across beneficiary sub-populations. As described in section II.J. of this final rule, CMS intends to conduct ongoing monitoring of model performance with a focus on beneficiary access measures and other indicators relevant to assessing potential effects on beneficiaries. To the extent feasible and consistent with applicable law and available data sources, CMS may consider whether model effects differ across beneficiary sub-populations that may be differentially affected by the model as part of its broader monitoring and assessment activities. CMS also

recognizes commenters' concerns regarding the potential downstream effects that changes in beneficiary access may have on health outcomes. As described in sections II.J. and II.P. of this final rule, CMS will assess such effects, as appropriate, through the model's broader quality and evaluation framework.

CMS acknowledges commenters' recommendation that the model include clear corrective action protocols, including the authority to remove drugs from the model if access is compromised. For example, as part of monitoring for impacts on access, CMS will monitor for potential drug availability issues that may impact beneficiary access to GLOBE Model drugs by reviewing available information, such as manufacturer sales data, Medicare Part B claims data, and other data sources as identified by CMS, for GLOBE Model drugs and other separately-payable Part B drugs, on a monthly basis beginning the first month of the first performance year (that is, April 2027). Such monitoring may include assessing whether changes in manufacturer production, distribution, or market participation for GLOBE Model drugs are associated with reductions in drug availability or beneficiary access. CMS will also monitor, using available claims and operational data as feasible, for changes in drug distribution patterns that may be associated with increased use of alternative distribution arrangements, such as white-bagging or brown-bagging, and assess whether such arrangements are associated with treatment delays, interruptions in therapy, changes in beneficiary cost-sharing or out-of-pocket costs, or other access-related concerns. CMS appreciates commenters' recommendations regarding enhanced monitoring of alternative distribution arrangements involving clinician-administered therapies. While CMS is not finalizing additional reporting requirements as part of the GLOBE Model, CMS may use, to the extent feasible, available claims data, operational data, and other information sources, as appropriate, to monitor for potential changes in drug distribution patterns and assess whether such changes may be associated with disruptions in beneficiary access to clinician-administered therapies. If CMS identifies evidence of potential drug availability issues for a GLOBE Model drug, CMS will review available data to determine whether issues also exist in non-Medicare markets in the U.S., such as commercially available markets or appear to exist solely in the Medicare market. If drug availability issues persist, CMS retains the authority and commitment to act through available mechanisms to address any issues related to beneficiary access or quality in a timely manner.

*Comment:* A few commenters raised concerns that the GLOBE Model's benchmark design could be susceptible to manipulation by manufacturers, including: increasing list prices for non-model drugs or in overseas markets to artificially inflate or deflate the international benchmark; exploiting gaps in the model's geographic scope to avoid model rebates; and engaging in distribution restrictions or supply chain changes to circumvent GLOBE obligations. Commenters recommended that CMS develop specific monitoring protocols to detect and deter these behaviors, including surveillance of international pricing trends, list price changes, and distribution patterns, with clear enforcement mechanisms and penalties for non-compliance.

*Response:* CMS appreciates the detailed concerns raised by commenters regarding the potential for manufacturer pricing manipulation and strategic behavior designed to circumvent the GLOBE Model's rebate obligations. CMS takes these concerns seriously and agrees that the integrity of the international benchmark—and the model's ability to achieve meaningful savings for Medicare beneficiaries—depends on robust safeguards against gaming and evasion. CMS notes that several features of the GLOBE Model's design provide structural protections against the manipulation scenarios described by commenters. For example, the Method I international benchmark is derived from publicly available and administratively reported pricing data across multiple comparator countries and CMS is maintaining the Method I benchmark throughout the performance period after initial identification, reducing the ability to distort the benchmark through pricing actions in a foreign market.

Nonetheless, CMS acknowledges that no model design is fully immune to strategic behavior, and that the concerns raised by commenters reflect real-world risks that warrant active monitoring and enforcement attention. To help safeguard against the risk that manufacturers may take steps to limit international drug pricing information that would be contained within existing data sources that are available to CMS, CMS is finalizing that if the Method I benchmark is identified at the time a Part B rebatable drug becomes a GLOBE Model drug (except in cases where data is unavailable), the Method I benchmark would remain in place for each applicable calendar quarter thereafter until the end of the model performance period. CMS will also monitor for changes in available international drug pricing information throughout the GLOBE Model payment period.

CMS is committed to ensuring that the GLOBE Model achieves its intended goal of reducing Medicare drug expenditures by holding manufacturers accountable for the prices they set in the U.S. We will continue to refine the monitoring and enforcement framework in response to stakeholder input and emerging evidence of manufacturer behavior, and we welcome ongoing engagement from stakeholders on these critical issues.

CMS recognizes that manufacturers may respond to the GLOBE Model in ways that could result in changes in pricing to drugs that have not been selected as part of the GLOBE Model. As part of the model test, CMS seeks to carry out a comprehensive evaluation of the impacts of the GLOBE Model, including evaluating any spillover effects as described in section II.P. of this final rule.

*Comment:* A few commenters highlighted that the proposed GLOBE Model would not exist in a policy vacuum and urged CMS to monitor how the model interacts with the Negotiation Program for Medicare Part B drugs. Key concerns include: beginning in 2028, for selected Medicare Part B drugs that have a negotiated MFP, Medicare payment will shift from being based on ASP+6 percent to MFP+6 percent, potentially causing significant financial losses for community oncology practices (estimated by commenters at $12–$25 billion); the GLOBE Model's rebate mechanism could serve as a model for preserving provider stability under the IRA, but only if the two frameworks are carefully coordinated; and overlapping or conflicting policies could create compounding financial pressures on providers. Commenters recommend that CMS establish cross-program monitoring to assess the cumulative impact of the GLOBE Model and IRA policies on provider viability, drug access, and patient care. A commenter suggested CMS delay the GLOBE Model until after the first negotiation cycle for Medicare Part B drugs and assess before additional Medicare Part B drug pricing changes are tested.

*Response:* CMS appreciates the thoughtful comments submitted regarding the interaction between the GLOBE Model and the Negotiation Program's framework. We acknowledge that the GLOBE Model is being tested within a broader and rapidly evolving

Federal drug pricing policy landscape, and that the cumulative effects of multiple concurrent changes on providers, beneficiaries, and the biopharmaceutical market warrant careful attention. To avoid direct interaction between the Negotiation Program's MFP framework and the GLOBE Model's alternative inflation rebate test, CMS proposed and is finalizing in this final rule that the model test would not apply during applicable calendar quarters while an MFP is in effect to avoid altering the market dynamics of these drugs.

*Comment:* A few commenters expressed concern that the GLOBE Model, in combination with other Federal drug pricing policies, could dampen incentives for biopharmaceutical innovation with long development cycles and high fixed costs. Commenters made the following monitoring recommendations: tracking manufacturer investment decisions and pipeline activity in therapeutic areas affected by GLOBE Model; assessing whether the GLOBE Model implementation correlates with reduced clinical trial activity or drug development in targeted disease areas; and monitoring for disproportionate impacts on small and mid-size biopharmaceutical companies. Commenters urged CMS to closely monitor how the GLOBE Model interfaces with manufacturer investment strategies and to report findings publicly as part of the annual evaluation process.

*Response:* CMS acknowledges and responds to the commenters' concerns related to potential impact of the GLOBE Model on the biopharmaceutical innovation ecosystem in the introduction of section II. We also refer to our plan in section II.P. of this final rule to develop rigorous analytic approaches for assessing the GLOBE Model's contribution to any observed changes in innovation activity and CMS's commitment to being transparent about the limitations of these analyses in its public evaluation reports.

*Comment:* A commenter asked for clarification on how findings from continuous monitoring will be used to guide mid-course changes to the model.

*Response:* CMS declines to specify at this time what specific model adjustments would be made in response to monitoring and evaluation findings as it would be difficult to project in advance what the evaluation or monitoring would reveal. CMS retains the authority and commitment to act through available mechanisms to address any meaningful negative impacts on beneficiary access or quality in a timely manner.

*Comment:* A commenter urges CMS to incorporate safeguards that account for the financial realities of office-based buy-and-bill practices.

*Response:* Medicare Part B providers and suppliers who furnish GLOBE Model drugs to OM beneficiaries in the model cohort will not be GLOBE Model participants. These providers and suppliers will continue to buy and bill for GLOBE Model drugs as usual and receive separate payment under Medicare Part B, as applicable. The GLOBE Model does not change the Medicare Part B payment limit or add-on payment (generally, ASP+6 percent). When the GLOBE Model beneficiary coinsurance adjustment applies, CMS will correspondingly adjust the Medicare payment so that the sum of the Medicare payment and the beneficiary's financial responsibility equals the Medicare Part B allowed amount, assuming no other claim adjustment applies. Accordingly, the GLOBE Model beneficiary coinsurance adjustment will not reduce the payment received by Medicare Part B providers or suppliers for furnishing a GLOBE Model drug. After consideration of the comments received, CMS intends to provide technical and educational materials such as user-friendly fact sheets or FAQs to better understand the goals of the GLOBE Model, including information for ways to report questions or concerns pertaining to the GLOBE Model.

2. Appeals Process

We proposed that the appeals processes established in 42 CFR 427.600 would apply. Additionally, we proposed that the enforcement provisions of section 1847A(i)(8) of the Act and the judicial review section 1847A(j) of the Act would apply.

We sought comment on our proposal and did not receive any comments.

*Final Decision:* CMS proposed that the appeals processes established in 42 CFR 427.600, as well as the enforcement provisions of section 1847A(i)(8) and the judicial review provisions of section 1847A(j) of the Act, would apply to the GLOBE Model. As discussed in section II.H. of this final rule, CMS is finalizing § 513.800 with modifications to clarify that the CMP and appeals provisions align with the corresponding provisions of the Medicare Part B Drug Inflation Rebate Program. CMS refers readers to section II.H. for additional discussion.

*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, healthcare provider, or beneficiary, operating rules may be established for whether entities, healthcare 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 entities, healthcare providers, beneficiaries, and dollars across different models does not occur.

As discussed in section II.F. of this final rule, we proposed 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 stated in the GLOBE Model proposed rule (90 FR 60305) that 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. We concluded that no modifications for the GLOBE Model were warranted at this time. 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 final rule, we proposed to monitor for shifts in prescribing and potential impacts on beneficiaries' access to care. We also stated that if, during implementation of the proposed GLOBE Model, CMS were to observe unintended impacts on beneficiaries or model operations (for example, in GLOBE Model geographic areas if CMS were to 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.

We also stated that, 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 stated that we expect there may be situations where a GLOBE Model eligible beneficiary who receives a GLOBE Model drug would also be assigned, aligned, or attributed to another CMS Innovation Center model or CMS program or initiative. We noted that overlap could also occur among healthcare providers and suppliers, health plans, prescription drug plans, and other entities that participate in such models, programs, or initiatives. We stated our belief that healthcare provider or beneficiary overlap between the GLOBE Model and other models, programs, and initiatives would not impact our ability to conduct the GLOBE Model evaluation or interpret findings. Therefore, we did not propose adjustments to the GLOBE Model when there is overlap of healthcare providers that prescribe, pharmacies and other entities that furnish or dispense, or beneficiaries who receive GLOBE Model drugs. Instead, we proposed that 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, EOM [197] uses standardized payment amounts [198] 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 initiatives, and that payments or recoupments are not double counted. Specifically, EOM uses standardized allowed amounts in calculations that include Medicare Part B drug claims. The Medicare Part B allowed amount represents the Medicare payment limit before beneficiary cost sharing liability is applied. We noted that, therefore, the proposed GLOBE Model beneficiary coinsurance percentage adjustment when applicable would not be expected to impact EOM calculations. We noted that 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 would have the proposed reduced beneficiary coinsurance applied. We also noted that some existing models and programs would not have overlap at the healthcare practitioner or participant level and do not impact manufacturers due to the way in which the model or program operates and makes payments.

We stated that, in response to the proposed GLOBE Model beneficiary coinsurance adjustment policy (as discussed in section II.G.7. of this final rule), healthcare 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 would result in more appropriate provision of care, we noted that 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.

As discussed in the GLOBE Model proposed rule (90 FR 60306), we anticipated model overlap may occur between the proposed GLOBE Model and future CMS models or programs not yet implemented. We stated that, if the 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, at the time we developed the GLOBE Model proposed rule, we did not propose to modify or adjust the GLOBE Model based on any CMS Innovation Center model or CMS program or initiative where overlap with the GLOBE Model would occur. We stated that, 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 ensure the feasibility of the GLOBE Model test and evaluation would be pursued through notice and comment rulemaking, whereas it might be appropriate for modifications or adjustments needed to ensure the feasibility of other Innovation Center model tests and their associated evaluations to be pursued through updates to model policies and data agreements, or program participation criteria or requirements.

We sought comment on our proposed approach to address overlap between the GLOBE Model and other ongoing or future CMS Innovation Center models and CMS programs. We also sought 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 sought comment 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.

The following is a summary of the comments received and our responses.

*Comment:* Commenters expressed a variety of views related to model overlap. A few commenters stated that it is not possible to comment on model overlaps because CMS has not provided a specific overlaps policy to which the public could react. Several commenters stated that the GLOBE Model proposed rule omitted specifics about how overlaps between the GLOBE Model and other Trump Administration initiatives would be addressed. In addition, several commenters stated that the GLOBE Model would interact with the voluntary GENEROUS Model making it impossible to measure the impact of the GLOBE Model, such as price changes. These commenters stated that manufacturer participation in both the GLOBE Model and the GENEROUS Model would confound and distort the GLOBE Model evaluation. Some commenters claimed that CMS would not be able to identify and measure manufacturers' response to the GLOBE Model due to manufacturers' participation in the GENEROUS Model and voluntary MFN commitments. Similarly, several commenters stated that manufacturers who have made voluntary commitments to the U.S. Government to reduce U.S. drug prices, pursue ''MFN-based'' pricing initiatives, make discount prices available directly to consumers, and repatriate foreign revenue realized due to successful U.S. trade policies should be exempt from the GLOBE Model. These commenters stated that CMS should codify that manufacturers who participate in the GENEROUS Model or have made MFN

[197] For information about the EOM, see: *https://www.cms.gov/priorities/innovation/innovation-models/enhancing-oncology-model.*

[198] 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).

commitments would be exempted from participation in the GLOBE Model otherwise there would be uncertainty and unpredictability about the future applicability of the GLOBE Model. A few commenters stated that CMS should clarify which manufacturers would be excluded from the GLOBE Model by participating in other Federal initiatives or CMS Innovation Center models and allow further opportunity for public comment on the GLOBE Model. Some commenters stated the GLOBE Model should be withdrawn to prevent adverse impacts on the GENEROUS Model.

In addition, several commenters claimed that the methodology differences between the GLOBE Model and GENEROUS Model benchmark approaches would add burden to CMS and manufacturers and create risks for measuring and attributing impacts of manufacturer responses to these models. Commenters stated that CMS has previously exempted participants from certain models to prevent distortive effects. In contrast, some commenters expressed concern that the GLOBE Model's potential to achieve savings would be lower if the number of GLOBE Model drugs is constricted through manufacturer exclusions. A few commenters stated that allowing larger manufacturers that participate in the GENEROUS Model to be excluded from the GLOBE Model would disadvantage smaller manufacturers that would be required to participate in the GLOBE Model. Commenters stated that manufacturer exemptions would cause the requirements of the GLOBE Model to apply to smaller and mid-sized companies differently than to larger companies. Several commenters suggested that, in general, small manufacturers should be excluded from the GLOBE Model because these companies may not qualify for the GENEROUS Model, are less able to pay model rebates, are more likely to invest in treatments for rare diseases, and are more likely to not be financially responsible for sales in the proposed reference countries.

*Response:* We disagree that CMS has not provided a specific overlaps policy to which the public could react. In section II.M.1. in the GLOBE Model proposed rule (90 FR 60305), we discussed our proposal to allow overlap between the GLOBE Model and other CMS Innovation Center models. We stated that CMS conducted an internal review of which models and programs could have potential overlap with the GLOBE Model and our belief that healthcare provider or beneficiary overlap between the GLOBE Model and other models, programs, and initiatives would not impact our ability to conduct the GLOBE Model evaluation or interpret findings. We proposed that other CMS Innovation Center models and CMS programs and initiatives, as determined by CMS, would make adjustments as necessary to maintain the integrity of such models, programs, and initiatives. We also stated that we anticipate that model overlap may occur between the GLOBE Model and future CMS models or programs not yet implemented. We further stated that, if the proposed GLOBE Model were 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 addition, we also stated that if certain manufacturers were excluded due to interactions with other CMS Innovation Center models or for any other reason, the impacts from the GLOBE Model could be significantly less than described in our analysis presented in the GLOBE Model proposed rule (90 FR 60312).

With respect to potential interaction with participation in the GENEROUS Model, we note that the GENEROUS Model Request for Applications (RFA) states, ''To ensure that data from the GENEROUS Model can be accurately evaluated and are not affected by potential distortions or confounding variables from overlapping participation in other models, CMS may, at its discretion, waive or modify the applicability of other CMMI Models or Model requirements. Any such waivers shall be provided for in GENEROUS Model PAs [participation agreements].'' [199] The GENEROUS Model PAs were not available at the time CMS developed the GLOBE Model proposed rule. In the interest of clarity and transparency, however, we note that in the process of implementing the GENEROUS Model, CMS has determined that a manufacturer's participation in the GLOBE Model could impact CMS's ability to isolate the effects of the GENEROUS Model. To safeguard the CMS Innovation Center's ability to attribute changes in Medicaid spending and quality of care for Medicaid beneficiaries under the GENEROUS Model, we note that CMS intends to use its authority under section 1115A(d)(1) of the Act to waive the requirements for mandatory participation of manufacturers of GLOBE Model drugs under § 513.100 as applicable for a calendar quarter within the GLOBE Model performance period where such manufacturer participates in the GENEROUS Model during such calendar quarter, as necessary for purposes of the GENEROUS Model test. This use of waiver authority will address the evaluation challenges related to overlapping participation in other models that would arise from a manufacturer's simultaneous participation in both models, consistent with CMS's stated intent as described in the GENEROUS Model RFA. We emphasize that the waiver of the requirements for mandatory participation of manufacturers of GLOBE Model drugs under § 513.100 as applicable would be effectuated under the CMS Innovation Center's authority to test the GENEROUS Model, a voluntary model that is not subject to notice and comment rulemaking.

We believe that the authority in section 1115A of the Act is broad and grants us significant flexibility in the design and implementation of models. As with all CMS Innovation Center models, CMS monitors for potential issues that could arise, including potential issues related to model overlaps, and has the authority to modify model design as determined by CMS. As we stated in the GLOBE Model proposed rule (90 FR 60305), if, during implementation of the GLOBE Model, we were to observe unintended impacts on beneficiaries or model operations, we intend to propose appropriate operational adjustments to the GLOBE Model through future notice and comment rulemaking. For all these reasons, we do not believe that the GLOBE Model should be withdrawn and decline to codify manufacturer exemptions from the GLOBE Model. In response to comments and for transparency, in section IV. of this final rule, the estimates in the final regulatory impact analysis assume that manufacturers that have signed GENEROUS Model participation agreements as of August 17, 2026 will have a waiver that waives the requirements of mandatory participation of manufacturers of GLOBE Model drugs and will therefore not participate in the GLOBE Model. We refer readers to sections II.E. and IV.E. in this final rule for comment summary and our responses related to potential GLOBE Model impacts on small manufacturers.

*Comment:* A commenter stated that the GLOBE Model does not have a mechanism to prevent overlap with the GUARD Model. Another commenter

[199] GENEROUS (GENErating cost Reductions fOr U.S. Medicaid) Model Request for Applications from Applicable Manufacturers Version: 2.1 Dated February 27, 2026. Available at: *https://www.cms.gov/priorities/innovation/files/generous-rfa.pdf*. For additional information on the GENEROUS Model see the model website at: *https://www.cms.gov/priorities/innovation/innovation-models/generous*.

stated that the USP DC categories included in the GLOBE Model should also be included in the GUARD Model to avoid shifts to more costly sites of care and maintain home infusion therapy services under Medicare Part B.

*Response:* As discussed in section II.B. of this final rule, the GLOBE Model will focus on drugs that are identified with certain USP DC categories. The proposed GUARD Model (90 FR 60338) would also focus on drugs that are identified with certain USP Medicare Model Guidelines categories, including some categories selected for the GLOBE Model. In designing the GLOBE Model, we have chosen to allow potential overlap with other CMS Innovation Center models and CMS programs and initiatives, including the GUARD Model to the extent that it would occur, because it would not result in operational duplication, as utilization of a specific dose of a drug for a beneficiary could not occur under both Medicare Part B and Part D. We note that allowing model overlap and inclusion of the same USP DC categories in both models would not likely serve as a mechanism to avoid potential shifts between Part B and Part D. As we stated in section IV.D.1 of this final rule, while likely minimal (we found that anticipated GLOBE model drugs did not have significant utilization in Medicare Part D), we anticipate that there could be behavioral changes from manufacturers and providers to incentivize the increased use of white-bagging, where drugs would be reimbursed for under the Medicare 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. To assess impacts of potential utilization shifts between Medicare Part B and Part D, CMS would use monitoring activities for both models. As discussed in section II.L. of this final rule, CMS will monitor for potential impacts that could arise during GLOBE Model implementation, including potential changes in site of care, and would address issues as warranted.

*Comment:* A commenter stated that overlap between the GLOBE Model and EOM may create significant complexity and should be further addressed.

*Response:* We appreciate the commenter's suggestion to further address potential overlap between the GLOBE Model and EOM. Under the voluntary EOM, participating oncology providers are incentivized to take on accountability for the total cost of care and the quality of care for Medicare beneficiaries receiving certain cancer therapies, including chemotherapy. EOM participants offer EOM beneficiaries services such as care planning and patient navigation, which can lead to more timely and tailored coordinated care. The EOM total cost of care benchmark is based on Medicare allowed amounts, which are not changed by the GLOBE Model.

As discussed in section II.L. of this final rule, CMS will monitor for potential impacts that could arise during GLOBE Model implementation, including potential interactions with other CMS Innovation Center models. Through these ongoing monitoring mechanisms, we anticipate that we would be able to identify any overlap concerns with EOM and develop strategies to address issues as warranted. In addition, the CMS Innovation Center frequently communicates with EOM participants and other model participants through our learning and diffusion activities. We anticipate that these existing communication channels will provide participants in other CMS Innovation Center models with efficient ways to share feedback on potential issues that may be related to model overlaps, including overlap with the GLOBE Model, and other CMS initiatives and programs.

*Comment:* A commenter stated that if the GLOBE Model includes cell and gene therapies then overlap with the CGT Access Model should be avoided.

*Response:* As discussed in section II.B.5. of this final rule, the GLOBE Model will exclude certain cell and gene therapies. This exclusion is specified in § 513.130(c)(1)(v).

*Comment:* A commenter stated that CMS does not address how the GLOBE Model would interact with the Better Approaches to Lifestyle and Nutrition for Comprehensive health (BALANCE) Model.

*Response:* We thank the commenter for sharing their concern about model overlap. Under the BALANCE Model, CMS will negotiate drug pricing and coverage terms with manufacturers of GLP–1 medications on behalf of state Medicaid agencies.[200] On April 21, 2026, CMS announced a delayed implementation of the Medicare Part D portion of the BALANCE Model, pending further evaluation and data collection.[201] As announced on July 1, 2026, eligible Medicare Part D beneficiaries may get certain GLP–1 medication through a separate short-term demonstration, the Medicare GLP–1 Bridge, through December 31, 2027.[202] At this time, GLP–1 medications, as categorized in the USP DC, are not listed within the USP DC categories that would be included in the GLOBE Model as specified in § 513.130. As such, there would not be overlap between the GLOBE Model and either the BALANCE Model or the Medicare GLP–1 Bridge demonstration related to drug inclusion criteria.

*Comment:* A commenter stated that hospitals might experience indirect negative impacts under the Hospital Value-Based Purchasing Program which is tied to outcomes for inpatients.

*Response:* We thank the commenter for mentioning potential indirect impacts on inpatient hospitals and Medicare beneficiaries that may have a connection with the GLOBE Model. During the GLOBE Model test period, CMS will monitor for changes in utilization, including trends in hospital readmissions that would be observable through monitoring claims data.

*Comment:* Several commenters stated that CMS should not test the GLOBE Model at this time because there are several concurrent changes occurring in Medicare, such as the Negotiation Program, the Medicare Part B and Part D Drug Inflation Rebate Programs, the Part D redesign, and outside the Medicare program, such as new direct to consumer sales and PBM reforms, that are reshaping market entry and competitiveness, research and development investments, and pricing strategies. A commenter stated that these changes are occurring alongside substantial operational disruptions as manufacturers respond to concurrent changes and the GLOBE Model's rebate approach risks diverting more resources from patient access and post-approval development.

*Response:* We understand that manufacturers can face multiple, simultaneous changes within and across markets. In designing the GLOBE Model, we considered ways to minimize overlap with other CMS Innovation Center models and CMS programs and initiatives.

As with all CMS Innovation Center models, CMS monitors for potential issues that could arise, including potential issues related to model overlap with other initiatives as well as changes

[200] Centers for Medicare & Medicaid Services. BALANCE (Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth) Model. Available at: *https://www.cms.gov/priorities/innovation/innovation-models/balance.*

[201] Centers for Medicare & Medicaid Services. HPMS Memos for WK 4 April 20–24. Available at: *https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-april-20-24.*

[202] For more information about the CMS Medicare GLP–1 Bridge is available at: *https://www.cms.gov/medicare/coverage/prescription-drug-coverage/medicare-glp-1-bridge.*

in the healthcare delivery ecosystem. As we stated in the GLOBE Model proposed rule (90 FR 60305), if, during implementation of the GLOBE Model, we were to observe unintended impacts on beneficiaries or model operations, we intend to propose appropriate operational adjustments to the GLOBE Model through future notice and comment rulemaking.

*Comment:* A commenter suggested that CMS should conduct and publish a comprehensive analysis of cumulative pricing obligations facing manufacturers subject to multiple simultaneous Federal pricing programs, including CMS Innovation Center models, the Negotiation Program, and the Medicaid Drug Rebate Program, to assess whether the cumulative effect of simultaneous obligations could generate unintended incentive effects on product development and market entry decisions, particularly for smaller manufacturers with concentrated portfolios. This commenter stated that layering of interconnected pricing obligations creates a complex regulatory environment in which a pricing decision affecting one program may trigger downstream consequences across others and may create pressure for manufacturers with multiple high-spending drugs in specialty categories, where revenues from existing products help finance research and development pipelines. This commenter also stated that features of the GLOBE Model are meaningful and distinguish it from broader external reference pricing frameworks that have historically raised more substantial innovation concerns, specifically the GLOBE Model focus on established products with demonstrated high utilization and no generic or biosimilar competition in the U.S.

*Response:* We appreciate the commenter's suggestion that CMS consider potential cumulative effects on manufacturers. We understand that manufacturers can face multiple, simultaneous pricing obligations within and across markets. In designing the proposed GLOBE Model, we conducted a robust analysis of potential layering of pricing obligations related to the Medicare and Medicaid programs and published our conclusions in the preamble of the GLOBE Model proposed rule (90 FR 60244 through 60321). Based on our analyses, we proposed that the GLOBE Model would not include Medicare Part B drugs for which an MFP is in effect under the Negotiation Program. In alignment with the Medicare Part B Drug Inflation Rebate Program, we also proposed that GLOBE Model rebate amounts would not apply to units of drug furnished to Medicare beneficiaries who have Medicaid coverage that may provide cost-sharing assistance, which means these units would not be subject to both the Medicaid Drug Rebate Program and GLOBE Model rebates. We further proposed that other CMS Innovation Center models, 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. We intend for those adjustments to consider cumulative impacts on manufacturers as appropriate.

We believe it would be impractical to conduct and publish a more comprehensive analysis of cumulative pricing obligations facing manufacturers before testing the GLOBE Model because any such analysis could only reflect a point in time retrospective view and would not be predictive of conditions during a future time or reliably inform GLOBE Model design. Instead, we have incorporated robust monitoring and evaluation activities into the final model design as discussed in section II.L. and section II.P. of this final rule.

*Final Decision:* After consideration of the public comments received, CMS is finalizing our proposed approach for overlap between the GLOBE Model and other CMS Innovation Center models and CMS programs and initiatives as discussed in the GLOBE Model proposed rule (90 FR 60305 through 60306). In response to comments and for transparency, in section IV. of this final rule, the estimates in the final regulatory impact analysis assume that manufacturers that have signed GENEROUS Model participation agreements as of August 17, 2026 will have a waiver that waives the requirements of mandatory participation of manufacturers of GLOBE Model drugs and will therefore not participate in the GLOBE Model.

2. Quality Payment Program

As we stated in the GLOBE Model proposed rule (90 FR 60306), the 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).[203] Specifically, GLOBE Model participants would be manufacturers of GLOBE Model drugs, and those entities are not healthcare providers and do not qualify to participate in the QPP or MIPS APM. We noted that Medicare allowed amounts for claims for GLOBE Model drugs submitted by healthcare providers that are eligible for participation in the QPP would not be changed under the GLOBE Model. Therefore, the cost element of the QPP would not be impacted by the GLOBE Model.

We received no comments on this topic. We are finalizing CMS's determination that the GLOBE Model does not qualify as an APM under the QPP.

*N. Interaction With Other Federal Programs*

As discussed in the GLOBE Model proposed rule (90 FR 60306), the 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 biological products), 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. As we stated in the GLOBE Model proposed rule (90 FR 60306), because 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 the manufacturer's best price determination.

We also stated that, although not required as part of manufacturer participation in the GLOBE Model, we expect that the GLOBE Model would lead manufacturers to seek to adjust prices in order to lower the amount of GLOBE Model rebates they would owe. However, we do not expect such

[203] For more information about APMs and MIPS APMs see *https://qpp.cms.gov/apms/overview.*

potential manufacturer behavioral response would result in a material impact on a manufacturer's Medicaid Best Price. Therefore, our estimates of potential model impacts (as presented in section IV. of this final rule) only reflect Medicaid savings related to the GLOBE Model via the reduced cost sharing and premiums that Medicaid pays on behalf of dual eligible beneficiaries in the model geographic areas. Dual eligible beneficiaries are people who are enrolled in both Medicare (Part A, Part B, or both) and Medicaid.

In addition, we noted that awareness of the GLOBE Model would likely drive an increase in purchasers' interest in obtaining lower drug prices from manufacturers. We also noted that 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. We noted that these behavioral responses may be possible because the 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. The resulting effect on the Medicaid drug rebate would depend upon the relationship of any best price change and any average manufacturer price (AMP) change.

The following is a summary of the comments received and our responses.

*Comment:* A commenter agreed that GLOBE Model rebates should be treated as rebates under section 1847A(i) of the Act and excluded from a manufacturer's determination of Medicaid Best Price.

*Response:* We thank the commenter for sharing their view that GLOBE Model rebates should be treated as rebates under section 1847A(i) of the Act and excluded from manufacturers' determination of Medicaid Best Price. As stated in the GLOBE Model proposed rule (90 FR 60306), CMS believes that because 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 the manufacturer's Medicaid Best Price determination.

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. As we stated in the GLOBE Model proposed rule (90 FR 60307), the GLOBE Model would focus on certain Part B rebatable drugs. Because Part B rebatable drugs are typically furnished in the outpatient setting and are most commonly injected or infused, the AMP for GLOBE Model drugs that are identified as 5i drugs [204] may be impacted by the model. Specifically, the AMP computation for 5i drugs that are not generally dispensed through retail community pharmacies encompasses sales and other financial transactions beyond those involving retail community pharmacies—such as sales to physicians, PBMs, and hospitals—as provided under section 1927(k)(1)(B)(i)(IV) of the Act and 42 CFR 447.504(d).

We also stated that, 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. We noted that, if a manufacturer lowers its prices for a GLOBE Model drug 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 or the difference between AMP and the best price of the drug). However, as discussed in section II.N.1.a. of this final 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 noted in the GLOBE Model proposed rule (90 FR 60307) 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's determination of the payment allowance for such drug would occur.

We did not receive comments specific to this topic.

2. Interaction With the 340B Program

The Health Resources and Services Administration (HRSA) administers the 340B Drug Pricing Program that allows certain hospitals and other healthcare 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 HHS may enroll in the 340B Program as covered entities. In the GLOBE Model proposed rule (90 FR 60307), we stated that 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 number of GLOBE Model billing units and total GLOBE Model rebate amount as discussed in section II.G.4. of this final rule.

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.[205] 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.

The following is a summary of the comments received and our responses.

*Comment:* A few commenters sought clarification on how the GLOBE Model would impact the 340B Program and whether CMS would monitor for changes in 340B prices and pharmacy drug acquisition costs. A commenter asked CMS to explore ways to insulate 340B price calculations from being affected by the GLOBE Model, if CMS determines the model could negatively impact 340B hospitals.

[204] Inhalation, infusion, instilled, implanted or injectable drugs.

[205] For more information about the 340B ceiling price calculation see *https://340bpricing.hrsa.gov/Help/CoveredEntity/Ceiling%20Price%20Lookup/Ceiling%20Price%20Lookup.htm.*

*Response:* As we noted in the GLOBE Model proposed rule (90 FR 60307), the GLOBE Model may indirectly affect 340B ceiling prices. To the extent that manufacturers adjust their drug prices in response to the GLOBE Model, there may be an effect on a drug's AMP and best price such that there could be a resulting impact on 340B ceiling price and drug acquisition costs for covered entities that enroll in the 340B Program.

Because 340B ceiling prices are confidential, CMS will monitor for potential impacts on the 340B Program through the GLOBE Model monitoring and evaluation activities described in section II.L. and section II.P. of this final rule. We note that the 340B Program, including its price calculation, is out of scope of the GLOBE Model.

*Comment:* A commenter stated that the mark-ups that 340B hospitals charge on Part B medications exceed the total price of those drugs in wealthy European countries and that these markups inflate insurance premiums and increase patients' coinsurance spending. The commenter suggests reforms are needed to ensure transparency and eliminate abuse of the 340B Program in order to improve affordability and access.

*Response:* We thank the commenter for sharing their concerns regarding the 340B Program. Reforms to the 340B Program are outside the scope of the GLOBE Model.

3. Interaction With Medicare

a. Original Medicare Part B

As discussed in section IV.D. of this final rule, we believe the GLOBE Model would result in lower net OM Part B 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 OM expenditures and beneficiaries' Medicare Part B premiums. In the GLOBE Model proposed rule (90 FR 60313), we estimated that total OM Part B savings would amount to $8.4 billion over the GLOBE Model payment period before accounting for changes in the Medicare Part B premium, and that there would be additional beneficiary premium savings of $1.4 billion over the GLOBE Model test period. We refer readers to section IV. of this final rule for the corresponding estimates that are presented in this final rule, which are $298 million in OM Part B benefit savings and $111 million in cost sharing and premium savings for OM Part B beneficiaries, respectively, based on the provisions finalized in this final rule.

As discussed in section IV.D. of the GLOBE Model proposed rule (90 FR 60312), we note that manufacturers' ASPs for GLOBE Model drugs may be higher or lower than they otherwise would be absent the GLOBE Model. In turn, OM Part B 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 also 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. Further, 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's determination of the payment allowance for such drug would occur.

The following is a summary of the comments received and our responses.

*Comment:* A few commenters sought clarification on how the GLOBE Model would impact the calculation of ASP, OM Part B payment limits for Medicare Part B drugs, and providers' acquisition costs. These commenters stated that reduced payment and compression of providers' drug revenue should be avoided and that constraining reimbursement for Medicare Part B drugs will limit treatment options for patients.

*Response:* The GLOBE Model will not directly impact manufacturers' ASPs, quarterly Medicare Part B payment limits for separately payable Part B drugs, or providers' acquisition costs. Manufacturers will remain responsible for their drug prices. To the extent that manufacturers adjust their drug prices in response to the GLOBE Model, manufacturers' ASPs for GLOBE Model drugs (and perhaps other drugs) may be higher or lower than they otherwise would be absent the GLOBE Model. Providers' acquisition costs may be higher or lower due to manufacturers' pricing decisions. Manufacturers will continue to report their ASPs to CMS quarterly. Because the GLOBE Model rebate amounts are rebates under section 1847A(i) of the Act, consistent with section 1927(c)(1)(C)(ii)(I) of the Act and section 1847A(c)(3) of the Act, manufacturers would not include GLOBE Model rebates in the calculation of the manufacturer's average sales price. As we stated in the GLOBE Model proposed rule (90 FR 60307), the OM Part B 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 also noted 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's determination of the payment allowance for such drug would occur. As discussed in section II.L. and section II.P. of this final rule, during the GLOBE Model test period, CMS will implement robust monitoring and evaluation activities. As we stated in the GLOBE Model proposed rule (90 FR 60305), if, during implementation of the GLOBE Model, CMS were to observe unintended impacts on beneficiaries or model operations, CMS intends to propose appropriate operational adjustments to the GLOBE Model through future notice and comment rulemaking.

b. Medicare Advantage

In the GLOBE Model proposed rule (90 FR 60307), we stated that MA plans and beneficiaries enrolled in MA plans would not be included in the GLOBE Model. We noted 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 OM 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 OM allowed amount per 42 CFR 422.100(f)(6)(i). We noted that, 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.D. of the GLOBE Model proposed rule, we expect the GLOBE Model would lower overall net OM 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. We stated that the overall decrease in OM expenditures would be considered in determining the rates for plan service areas. We noted that 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 OM 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, we noted that, if the GLOBE Model is finalized, the MA rate book calculations would reflect changes in OM expenditures due to the impact of the GLOBE Model. We also noted 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 the GLOBE Model proposed rule (90 FR 60313), we estimate that MA benchmarks and bids may be lower, resulting in $7.5 billion in savings over the model period before accounting for changes in the Medicare Part B premium. In turn, we noted that MA plans may reduce supplemental benefits and increase MA beneficiary out-of-pocket costs. We also noted that there is much uncertainty around the assumptions for this estimate.

We note that, in section IV. of this final rule, the final regulatory impact analysis aligns with the final policies set forth in this final rule and estimates that MA benchmarks and bids may be lower, resulting in $288 million in savings over the model period before accounting for changes in the Medicare Part B premium.

The following is a summary of the comments received and our responses.

*Comment:* Several commenters stated that the GLOBE Model could have a negative impact on care for beneficiaries who are enrolled in MA plans if such plans reduce their bids and supplemental benefits in response to lower MA benchmarks that are based on lower OM spending due to the model. A few commenters stated that reduced supplemental benefits can have negative consequences for Medicare beneficiaries with low incomes, those with health disparities, and those enrolled in Special Needs MA plans that offer critical supplemental benefits to support access to key needs like food, transportation, and other vital services not covered under OM. Commenters stated that CMS should not proceed with the GLOBE Model without protecting MA beneficiaries from unintended consequences. In addition, a commenter claimed that GLOBE Model impacts on MA plans would complicate CMS's evaluation of the model. Another commenter requested that CMS issue rate-setting guidance to MA plans to prevent unintended benchmark volatility.

*Response:* As stated in the GLOBE Model proposed rule (90 FR 60308), our proposed approach is consistent with treatment of payments made under other CMS Innovation Center models and the Medicare Shared Savings Program. We also note that MA rate book calculations would reflect changes in OM spending due to the impact of the GLOBE Model, and that there is much uncertainty around the assumptions for our estimate of potential impacts on MA benchmarks and bids, and MA plans. As discussed in section IV. of this final rule, based on the final policies set forth in this final rule, we present our estimate of potential impacts on the MA program. As shown in Table 13 and Table 14, respectively, our updated analysis estimates $288 million in total MA payment savings and $90 million in total premium savings for MA beneficiaries over the model period. This estimate includes the finalized drug inclusion and exclusion criteria in § 513.130 and other assumption impacts as further described in section IV. of this final rule. Based on this updated analysis, we believe that the GLOBE Model as finalized in this final rule may mitigate the concerns raised by commenters. At this time, we decline to commit to issuing rate-setting guidance to address potential GLOBE Model impacts, due to the uncertainty around the assumptions for our estimate of potential model impacts on MA plans and beneficiaries.

*Comment:* A few commenters stated that MA plans would not benefit from lower costs of GLOBE Model drugs and that MA beneficiaries should not be disadvantaged as OM Part B spending and MA benchmarks decrease because of the GLOBE Model. A commenter suggested including beneficiaries who are in MA plans and receive GLOBE Model drugs from out-of-network providers in the model because these beneficiaries can face coinsurance up to 50 percent. Another commenter stated that CMS should reconsider excluding MA units from the Medicare Part B Drug Inflation Rebate Program.

*Response:* We thank the commenters for these suggestions to potentially include MA beneficiaries within the model test. At this time, the Medicare Part B Drug Inflation Rebate Program does not include MA units in Medicare Part B drug inflation rebate amount calculations due to operational considerations. Therefore, we are not including MA beneficiaries within the GLOBE Model. We will revisit this topic for future consideration should the Medicare Part B Drug Inflation Rebate Program include MA units in Medicare Part B drug inflation rebate amount calculations.

*Final Decision:* After considering the public comments received and the existing statutory and regulatory requirements applicable to the Medicare program generally and to MA rate setting in particular, CMS is finalizing our proposed approach for how the GLOBE Model may interact with the MA program. We refer readers to the final regulatory impact analysis in section IV. of this final rule for additional discussion on expected changes in MA benchmarks and the corresponding change in MA payments and potential impacts on MA beneficiaries.

*O. Medicare Program Waivers*

1. Overview

In the GLOBE Model proposed rule (90 FR 60308 through 60309), we stated our belief that it may be necessary to waive certain requirements of title XVIII of the Act for the testing of the GLOBE Model. We proposed to use our waiver authority under section 1115A(d)(1) of the Act to waive several Medicare program requirements, as further discussed in this section of this final rule. 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 Medicare program requirements as necessary to carry out the provisions of section 1115A of the Act with respect to testing models.

We sought comments on other possible waivers under section 1115A of the Act of certain Medicare program rules beyond those specifically discussed in this final rule that might be necessary to test this model. We stated that 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.

The following is a summary of the comments received and our responses.

*Comment:* Commenters stated the repurposing of an entire statutory program in this manner is not a permissible waiver and represents an ultra vires assertion of authority beyond what is granted in section 1115A of the

Act. They state the Supreme Court has rejected the notion that agency waiver authority is limitless, denouncing the use of waiver authority to ''create a novel and fundamentally different'' program from the underlying statute. The commenters contend that the agency's action is particularly troubling here given that the international reference pricing metric CMS now proposes to ''test'' is one that was specifically considered and soundly rejected by Congress just over 3 years ago.

*Response:* CMS respectfully disagrees with the commenter's characterization of GLOBE as an ultra vires exercise of authority and maintains that the GLOBE Model falls squarely within the broad authority granted to the CMS Innovation Center under section 1115A of the Act.

Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models that have the potential to reduce program expenditures under Medicare, Medicaid, or CHIP while preserving or enhancing the quality of care furnished to beneficiaries. Congress deliberately crafted this authority broadly, granting the CMS Innovation Center significant discretion to design and test models that address the drivers of program costs—including drug pricing—without requiring separate legislative authorization for each model tested. Critically, in section 1115A(d)(1) of the Act, Congress expressly authorized the Secretary to waive any Medicare requirements ''as may be necessary solely for the purpose of carrying out this section,'' and expressly bounded that authority with limiting conditions. CMS is not invoking broad, general statutory language to claim transformative power; rather, CMS is acting within a detailed, purpose-specific statutory framework that Congress designed precisely for this type of model test.

The GLOBE Model is designed to test whether aligning Medicare drug payments more closely with prices paid in comparable international markets can reduce program expenditures while maintaining beneficiary quality of care. This objective is directly consistent with the cost-reduction and quality-preservation purposes of section 1115A of the Act. Moreover, CMS's approach in designing the GLOBE Model is consistent with the manner in which the CMS Innovation Center has exercised its authority under section 1115A of the Act across a wide range of models throughout its history. Since its establishment, the CMS Innovation Center has routinely tested alternative payment methodologies that alter how Medicare pays for items and services, including alternatives to existing statutory payment formulas. For example, OCM tested, and EOM is testing, episode-based payment approaches that alter standard OM Part B reimbursement for cancer care; the BPCI and BPCI Advanced models restructured Medicare payment for episodes of care across a broad range of clinical conditions; and the CJR Model, which, like the GLOBE Model, was implemented on a mandatory basis, altered Medicare payment for lower extremity joint replacement procedures across geographically selected markets. The GLOBE Model's alternate approach to the Medicare Part B drug inflation rebate amount calculation using international drug pricing benchmarks represents the same category of payment model innovation that the CMS Innovation Center was designed and authorized to test.

The commenter invokes the Supreme Court's admonition against using waiver authority to create programs that are ''novel and fundamentally different'' from the underlying statute. See *Biden* v. *Nebraska,* 600 U.S. 477 (2023). In that case, the Supreme Court held that, under the HEROES Act, the Secretary of Education could not rely on authority to waive or modify statutory or regulatory provisions applicable to student financial assistance programs as deemed necessary in connection with a war or other military operation or national emergency, to implement a broad student loan forgiveness program, as the latter was statutory provisions that had vast economic and political significance without clear congressional authorization. The GLOBE Model is distinguishable on the basis that the model falls squarely within the purpose-specific statutory framework of section 1115A of the Act that expressly authorizes the CMS Innovation Center to test time-limited innovative payment models, waive any Medicare requirement ''as may be necessary solely for the purpose of carrying out this section with respect to testing models,'' and evaluate the results against defined statutory criteria. Unlike the action at issue in *Biden* v. *Nebraska,* which canceled approximately $430 billion in Federal student loans and completely erased the debts of 20 million borrowers pursuant to the claimed authority under the HEROES Act, the GLOBE Model (1) tests a targeted alternative rebate amount calculation under the Medicare Part B Drug Inflation Rebate Program in accordance with section 1115A of the Act's statutory objectives of reducing program expenditures while preserving or enhancing quality of care, (2) is limited to a random selection of ZCTAs representing approximately 25 percent of OM Part B enrollees, (3) focuses on a subset of Part B rebatable drugs, (4) operates only for a limited test period from January 1, 2027 to March 31, 2034 (further discussed in section II.A. of this final rule), (5) is estimated to produce overall savings of $440 million [206] in OM Part B net spending (where overall total OM Part B drug spending was $81.90 billion according to 2025 claims data), (6) is evaluated for impacts to program expenditures and quality of care in accordance with section 1115A(b)(4) of the Act, (7) is subject to specific statutory requirements for expansion should the CMS Innovation Center seek to expand the duration and the scope of the model test pursuant to section 1115A(c) of the Act, and (8) is subject to regular reporting to Congress under section 1115A(g) of the Act. Thus, the GLOBE Model does not represent the type of action at issue in *Biden* v. *Nebraska.* Accordingly, CMS does not believe the GLOBE Model presents the type of sweeping, transformative agency action that the major questions doctrine is intended to constrain.

CMS also respectfully disagrees with commenters' argument that, because Congress considered and rejected international reference pricing in prior legislation, CMS may not test such an approach under section 1115A of the Act, for several reasons.

The GLOBE Model remains a Medicare payment model—it operates within the Medicare program, applies to Medicare-covered drugs, and is designed to test whether a specific payment methodology can achieve the statutory goals of section 1115A of the Act. CMS therefore does not agree that the GLOBE Model crosses the line from permissible model innovation into impermissible program transformation.

The commenter argues that because Congress considered and rejected international reference pricing in prior legislation, CMS may not test such an approach under section 1115A of the Act. CMS respectfully disagrees with this reasoning for several reasons.

First, the scope and structure of the GLOBE Model differ materially from the legislative proposals previously considered by Congress in establishing the Negotiation Program, where Congress considered and did not adopt a cap for negotiated prices that was based on foreign reference prices.

[206] Overall Medicare Part B net spending savings are calculated by adding OM Part B benefit savings and MA payment savings and then subtracting the premium offset.

Determining applicable benchmarks for ceilings negotiated in good faith is a very different context from the GLOBE Model, which is a time-limited model test that is scoped to a particular set of GLOBE Model Drugs when administered to a model cohort that represents 25 percent of OM Part B beneficiaries, and is not a permanent statutory program. Thus, the fact that the Congress that enacted the IRA did not adopt the reference pricing provision in this very different context is not indicative of the kind of testing the Congress that enacted the Affordable Care Act would have condoned under section 1115A of the Act. To the contrary, the GLOBE Model has been designed in accordance with the limitations of section 1115A of the Act to generate evidence about the effects on Medicare expenditures and beneficiaries' quality of care of considering international pricing data in alternative payment methodologies for drugs payable under OM Part B. This evidence can inform future policy decisions by Congress, as envisioned by section 1115A(g) of the Act which states that reports to Congress on activities under section 1115A of the Act ''shall provide such recommendations as the Secretary determines are appropriate for legislative action to facilitate the development and expansion of successful payment models.'' Thus, testing the GLOBE Model is precisely the kind of evidence-generating function that section 1115A of the Act was designed to support.

Further, the legislative history of the IRA cannot override the clear language of section 1115A of the Act in providing the CMS Innovation Center the authority to test this model. The rejected provision of a subsequent Congress cannot constrain the ambit of the plain text under section 1115A of the Act, nor agency action under a different Administration that complies with the plain terms of the statute. As the Supreme Court held in *Loper Bright Enterprises* v. *Raimondo,* courts must give statutory text its ordinary meaning in context. Read according to its ordinary meaning, section 1115A of the Act expressly authorizes the Secretary to test ''innovative payment and service delivery models'' and to waive Medicare payment requirements ''as may be necessary solely for the purpose of carrying out this section with respect to testing models.'' The ordinary meaning of this language encompasses a time-limited, geographically scoped test regarding an innovative approach to the payment of certain drugs under Medicare Part B—precisely what the GLOBE Model proposes. The plain text of section 1115A of the Act, read in its full statutory context, affirmatively supports CMS's authority here.

*Comment:* Many commenters argued that the GLOBE Model misuses CMS's waiver authority. The CMS Innovation Center statute authorizes waivers of certain Social Security Act provisions only ''as may be necessary'' to carry out a Phase I test. Commenters noted that CMS is not actually proposing to waive any statutory provision; rather, it is seeking to impose new obligations on manufacturers that go beyond existing law; to ''waive'' means to voluntarily relinquish a legal right or refrain from enforcing a claim, not to create new mandates or rewrite statutory frameworks. Commenters stated that the GLOBE Model, while styled as a ''model,'' effectively seeks to implement broad, far-reaching authority that Congress has not authorized, analogous to the student loan debt cancellation case in which the U.S. Supreme Court rejected an agency's attempt to use a limited waiver provision to rewrite large sections of law. Commenters cited *Biden* v. *Nebraska,* 600 U.S. 477 (2023) and related Supreme Court precedent to argue that Congress must speak clearly before an agency can unilaterally alter large sections of the American economy, which GLOBE attempts to do. Commenters requested that CMS withdraw the model or, at minimum, significantly narrow its scope to align with permissible waiver authority.

*Response:* CMS disagrees with commenters' suggestion that the GLOBE Model misuses the waiver authority in section 1115A(d)(1) of the Act, as the waivers proposed in the GLOBE Model proposed rule (90 FR 60308 through 60309) are necessary to test the GLOBE Model. CMS believes that the proposed waivers align with how CMS has applied the necessity standard across dozens of prior CMS Innovation Center models.

For the GLOBE Model, waivers of standard Medicare payment rules are functionally necessary because without waiving the standard payment methodology, CMS cannot test an alternative payment approach—the model's core purpose would be legally impossible to implement. This is exactly the scenario section 1115A(d)(1) of the Act was designed to address. Furthermore, CMS has precedent for issuing this type of waiver in other CMS Innovation Center models like the OCM, Primary Care First Model, and End-Stage Renal Disease Treatment Choices Model. In all those CMS Innovation Center models, CMS used section 1115A(d)(1) of the Act to waive the specific statutory payment rules that would otherwise prevent the alternative payment model from operating. The GLOBE Model follows this well-established pattern.

We believe this is a permissible use of our statutory waiver authority, and not an impermissible rewrite of the statute. The proposed waivers only apply to GLOBE Model beneficiaries (not all Medicare beneficiaries). The waivers themselves are time-limited to the GLOBE Model performance period. The waivers and the GLOBE Model itself are subject to the model's statutorily mandated evaluation and both the waivers and the GLOBE Model itself can be terminated if the model fails to meet statutory requirements regarding quality of care and savings. Finally, the waivers are instrumentally tied to the model's testing purpose. All of these reasons demonstrate the intent of CMS to create a permissible waiver.

Finally, CMS disagrees with commenters that the GLOBE Model raises major questions doctrine concerns. Congress created the CMS Innovation Center for the specific purpose of testing ''innovative payment and service delivery models;'' expressly authorized the Secretary to waive Medicare payment requirements under section 1115A(d)(1) of the Act ''as may be necessary solely for the purpose of carrying out this section;'' and expressly bounded the authority with limiting conditions. CMS is not using broad, general statutory language to claim transformative power. CMS is acting in a detailed, purpose-specific statutory framework that Congress designed precisely for this type of model test. For a more robust response to the major questions doctrine comment, we refer readers to the introduction of section II. of this final rule.

*Comment:* Many commenters believed that CMS's authority under section 1115A(d)(1) of the Act to ''waive'' statutory provisions does not authorize the agency to create entirely new rebate obligations. Commenters contended that the plain meaning of ''waive''—to abandon, refrain from enforcing, or surrender a requirement—permits CMS only to forbear enforcement of existing statutory requirements, not to substitute or supplement them with novel obligations. Commenters stated that under the GLOBE Model, the existing Medicare Part B and Part D inflation rebates authorized by Congress under the IRA would continue to apply in full, meaning CMS is not actually waiving anything. Instead, CMS would be layering on an additional, foreign-reference-pricing-based rebate obligation unrelated to inflation.

Commenters argued this is the opposite of a waiver—it increases regulatory burdens rather than relaxing them. Commenters further cited *Biden* v. *Nebraska,* in which the Supreme Court held that authority to ''waive or modify'' statutory provisions does not grant an agency unlimited power to rewrite statutes. The Court found that drafting ''radically new text'' by ''waiving provisions root and branch'' constitutes an impermissible ''exhaustive rewriting of the statute'' that exceeds the bounds of statutory authority. Commenters argued the GLOBE Model suffers from the same defect, as it would effectively create a new section of the Act imposing a novel foreign-pricing-based rebate scheme rather than easing existing requirements.

*Response:* We thank the commenters for their detailed legal analysis regarding the scope of CMS's waiver authority under section 1115A(d)(1) of the Act. We respectfully disagree with the commenters' characterization of the GLOBE Model's legal basis and the scope of the CMS Innovation Center's statutory authority.

Section 1115A(d)(1) of the Act grants the CMS Innovation Center authority to waive such requirements of titles XVIII and XIX of the Act as the Secretary determines necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models. As described in this section of this final rule, CMS is exercising that waiver authority by waiving specific statutory provisions, including sections 1847A(i), 1833(a), and 1833(t) of the Act, as well as associated regulatory provisions at 42 CFR 410.152(m), 419.41(e), 489.30(b)(1), and 489.30(b)(6), to the extent necessary to permit the testing of the GLOBE Model's alternative payment methodology. These are targeted, model-specific waivers directly tied to the testing objectives authorized under section 1115A of the Act.

We disagree with the commenters' assertion that CMS is not ''actually waiving anything'' under the GLOBE Model. Pursuant to its statutory authority under section 1115A of the Act, CMS is testing an innovative payment model that relies on an alternative rebate methodology for calculating Medicare Part B drug inflation rebate amounts using international drug pricing benchmarks in order to reduce program expenditures while preserving or enhancing beneficiary quality of care. In order to test this innovative payment model in accordance with section 1115A of the Act, we need to utilize our waiver authority under section 1115A(d)(1) of the Act to waive the existing requirements regarding the Medicare Part B drug inflation rebate amount calculation and the invoicing timelines that conflict with novel elements of this innovative payment model. Without this waiver of the existing, conflicting requirements under the Medicare Part B Drug Inflation Rebate Program, we would be unable to test whether a payment model that uses an alternative method for calculating Medicare Part B drug inflation rebate amounts for certain separately payable Part B drugs and biological products reduces costs for OM beneficiaries and the Medicare program while preserving quality of care. That is, under our statutory authority under section 1115A(b)(1) of the Act, we are testing this payment model relying upon a novel rebate methodology for a subset of drugs and biological products payable under Part B to observe effects on Medicare expenditures and beneficiaries' quality of care. Waiving the existing, conflicting requirements of the Medicare Part B Drug Inflation Rebate Program is necessary to test the alternative rebate calculation for the treatment group, which constitutes the 25% of Medicare beneficiaries that reside in the selected ZCTAs for the subset of Part B rebatable drugs that would be GLOBE Model drugs. However, for the control group, the existing requirements of the Medicare Part B Drug Inflation Rebate Program remain in place to serve as a comparison group for the treatment group in this model test. To operationalize the waiver of the existing, conflicting requirements of the Medicare Part B Drug Inflation Rebate Program in the treatment group without disrupting the existing Medicare Part B drug inflation rebate amount calculation, reports, and other operational functions in the control group, we have chosen to invoice the total GLOBE Model rebate amount via the incremental approach as discussed in section II.G.8. of this final rule. Commenters' concerns and arguments that CMS is not waiving anything do not account for how we must test the alternative payment methodology in the treatment group against the existing requirements in a comparison group as part of this innovative payment model test.

With respect to the commenters' argument that the GLOBE Model's rebate obligation is a novel addition rather than a relaxation of existing requirements, we note that section 1115A(d)(1) of the Act authorizes the waiver of statutory requirements ''to the extent necessary'' to carry out the model test. The waiver of specific payment and cost-sharing provisions in sections 1847A(i), 1833(a), and 1833(t) of the Act ensures the conflicting existing requirements do not prevent the CMS Innovation Center from testing the GLOBE Model's alternative rebate amount calculation and payment structure. To emphasize, without these waivers, the existing statutory payment framework would preclude the model test from functioning as designed. The GLOBE Model rebate obligation is the direct consequence of the exercise of that waiver authority.

Our waiver authority under section 1115A(d)(1) of the Act enables the implementation of our statutory authority under section 1115A(b)(1) of the Act to test payment and service delivery models—indeed, these two authorities work in concert. To interpret section 1115A of the Act's grant of statutory authority as limited only to the waiver authority under section 1115A(d)(1) of the Act not only ignores the rest of the statutory text including section 1115A(b)(1) of the Act, but also suggests a tortured reading of the statute where CMS could test payment and service delivery models only to the extent they could be sculpted in the negative from existing payment and service delivery frameworks—a reading incompatible with both the surrounding text and the explicit purpose and mission to innovate.

CMS acknowledges commenters' reliance on *Biden* v. *Nebraska* for the proposition that ''waiver'' authority does not permit an agency to draft ''radically new text'' in place of existing statutory provisions. However, CMS believes the GLOBE Model is distinguishable from the circumstances addressed in that case. CMS also does not believe the GLOBE Model implicates the concerns raised in *Biden* v. *Nebraska.* In that case, the Supreme Court held that the HEROES Act did not clearly authorize the Secretary of Education to implement a broad student loan forgiveness program, emphasizing that agencies may not rely on general statutory authority to take actions of vast economic and political significance without clear congressional authorization. The GLOBE Model is distinguishable because section 1115A of the Act is not a general or ancillary grant of authority, but rather a detailed, purpose-specific statutory framework that expressly authorizes the CMS Innovation Center to test alternative payment models, waive applicable Medicare requirements, and evaluate the results against defined statutory criteria. The GLOBE Model operates squarely within these express statutory

parameters and does not represent the type of action at issue in *Biden* v. *Nebraska.* Accordingly, CMS does not believe the GLOBE Model presents the type of sweeping, transformative agency action that the major questions doctrine is intended to constrain.

The GLOBE Model does not eliminate or nullify the existing IRA inflation rebate framework. Rather, CMS is exercising its waiver authority to test an alternative payment methodology—specifically using international drug pricing information to identify a benchmark that reflects prices paid in a set of economically comparable countries—as part of a defined, time-limited model test expressly authorized by Congress under section 1115A of the Act. The existing Medicare Part B Drug Inflation Rebate Program remains operative, and the GLOBE Model's operational approach for invoicing incremental rebate obligations is designed to facilitate testing whether an alternative pricing approach can reduce Medicare expenditures while preserving quality of care, consistent with the statutory purposes of section 1115A of the Act.

CMS further notes that section 1115A of the Act was enacted by Congress with the express purpose of testing innovative payment and service delivery models, and that the statute's waiver authority was designed to provide the CMS Innovation Center with the flexibility necessary to conduct such tests. CMS believes that the best reading of the statute supports the agency's ability to test alternative rebate structures as part of a mandatory model, provided such testing is consistent with the statutory criteria set forth in section 1115A of the Act.

We acknowledge that the GLOBE Model's rebate structure represents a novel approach to drug pricing within the Medicare program. However, novelty alone does not render a model test or its associated waivers impermissible under section 1115A of the Act. The CMS Innovation Center's mandate is precisely to test new and innovative approaches to payment and service delivery that have the potential to reduce program expenditures while preserving or enhancing quality of care. CMS believes that the waivers finalized in this rule fall squarely within the scope of the waiver authority conferred by section 1115A(d)(1) of the Act and are necessary to carry out the GLOBE Model test as designed.

*Comment:* A commenter acknowledged CMS's authority under section 1115A of the Act to waive statutory provisions, including sections 1833 and 1847A of the Act, to test alternative approaches to drug pricing and beneficiary coinsurance. However, the commenter argued that the GLOBE Model proposed rule does not establish a corresponding obligation or mechanism to ensure that adjustments made pursuant to waiver authority result in net affordability improvements for beneficiaries. The commenter stated that CMS's own impact analysis acknowledges the potential for reductions in supplemental benefits and other downstream cost effects that may offset any coinsurance changes.

*Response:* CMS acknowledges the commenter's observation that the GLOBE Model proposed rule does not establish an explicit mechanism to guarantee that coinsurance adjustments will result in net affordability improvements for all beneficiaries. CMS takes seriously its obligation to ensure that model tests do not adversely affect beneficiary access to care or financial well-being.

CMS notes that the GLOBE Model is designed to test whether an alternative rebate amount calculation reduces Medicare spending while preserving or enhancing the quality of care for Medicare beneficiaries. The model evaluation will assess if the model can generate meaningful savings at the program level, with the expectation that such savings will, over time, contribute to reduced cost-sharing burdens for Medicare beneficiaries. CMS's use of waiver authority under section 1115A(d)(1) of the Act to waive the conflicting requirements under sections 1833 and 1847A of the Act is intended to enable the testing of alternative coinsurance calculation methodologies that may more directly reflect the lower net payments for GLOBE Model drugs achieved under the model.

CMS recognizes, however, that program-level savings as described in section IV. of this final rule, do not automatically translate into patient-level affordability improvements, and that downstream effects, including potential reductions in supplemental benefits, may offset some of the anticipated coinsurance reductions for certain beneficiaries.

*Final Decision:* After considering the public comments received, CMS is proceeding with its decision to include statutory waivers in the GLOBE Model. The following sections describe in detail the specific waivers being finalized in this final rule.

2. Waiver of the Calculation of the Rebate Amount

In section II.O.2. of the GLOBE Model proposed rule, (90 FR 60308), we proposed to waive program requirements that are necessary solely for the purposes of testing the GLOBE Model. Specifically, in § 513.1000(a), we proposed to waive the Medicare Part B drug inflation rebate amount calculation provisions, as described in section 1847A(i)(3) of the Act and 42 CFR 427.302 and 42 CFR 427.301, which describe the calculation of the rebate amount. We stated that we believe this is necessary in order to implement the alternative calculation for the GLOBE Model rebate amount as described in section II.G. of this final rule. We also stated our belief 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) of 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 stated our belief that this supports our implementation of the GLOBE Model test and innovative payment models. We also stated that the GLOBE Model would test an alternative approach to the Medicare Part B drug 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, and that we expect that this alternative approach 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 stated our belief that the proposed waiver of the Medicare Part B drug 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 final rule).

We sought comment on our proposed waiver of the Medicare Part B drug inflation rebate amount calculation provisions as described in section 1847A(i)(3) of the Act.

*Final Decision:* CMS received no comments on this proposed provision. Accordingly, CMS is finalizing this provision as proposed, without modification. CMS has made a non-substantive technical correction to correct a drafting error in § 513.1000(a)

so that ''rebate calculation'' is replaced with ''rebate amount calculation'' and also corrected a typographical error with the removal of the phrase ''of this chapter''. For consistency, CMS uses ''alternative rebate amount calculation'' throughout this final rule as applicable.

3. Waiver of Timing Requirements

In § 513.1000(b), we proposed to waive program requirements that are necessary solely for the purposes of testing the GLOBE Model. As described in section II.G.8. of the GLOBE Model proposed rule (90 FR 60299), we considered two proposals for invoicing GLOBE Model rebate amounts. Under both approaches, we proposed to waive section 1847A(i)(1) of the Act and instead we proposed the following deadlines, effective dates, and time period requirements for the GLOBE Model under either option.

For the combined invoicing approach, we noted 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. We proposed 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.a. of the GLOBE Model proposed rule and the information in 42 CFR 427.501. We also proposed, for each calendar quarter beginning on or after October 1, 2026, the manufacturer of a GLOBE Model Drug shall, for such drug, no 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 § 513.500(a) for such drug for such calendar quarter.

For the incremental invoicing approach, we noted 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 could be issued. As such, we similarly proposed that, for each calendar quarter, 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 of a GLOBE Model drug the information described in section II.G.8.b. of the GLOBE Model proposed rule. We also proposed, for each calendar quarter beginning on or after October 1, 2026 (which was based on the proposed model start), 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 incremental GLOBE Model rebate amount due as set forth in § 513.520 for such drug for such calendar quarter.

We stated our belief that these waivers are necessary to implement the GLOBE Model on the proposed timeline given various operational considerations necessary to calculate GLOBE Model rebate amounts. We stated our belief that, by issuing Rebate Reports 2 months later than specified in section 1847A(i)(a)(1) of the Act, under the combined invoicing approach, 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 manufacturers of GLOBE Model drugs timely. As such, under the combined invoicing approach, we proposed waiving section 1847A(i)(1) 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. We stated our belief that, under the incremental invoicing approach, by 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 to provide the information needed for the incremental GLOBE Model Rebate Report. As such, under the incremental invoicing approach, we proposed waiving section 1847A(i)(1) of the Act to the extent necessary to allow CMS to provide the incremental GLOBE Model rebate information to manufacturers of GLOBE Model drugs.

We sought comments on our proposed waiver of section 1847A(i)(1) of the Act. We received comments related to the combined and incremental invoicing approach and refer readers to section II.G.8. of this final rule for our response and final decision related to those comments. We note that CMS is finalizing the incremental invoicing approach in this final rule.

*Final Decision:* After considering the public comments received regarding invoicing, CMS is finalizing the inclusion of a waiver of section 1847A(i)(1) of the Act to the extent necessary to allow CMS to test an alternative invoicing procedure for GLOBE Model rebate amounts, including providing the incremental GLOBE Model rebate information to manufacturers of GLOBE Model drugs, without modification. Accordingly, CMS is finalizing § 513.1000(b) without modification.

4. Waivers of Section 1833 of the Act (Payment of Benefits)

In section II.G.7. of the GLOBE Model proposed rule (90 FR 60309), we stated that 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 claims. Accordingly, we stated our belief that 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. In addition, we stated our belief that 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, we stated our belief that 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.

*Final Decision:* CMS received no comments on this proposed provision. Accordingly, CMS is finalizing § 513.1000(c) as proposed with one typographical correction to remove the phrase ''of this chapter.''

*P. Evaluation*

As stated in section II.P. of the GLOBE Model proposed rule (90 FR 60309), CMS 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 CMS Innovation Center models, which would include the GLOBE Model, are rigorously evaluated on their ability to improve quality without increasing costs or to reduce costs while preserving or enhancing quality. In addition, we routinely evaluate monitoring data from CMS 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 proposed evaluation methodology accounts for the GLOBE Model's innovative alternative benchmark for the Medicare Part B drug 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. As we stated in the GLOBE Model proposed rule (90 FR 60309), CMS expects the model would reduce program expenditures for Medicare Part B while preserving or enhancing beneficiaries' quality of care. We noted the evaluation would employ a design to provide evidence that the proposed intervention would reduce program expenditures 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, including out-of-pocket costs of GLOBE Model 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 GLOBE Model 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 GLOBE Model 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 healthcare 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 GLOBE Model drugs). We would also examine non-drug healthcare utilization that may change because of the GLOBE Model to estimate any impacts on access to care. Examples of other non-drug healthcare utilization include hospitalizations, emergency department visits, and condition specific utilization related to a given sub-group of beneficiaries. The impact estimates would reflect the collective effect of the GLOBE Model's changes to Medicare payments and quality of care.

The following is a summary of the comments received and our responses.

*Comment:* Commenters stated a perceived lack of testing rationale and experimental design and stated CMS did not articulate a credible testing hypothesis, because any reduction in program expenditures is preordained, or did not establish the criteria to assess the ''results'' of the test or an experimental design. A few commenters raised concerns about the validity of the GLOBE Model's comparison group since manufacturers set list prices nationally. Commenters stated that if manufacturers raise list prices nationally, it could invalidate the comparison group. Another commenter stated CMS has ''not provided affirmative evidence that international prices for Part B drugs are lower'' than U.S. ASP-based methodology and as such, is a ''flawed premise'' for launching this model.

*Response:* CMS thanks commenters for raising these concerns. CMS disagrees with commenters' characterizations of the GLOBE Model as lacking a credible testing hypothesis, adequate evaluation framework, or meaningful control group. The GLOBE Model satisfies the statutory requirements of section 1115A of the Act and is designed to generate reliable evidence to assess the GLOBE Model's effects.

CMS disagrees that no meaningful control group exists against which to measure the model's effects. The model's geographic scope—covering approximately 25 percent of OM Part B beneficiaries and spending—is a deliberate design feature that enables a randomized control trial which compares the cost and quality outcomes associated with those beneficiaries in the control regions to those outside of it.

CMS recognizes that the GLOBE Model may have spillover effects that result in manufacturers choosing to raise list prices nationally. A main research question would assess how manufacturers respond to the model. If CMS determines that manufacturers modify list prices for GLOBE Model drugs among the randomized comparison group, CMS would consider deploying alternative evaluation strategies to assess the model's impact on list prices. For example, CMS could construct an alternative comparison group comprised of drugs that are not eligible for the GLOBE Model based on drug classification or spending threshold. Alternative comparison groups would enable CMS to create a credible comparison group in the face of potential spillover effects. CMS has experience accounting for potential spillover effects of a model by using multiple comparison groups. For example, in the Comprehensive Primary Care Plus (CPC+) Model, non-model practices in the same markets with substantial CPC+ practices were likely exposed to similar regional care transformation pressures, payer initiatives and learning collaboratives. To address this, the CPC+ Model evaluation used a within-market comparison group of non-CPC+ practices in the same regions, since these practices shared similar regional characteristics. Another comparison group of non-CPC+ practices outside of CPC+ regions was used in sensitivity analyses to test whether within-market spillover was attenuating estimated market effects.

CMS disagrees that the model lacks a credible testing hypothesis or is based on a flawed premise. The model tests a specific, meaningful hypothesis that calculating Medicare Part B drug inflation rebates using benchmarks that are informed by international drug prices will reduce Medicare program spending while preserving or enhancing the quality of care. As stated in the background section of the GLOBE Model proposed rule (90 FR 60250 through 60251) and this final rule, we believe prices for Part B rebatable drugs in reference countries are, on average, generally lower than what Medicare pays. The purpose of the GLOBE Model is to test if this hypothesis will reduce Medicare program spending while preserving or enhancing the quality of care. The model does not mandate how participants respond to the model in ways that ensure net Medicare savings are predetermined.

As proposed (90 FR 60310), the model evaluation will study key evaluation questions such as how manufacturers respond to the model and how those responses affect Medicare expenditures

and beneficiary quality of care—precisely the kind of behavioral uncertainty that characterizes a genuine test. This approach is consistent with prior CMS Innovation Center models, such as the CJR Model, which established mandatory savings targets but predicated the test on observing and learning from how participants responded to those targets.

Further, the magnitude of any expenditure reduction, the distribution of savings across drug categories, the behavioral responses of manufacturers and providers, and the effects on beneficiary access and health outcomes all remain uncertain. These uncertainties constitute substantive research questions that the GLOBE Model evaluation is specifically designed to address.

*Comment:* Several commenters raised concerns about the confounding effects of the GENEROUS Model, voluntary MFN commitments with manufacturers, the Negotiation Program, the Medicare Part B Drug Inflation Rebate Program, and broader Administration initiatives. Commenters were concerned that multiple co-occurring initiatives make it difficult to isolate and causally attribute any observed changes in Medicare program expenditures or beneficiary quality of care to the GLOBE Model.

*Response:* CMS thanks the commenters for their concerns regarding the potential confounding effects of multiple co-occurring initiatives. CMS acknowledges that the GLOBE Model will be implemented concurrently with other programs and within a changing environment. CMS also recognizes it is important for the evaluation to isolate the effects of the GLOBE Model to assess its impact on Medicare spending and quality of care, within the context of co-occurring initiatives. To enable the isolation of GLOBE Model's effects on the model's primary outcomes related to costs and quality, CMS will use randomized geographic regions to compare the outcomes in the intervention group to those of the comparison group. Many co-occurring initiatives described by commenters would affect both the GLOBE Model intervention and comparison groups such that CMS's evaluation would be able to remove the effect of those initiatives. In the event that there is concern about serious confounding associated with interactions between multiple CMS Innovation Center models, CMS will develop an overlap policy designed to mitigate risks and preserve the test and evaluation for each model. CMS will address the specifics of the GLOBE Model evaluation in the model evaluation documentation.

The CMS Innovation Center implements models in a changing environment, and model evaluations deploy robust techniques to control the effects of overlaps with co-occurring initiatives and spillovers between the model and the environment within the model is tested. The CMS Innovation Center has extensive experience evaluating models in the presence of confounding factors. For example, evaluations of CMS Innovation Center models such as Pioneer ACO Model, Comprehensive Primary Care Model, CPC+ Model, BPCI Model, BPCI Advanced Model, and OCM have provided examples of how to account for overlapping participation with other center models or the Shared Savings Program to isolate the causal effects of their respective model. We note that CMS has addressed these challenges in the evaluation of state-level models, such as the Maryland Total Costs of Care Model which faces the methodological challenge of isolating the model-specific effects in a state whose outcomes were shaped by the predecessor All-Payer Model. CMS's portfolio of evaluations of CMS Innovation Center models—including models implemented during periods of significant concurrent policy changes—demonstrate the agency's capacity to apply rigorous methodological controls to address potential confounding factors arising from co-occurring initiatives. CMS will apply the same level of methodological rigor to the evaluation of the GLOBE Model, including through the use of appropriate comparison groups, statistical controls, and sensitivity analyses designed to isolate the model's effects from those of concurrent changes. This evaluation approach is consistent with CMS's statutory obligation under section 1115A(b)(4) of the Act to evaluate each tested model's effects on program expenditures and quality of care, and to use that evidence to inform decisions regarding the model's continuation, expansion, or termination.

*Comment:* Several commenters asserted that CMS has failed to articulate a testable hypothesis regarding the GLOBE Model's impact on quality of care. Commenters stated that the proposal for the GLOBE Model evaluation does not satisfy the statutory requirements that CMS Innovation Center models must evaluate quality of care, including patient-level outcomes, patient satisfaction, and other patient-centeredness criteria.

Specifically, commenters stated that while CMS proposes to monitor domains such as out-of-pocket costs, utilization, and access to GLOBE Model drugs, CMS did not specify what hypothesis these quality measures are designed to test, and that, without a clear hypothesis—including whether the model's impact on quality would be neutral, positive, or negative, CMS cannot credibly claim it is ''testing'' a model under the belief it will preserve or enhance quality of care, as required by statute. Some of the commenters stated that the absence of a quality hypothesis is not merely a procedural deficiency; it is a fundamental flaw that undermines the legal basis for the model under section 1115A of the Act. Commenters urge CMS to either articulate a clear, testable quality hypothesis or withdraw the model.

*Response:* CMS thanks commenters for their thoughtful feedback. CMS disagrees with commenters that it has failed to articulate a testable hypothesis for the GLOBE Model. CMS recognizes the importance of a testable hypothesis for CMS Innovation Center models and affirms that both cost and quality are co-equal objectives under section 1115A of the Act. In section II.P. of the GLOBE Model proposed rule (90 FR 60309 through 60310), CMS described the GLOBE Model evaluation design, evaluation methods, data collection methods, key evaluation research questions, evaluation period, and anticipated reports. CMS stated that the evaluation would employ a design to provide evidence that ''the proposed intervention would reduce the cost of these [GLOBE Model] drugs and would maintain or enhance the quality of care for Medicare beneficiaries.'' CMS considers this statement a clear and explicit articulation of the model's testable hypothesis.

Further, as described in section II.J. of this final rule, CMS will assess measurable patient-level impacts on quality, including, but not limited to, access to Part B drugs, treatment continuity, utilization patterns, and downstream healthcare utilization, using claims-based measures and other data sources. These quality measures directly correspond to the quality domains identified in the GLOBE Model evaluation hypothesis.

The evaluation will be designed to enable CMS to identify the causal effects of the GLOBE Model on quality by comparing outcomes for eligible beneficiaries randomly selected into model—as discussed in section II.D. of this final rule—to those of beneficiaries not selected as part of the model test. This randomized design strengthens the evidentiary value of the evaluation and supports CMS's ability to draw credible conclusions about the model's impact on quality of care.

For these reasons, CMS disagrees that the GLOBE Model lacks a testable quality hypothesis or that the evaluation framework fails to satisfy the statutory requirements of section 1115A of the Act, and declines to withdraw the model on this basis.

*Comment:* We received many comments that provided suggestions for the model evaluation, including aspects to address in the GLOBE Model's evaluation framework. Commenters emphasized the need for clearly defined access and quality objectives with aligned evaluation metrics. Commenters suggested that included measures pertain to quality, costs, innovation, access, market impacts, and effects of the model. Commenters recommended quality measures that focus on patient access, drug utilization, care delivery patterns, site-of-care shifts, provider participation, prescriber changes, frequency of drug administration, care continuity, downstream medical costs, utilization patterns, and patient experience. Commenters also highlighted the importance of evaluating effects on patients and the cost savings they might achieve, suggesting that CMS include patient-reported outcome measures and implement a beneficiary survey to better understand how the model affects patient access to care and overall quality of care. A commenter emphasized that patient-centered affordability should be evaluated using a total cost of care framework that considers medical and drug spending together, alongside patient access and outcomes.

A few commenters recommended that the evaluation assess impacts on specific sub-groups, including oncology patients, rare disease patients, dual eligible beneficiaries, and Medicaid beneficiaries. Commenters also recommended that CMS establish a comprehensive evaluation framework that would track effects on innovation, research and development activity and market access outcomes. Several commenters recommended that the evaluation explicitly assess spillover effects beyond the model's direct scope, including impacts on MA (premiums, benefit design, coverage flexibility), Medicaid, and the broader innovation ecosystem. A few commenters recommended that the evaluation framework incorporate monitoring of market and behavioral responses—including manufacturer contracting and rebate strategy adjustments—and assess how those responses affect care delivery, provider participation, and therapy availability. A commenter also recommended examining how participant responses may have subsequent market impacts in countries that use reference pricing.

A commenter recommended an evaluation of the role of pharmacists, proposing specific quality measures in the GLOBE Model that recognized pharmacists as key stakeholders in drug access and administration. A commenter recommended evaluating pharmacy reimbursement for Part B drugs. A commenter stated that CMS should allow stakeholders an opportunity to weigh in on the specific evaluation outcome measures that will be included in the evaluation.

*Response:* CMS thanks commenters for these suggestions. In accordance with section 1115A(b)(4)(A)(i) of the Act, the GLOBE Model ''evaluation shall include an analysis of the quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness criteria determined appropriate by the Secretary.'' As described in section II.J. of this final rule, CMS plans to monitor quality measures related to: drug utilization; out-of-pocket costs; frequency and regularity of administration of Part B drugs; changes in site of service; changes in prescriber of the Part B drugs; and downstream healthcare utilization. These measures will also guide the evaluation of the model's impact on quality of care.

CMS believes that the main research questions are broad enough to address the evaluation of the suggested outcomes and sub-group analyses. CMS will evaluate the model's impact on: cost, including the total cost of care; market impact; quality, including claims-based quality measures; patient experience; and unintended consequences. The evaluation of unintended consequences will include an assessment of spillover effects on non-targeted populations in the U.S., such as the MA population. CMS will also examine model's effects on key sub-groups—including beneficiaries with cancer—and will consider evaluating other meaningful sub-groups, such as dual eligible beneficiaries or patient groups with rare diseases.

As stated in section II.J. of this final rule, CMS will consider the use of surveys to assess patient experience. The evaluation will also examine, through primary data collection activities, how participants respond to the model, including if they change their pricing strategy, their approach to research and development, and availability of drugs in reference priced countries.

CMS declines to commit to measuring patient-reported outcomes as part of the GLOBE Model evaluation. Patient-reported outcomes provide an important measure of patient's response to clinical treatments. However, the data is not widely available for both comparison and intervention populations to be usable by CMS's evaluation of the GLOBE Model. Instead, CMS intends to evaluate patient experience, by relying on existing patient experience survey information that would be available for both comparison and intervention beneficiaries.

CMS notes that some of the topics raised by commenters fall outside the scope of the GLOBE Model. For example, CMS does not intend to assess the role of pharmacists in the model as a primary outcome of the model, nor does it intend to evaluate the model's impacts on pharmacy reimbursement or on markets in other countries.

CMS declines to post a complete list of evaluation measures for stakeholder input beyond what has been described in sections II.J. and II.P. of the GLOBE Model proposed rule and this final rule. CMS will, however, take the commenters' suggestions into consideration as it develops and implements the evaluation framework.

*Comment:* A commenter requested that CMS clarify how findings from the continuous monitoring and evaluation, including the evaluation report, would be used to inform the model adjustments, particularly if the evaluation finds meaningfully negative impacts on access, treatment availability, or quality of care.

*Response:* CMS intends to use the findings from our monitoring data as well as those from our annual public evaluation reports to make recommendations to the Secretary regarding any adjustments over the course of the model's implementation. For example, based on monitoring and evaluation findings, CMS may recommend to the Secretary that CMS seek to modify the GLOBE Model through notice and comment rulemaking, as needed.

CMS declines to specify in this final rule what specific model adjustments would be made in response to monitoring and evaluation findings. CMS retains the authority and commitment to act through available mechanisms to address any meaningful negative impacts on beneficiary access or quality in a timely manner.

*Final Decision:* CMS has carefully considered all public comments received regarding the GLOBE Model evaluation framework. Because the evaluation approach is not established through regulatory text, it is not subject to finalization in this final rule. CMS appreciates the thoughtful input

provided by commenters and will take those recommendations into consideration as it develops and refines the evaluation framework. The evaluation methodology will be communicated through sub-regulatory guidance and model documentation, as appropriate.

2. Data Collection Methods

As we stated in the GLOBE Model proposed rule (90 FR 60309), 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 Medicare Part B drugs, we would analyze data on drug utilization patterns, pricing, and expenditures in OM. 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.

Because the evaluation approach is not established through regulatory text, it is therefore not subject to finalization in this final rule. Comments received on the proposed data collection method are summarized under II.P.1. of the final rule.

3. Key Evaluation Research Questions

As stated in the GLOBE Model proposed rule (90 FR 60310), 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 (§ 513.410 and § 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, what amount and how were they achieved?
- 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?
- 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?
- 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 while still being a time-limited test. 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.

Comments on our proposal are summarized and responded in section II.P.1. of this final rule.

4. Evaluation Period and Anticipated Reports

As proposed in the GLOBE Model proposed rule, 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. We stated the evaluation period would encompass the entire test period, with a baseline period of up to 3 years prior. We also stated that 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. Further, we stated that we plan to evaluate the GLOBE Model on a continuous basis and release public evaluation reports annually. We note that, in response to comments received, as discussed in section II.A. of this final rule, we are finalizing that the model start date will be January 1, 2027, with a 5-year performance period and 7-year payment period beginning on April 1, 2027.

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 GLOBE Model test period would be important for ultimately synthesizing and validating results.

We also stated that, 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.

The following is a summary of the comments received and our responses.

*Comment:* A commenter asked CMS to specify the outcome measures, analytic methods, or level of disaggregation that will be reported publicly and annually.

*Response:* CMS acknowledges the commenters' concern and provides the following additional specificity regarding the evaluation framework. CMS reaffirms that the GLOBE Model evaluation will assess two co-equal statutory objectives: (1) whether the model reduces Medicare program expenditures, and (2) whether it preserves or enhances quality of care for beneficiaries. These objectives derive directly from section 1115A of the Act and constitute the primary evaluation endpoints. As such, CMS declines to adopt this recommendation. CMS is committed to producing reports that include an analysis of the quality of care furnished under the model and the changes in spending by reason of the model, as required by statute. CMS does not specify in advance for the public which outcome measures, methods and level of disaggregation will be in each annual report. This enables CMS to comply with statute while preserving flexibility to release reports based on the availability and appropriateness of data and methods.

*Final Decision:* CMS has carefully considered all public comments received regarding the GLOBE Model evaluation framework. Because the evaluation approach is not established through regulatory text, it is not subject to finalization in this final rule. CMS appreciates the thoughtful input provided by commenters and will take those recommendations into consideration as it develops and implements the evaluation framework. The evaluation methodology will be communicated through sub-regulatory

guidance and model documentation, as appropriate.

## III. Collection of Information Requirements

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and CHIP 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 final rule need not be reviewed by the Office of Management and Budget (OMB).

*Final Decision:* CMS received no comments on the collection of information requirements and is therefore finalizing them as proposed.

## IV. Final Regulatory Impact Analysis

### *A. Statement of Need*

As discussed in section I.B. of the Globe Model proposed rule (90 FR 60246) and this final rule, studies have revealed that U.S. prices for prescription drugs are 422 percent higher than other countries.[207] Further, CMS data and other studies show that OM Part B drug spending [208] has grown by 85.8 percent ($18.7 billion) [209] from 2014 to 2021 with the standard monthly Medicare Part B premium for beneficiaries increasing by 41.5 percent ($104.90 [210] to $148.50 [211]), and that the pace of growth has varied across disease categories. For example, according to a recent report,[212] drugs classified in immunology, oncology, rheumatology, endocrinology, and ophthalmology are among the top 20 therapeutic classes based on spending or prescriptions volume in the U.S., and drugs in these categories have shown notable growth between 2023 and 2024. This trend is also observed in OM Part B rebatable drugs, where these five therapeutic classes represent at least $42 billion (60 percent) in OM Part B allowed charges in 2024.[213] [214] Under the IRA, some Medicare beneficiaries have seen savings for some drugs,[215] but recent surveys revealed that Medicare beneficiaries continue to experience challenges in access to medication due to cost.[216] [217] [218] Further, according to a report,[219] Medicare spending doubled between 2010 and 2023, increasing from $0.5 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.[220] [221] CMS analysis of claims data shows that total OM Part B drug spending in 2025 was $81.90 billion, with more than 60 percent ($51.71 billion) of this spend being 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.[222] Further, data reveal that OM program spending is highly concentrated among a small number of beneficiaries—the costliest 25 percent of beneficiaries accounted for 85 percent of Medicare spending.[223] The associated costs of medication non-adherence can be significant (up to $290 billion per year).[224] Similarly, research has also found an increased risk of mortality among patients with certain types of cancer who filed for bankruptcy, compared with those who did not file.[225]

This rulemaking is necessary to implement and test an alternative approach to calculating Medicare Part B drug inflation rebate amounts 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 final rule, the model test will include more than one method for identifying a benchmark amount for the alternative rebate amount calculation and the model evaluation will assess the impacts of using different sources for international drug pricing information. CMS expects that the innovative alternative rebate amount calculation will 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 final rule, the GLOBE Model will establish an approximate 7-year GLOBE model test (January 1, 2027 to March 31, 2034) applicable to a subset

[207] Assistant Secretary for Planning and Evaluation. Comparing Prescription Drugs in the U.S. and Other Countries: Prices and Availability. Contractor Project Report, February 2024. Available at: *https://aspe.hhs.gov/sites/default/files/documents/f96a072f8f82f3ba546abd52bfcaeb57/aspe-cover-idr-pricing-availability.pdf.*

[208] Measured by drug allowed charges.

[209] Office of the Assistant Secretary for Planning and Evaluation. Medicare Part B Drugs: Trends in Spending and Utilization, 2008–2021, June 9, 2023. Available at: *https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf.*

[210] Centers for Medicare & Medicaid Services. CMS announces major savings for Medicare beneficiaries. Available at: *https://www.cms.gov/newsroom/press-releases/cms-announces-major-savings-medicare-beneficiaries.*

[211] Centers for Medicare & Medicaid Services. 2021 Medicare Parts A & B Premiums and Deductibles. Available at: *https://www.cms.gov/newsroom/fact-sheets/2021-medicare-parts-b-premiums-and-deductibles.*

[212] HDA Research Foundation. HDA 96th Edition HDA Factbook. The Facts, Figures, and Trends in Healthcare (2025–2026). Available at: *https://www.hda.org/publications/.*

[213] Dickson, S.R., and James, K.E. *Medicare Part B Spending on Macular Degeneration Treatments Associated with Manufacturer Payments to Ophthalmologists.* JAMA Health Forum, 2023, 4 (9): e232951. doi:10.1001/jamahealthforum.2023.2951.

[214] 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 Epidemio, 2024, 31(5): 468–477. *https://doi.org/10.1080/09286586.2024.2310854.*

[215] Centers for Medicare & Medicaid Services. 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, 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.*

[216] 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.*

[217] 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/.*

[218] 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.

[219] 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.*

[220] 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.

[221] 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.*

[222] 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.*

[223] 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.*

[224] 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.

[225] Ramsey, Scott D., et al. *Financial Insolvency as a Risk Factor for Early Mortality Among Patients With Cancer.* Journal of Clinical Oncology, 2016, 34(9): 980–986. doi: 10.1200/JCO.2015.64.6620.

of separately payable Medicare Part B rebatable drugs that are furnished in the outpatient setting to cohort beneficiaries and paid under the GLOBE Model. As described in section II.E. of this final rule, and subject to certain exclusions as discussed in section II.B. of this final rule, participants will be manufacturers of GLOBE Model drugs. GLOBE Model participants will 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 final rule. *Final Decision:* As described in this section IV. of this final rule, we present our estimate of the impacts of the GLOBE Model as finalized in this final rule, considering more recent claims data and current evidence on the impacts of financial toxicity on morbidity. Section IV.B. of this final rule compares the GLOBE Model proposed rule estimated impact savings ($2.3 billion annualized) to this final rule estimated impact savings ($80 million annualized). The annualized amount in this final rule is lower than the GLOBE Model proposed rule because of the finalized policies and other considerations detailed in section IV.B. of this final rule. The details of these policy changes may be found in the narrative surrounding the Accounting Table (Table 10) below as well as the estimated impacts, particularly Table 13, of section IV.D. of this final rule.

*B. Overall Impact*

We have examined the impacts of this final rule as required by Executive Order 12866, ''Regulatory Planning and Review''; Executive Order 13132, ''Federalism''; Executive Order 13563, ''Improving Regulation and Regulatory Review''; Executive Order 14192, ''Unleashing Prosperity Through Deregulation''; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Act (impact on small rural hospitals); section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4); and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, as well as 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.

In our GLOBE Model proposed rule, we prepared a regulatory impact analysis that presented the estimated costs and benefits associated with the proposed policies that would have resulted in an overall savings of $8.4 billion in OM Part B net spending during the model before accounting for changes in the Medicare Part B premium. We also estimated savings for the MA program of $7.5 billion before accounting for changes in the Medicare Part B premium 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 the 2026 to 2032 period, we estimated that the GLOBE Model, as proposed in the GLOBE Model proposed rule, would generate overall cost savings of approximately $2.3 billion in Medicare Part B net spending at both the 3 and 7 percent discount rates.

In response to comments received, we are finalizing the following policy changes in the final rule that are reflected in the accounting statement in Table 10 and other corresponding tables in this regulatory impact analysis:

- Exclusion criteria finalized in § 513.130(c) that excludes (1) a Part B rebatable drug that is designated as a drug for one or more rare diseases or conditions under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) and for which the only approved indication (or indications) is for one or more such rare disease or conditions; (2) a Part B rebatable drug that is a product listed on the FDA Approved Cellular and Gene Therapy Products website; and (3) a Part B rebatable drug that is a plasma-derived product as set forth in 42 CFR 427.400.
- Data used for calculation of the GDP (PPP) adjuster is the real GDP per capita based on purchasing power parity available in the World bank World Development Indicators, if available, otherwise the International Monetary Fund finalized in § 513.430(b).
- Shifting the model start date from October 2026 to January 2027 finalized in § 513.1(c).

Additionally, the accounting statement (Table 10) and the estimated impacts (Tables 13 through 15) reflects the exclusion of drugs from manufacturers that, at the time of this analysis, we assumed have signed agreements with CMS to participate in the GENEROUS Model that waives the requirements for mandatory participation of manufacturers of GLOBE Model drugs under § 513.100 as further discussed in section II.M. of this final rule.

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 of the finalized policies in this final rule, and as shown in Table 13, the total federal savings to Medicare including Original Medicare and Medicare Advantage and including savings from benefits and premiums exceeds $100 million in 2028 through 2030. Therefore, the Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant according to section 3(f)(1) of E.O. 12866.

*C. Accounting Statement and Table*

As required by OMB Circular A–4, (available at *https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf*) in Table 10, we have prepared an accounting statement showing the transfers and costs associated with the provisions of this final rule reflecting the 5-year performance period of the GLOBE Model from 2027 through 2032 and the approximate 7-year payment period from 2027 through 2034 as presented in Tables 13 and 15. Table 10 was based on the analysis discussed in section IV.D. of this final rule (Estimated Impacts). The costs for manufacturers to prepare submissions associated with voluntary net price reporting, discussed in section IV.D.3. of this final rule, was not directly included since after rounding, these costs are marginal. Similarly, the savings to beneficiaries presented in Table 14 is not included in these tables which estimate impact on the Federal Supplementary Medical Insurance Trust Fund. We estimate that the GLOBE Model will result in an overall savings of $298 million in OM Part B net spending during the model before accounting for changes in the Medicare Part B premium. In this estimate, we assume manufacturer behavior changes

and beneficiary utilization changes. We also estimate savings for the MA program of $288 million before accounting for changes in the Medicare Part B premium due to the way CMS calculates MA rates based on OM claims which would include claims paid under the GLOBE Model beginning with rate setting for 2028, and savings for the Medicaid program of $39 million, of which roughly $23 million will be Federal savings in both premiums and cost-sharing and roughly $15 million would be State savings in both premiums and cost sharing (totals may differ due to rounding). When annualized over 2027 to 2032, we estimate that the GLOBE Model will result in an overall cost savings in Medicare Part B net spending of approximately $80 million at either the 3 percent or 7 percent rates of discount.

**TABLE 10: ACCOUNTING STATEMENT: ESTIMATED TRANSFERS AND COSTS FOR CONTRACT YEARS 2027-2032**

| Category | 3% Discount Rate | 7% Discount Rate |
|---|---|---|
| **TRANSFERS ($millions)** | | |
| Annualized monetized transfers, in 2026 dollars, from Manufacturers to the Medicare and Medicaid Trust Funds ($millions) | 80.0 | 80.3 |

*D. Estimated Impacts*

In this section we discuss the estimated overall impact of the GLOBE Model, as finalized in this final rule, on the Medicare and Medicaid programs. This estimate uses the Medicare Part B baseline that was available to CMS at the time CMS developed the GLOBE Model proposed rule. We also show the paperwork (information) burden.

1. Estimated Impacts to Medicare

The GLOBE Model tests an alternative to the existing 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 GLOBE 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 ''incremental per unit GLOBE Model rebate amount'' as set forth in § 513.510). The rebates will exclude units that are currently exempt from the existing 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, cell and gene therapy status, orphan drug status, human plasma derivation, ineligibility for the Medicare Part B Drug Inflation Rebate Program, or competitive status within the market. These estimates assume that manufacturers participating in the GENEROUS Model as of August 17, 2026 will not participate in the GLOBE Model. Changes in the mix of manufacturers participating in GENEROUS would affect these estimates. The model does not change the add-on payment, which will remain at 6 percent of ASP for most Medicare Part B drugs. In developing our estimate of the potential Medicare savings of the model, we started with 2024 Medicare Part B claims data for GLOBE Model drugs. The CMS Office of the Actuary 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 GLOBE Model drugs would have comprised approximately 3 percent of non-dual eligible, non-340B OM Part B drug spending for 2024. This reflects the exclusion of drugs from manufacturers that, at the time of this analysis, we assumed have signed agreements with CMS to participate in the GENEROUS Model, offering discounts for drugs provided to Medicaid enrollees.

The model excludes drugs that are paid based on an MFP that has been negotiated through the Negotiation Program; as drugs are selected for the Negotiation Program and have a payment limit that is based on MFP, we expect the proportion of drugs targeted by the GLOBE 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 Medicare Drug Rebate and Negotiations Group within CMS. By the end of the model window, we estimate that GLOBE Model drugs comprise approximately 2 percent of non-dual eligible, non-340B OM Part B drug spending for 2024, which reflects the increased amount of spending expected to be subject to the Negotiation Program over time. The GLOBE Model geographic areas will be selected to comprise 25 percent of OM Part B beneficiaries further reducing the drug spending targeted by the model to under 1 percent. The model also limits itself to the following USP DC categories: Antigout Agents, Antineoplastics, Blood Products and Modifiers, Central Nervous System Agents, Immunological Agents, Metabolic Bone Disease Agents, and Ophthalmic Agents. Additionally, the GLOBE Model will not include generics and biosimilar biological products or sole-source drugs or sole-source biological products below a minimum spend threshold ($100 million) over a 12-month period (as further specified in § 513.130(b)(3) and § 513.130(d)), and excludes the following as specified in § 513.130(c): (1) a Part B rebatable drug that is designated as a drug for one or more rare diseases or conditions under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) and for which the only approved indication (or indications) is for one or more such rare disease or conditions; (2) a Part B rebatable drug that is listed on the FDA Approved Cellular and Gene Therapy Products website; and (3) a Part B rebatable drug that is a plasma-derived product as set forth in 42 CFR 427.400.

Additionally, the numeric estimates (as displayed in Tables 11 and 12) in this analysis reflect calculations 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 by the CMS Innovation Center, after adjustments for the real GDP per capita based on purchasing power parity available in the World Bank World Development Indicators finalized in § 513.430(b). These updates are reflected in our final estimate. On average, these international

benchmarks [226] were 68 percent below the 2024 ASPs for potential 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.

Under the GLOBE Model, manufacturers would be eligible to report international net pricing data, and if on average those prices are higher than the per unit Method I GLOBE Model benchmark, the per unit Method II GLOBE Model benchmark would become the applicable benchmark for the GLOBE Model rebate amount calculation. We therefore anticipate that manufacturers will report their international net price data to CMS in cases where that data shows higher prices than the per unit Method I GLOBE Model benchmark. In our analysis, 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 60 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 per capita and Purchasing Power Parity) for GLOBE Model drugs (see Table 11). Table 11 shows an example of how this response was measured for the pricing of a hypothetical drug.

**TABLE 11: ESTIMATES USED TO INFORM THE ANTICIPATED MANUFACTURER REPORTING ASSUMPTION**

| HCPCS Code | Method I Benchmark | GDP and PPP Adjusted Average of all Reference Countries |
|---|---|---|
| JYYYY | $100 | $160 |

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 2027 price data and reaching 60 percent in the 2030 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 utilization at the start of the performance period 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**

| | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 |
|---|---|---|---|---|---|---|
| Phase-in of Method II Benchmark Adjustment | -10% | -20% | -30% | -40% | -50% | -60% |

For drugs with significant Medicare Part B and Part D utilization we also anticipate that there would be behavioral changes from manufacturers and providers to increase the use of white-bagging, where drugs are reimbursed under the Medicare 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 Medicare Part B drug spending for GLOBE Model drugs to comparable NDCs in the Medicare Part D program to identify drugs that have a high potential to be moved to the Medicare Part D benefit. We found that anticipated GLOBE Model drugs did not have significant utilization in Medicare Part D.

We also included an induced utilization effect reflecting the potential for increased use of drugs among OM beneficiaries in model regions in response to lower cost sharing required for GLOBE Model drugs. As many OM beneficiaries are either dual eligible status or have supplemental prescription drug coverage, we estimate a relatively small increase in total gross Medicare Part B drug spending on average in the first model year for beneficiaries in model geographic areas (less than 0.1 percent). This effect decays over time reflecting the lower expected total GLOBE Model rebate amounts over the life of the model.

After accounting for the effects, we calculated the expected OM 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 will 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 Medicare Part B premiums. Table 13 represents the final estimated benefit savings and the proportion reflected in beneficiary Medicare Part B premiums versus Federal government savings on a fiscal year cash basis. Our estimate assumes initial rebate payments will be complete and future reconciliation payments will be zero which implies no impact for 2033 and subsequent years.

[226] At the time of this analysis and using the most current data available to CMS, the RIA includes international drug data from the same data source at the highest level of the hierarchy, namely data with drug-specific sales and corresponding volume as described in § 513.310(c)(2)(i). Specifically, the data source used included 17 of the 19 reference countries in § 513.310(b) that may be used in the GLOBE Model to identify a per unit GLOBE Model benchmark.

**TABLE 13: ESTIMATED IMPACTS TO MEDICARE**

| Medicare Impacts ($millions) | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | Total |
|---|---|---|---|---|---|---|---|
| OM Benefit Savings | 0 | 58 | 86 | 90 | 41 | 22 | 298 |
| Medicare Advantage Payment Savings | 0 | 90 | 105 | 52 | 29 | 12 | 288 |
| Premium Offset | 0 | 37 | 48 | 35 | 18 | 9 | 147 |
| Total Federal Savings | 0 | 112 | 143 | 106 | 53 | 26 | 440 |

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 will 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 will result in beneficiary savings by reducing the Medicare Part B premium for all beneficiaries. Additionally, OM beneficiaries would see a reduced coinsurance on model drugs via the existing mechanism for adjusting the Medicare Part B coinsurance for drugs with an inflation rebate. MA plans must offer comparable cost sharing to OM beneficiaries and so MA beneficiaries would see benefit savings on their Medicare Part A and Part B benefits; however, these savings would be offset by reductions in supplemental benefits due to the reduction in MA benchmarks described in the previous paragraph. Table 14 shows impacts to beneficiaries on a calendar year basis. Note that beneficiary impacts conclude on March 31, 2032 as that represents the end of the GLOBE Model performance period.

**TABLE 14: ESTIMATED IMPACTS TO MEDICARE BENEFICIARIES**

| Beneficiary Impacts ($ millions) | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | Total |
|---|---|---|---|---|---|---|---|
| Cost Sharing Savings for OM Beneficiaries | 12 | 15 | 14 | 4 | 3 | 1 | 50 |
| Supplemental Benefit Savings for MA Beneficiaries | 0 | -9 | -9 | -3 | -2 | -1 | -23 |
| Premium Savings for OM Beneficiaries | 8 | 22 | 20 | 6 | 5 | 1 | 61 |
| Premium Savings for MA Beneficiaries | 11 | 31 | 30 | 9 | 8 | 2 | 90 |
| Total Out-of-Pocket Savings | 31 | 59 | 55 | 16 | 13 | 3 | 177 |

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 properly quantify the level of impact they would have on GLOBE Model rebates:

- We expect that manufacturers with drugs selected for the Negotiation Program would be less inclined to give discounts below the statutorily specified ceiling. We expect this effect to be small based on the ceilings specified by the IRA for Medicare Part B drugs.
- As 340B units are excluded from the calculation of the total 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. Additionally, the mix of 340B and non-340B utilization may change organically over time, yielding changes to the number of excluded units from the GLOBE Model.
- 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 spending is for a given drug outside of Medicare. We welcomed comments on the probability and magnitude of this response but did not receive any.
- 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 Negotiation Program if they see it being more favorable for their reimbursement. Given the criteria for being selected for the Negotiation Program, we believe it would be difficult for manufacturers to achieve this. Additionally, the model does not impact reimbursement for all OM 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 will be higher than OM. It is not clear how much more favorable MA reimbursement would be for manufacturers and so we have not included this in our estimates.

The following is a summary of the comments received and our responses.

*Comment:* A few commenters expressed concerns about the underlying assumptions of the initial regulatory impact analysis (RIA) and how the estimated benefits or costs were determined. Commenters also stated that the RIAs in GUARD and GLOBE appear to conflict in their assumptions leading to different potential impacts and outcomes for each model, and that CMS did not provide sufficient impact analysis to support demonstrating that the international pricing benchmark will reliably result in lower total costs net of manufacturer price concessions. Commenter shared concerns that the cost-saving projections depend heavily on the assumption that tying rebates to an international benchmark will lower net Medicare Part B drug spending.

*Response:* We thank the commenters for sharing their feedback on the initial RIA. We disagree that CMS did not account for major impacts of the GLOBE Model. Section IV.D. of the GLOBE

Model proposed rule (90 FR 60312 through 60318) explicitly identified broader potential financial consequences including price increases, white-bagging, increased OM utilization, and impact on MA and OM cost-sharing and premiums. Further, the GLOBE and GUARD Models are two separate CMS Innovation Center models that address different markets: the GLOBE Model addresses certain separately payable Medicare Part B physician administered drugs that are furnished to OM beneficiaries, whereas the GUARD Model addresses Part D drugs. The scope of drugs, beneficiaries, and participants therefore varies between the GLOBE Model and the GUARD Model as do the policies in each model. As such, we would not expect similar effects on the market or market participants, or the same set of assumptions to apply. Finally, we believe that the section IV.D. of the GLOBE Model proposed rule demonstrated that the international pricing benchmark would reliably result in lower total costs as illustrated in the modeling of the per unit Method I and per unit Method II GLOBE Model benchmarks for the illustrated 2024 GLOBE drug list in Table 4, where 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 final 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)). This ensures net prices are equal to or lower than they would be for these drugs absent the model.

*Comment:* A few commenters urged CMS to more thoroughly assess the unintended consequences and overall costs of the GLOBE Model to Medicare, particularly whether it will truly reduce drug prices without harming beneficiary access.

*Response:* We thank the commenters for their input regarding potential unintended consequences and overall impacts of the GLOBE Model on Medicare. In section IV.D. of the GLOBE Model proposed rule (90 FR 60312 through 60318) and this final rule, CMS describes the potential direct and indirect impact of the GLOBE Model and how it may interact with other federal programs. Overall, we expect the GLOBE Model will lower overall net OM expenditures and out-of-pocket costs for patients through reduced drug costs. In section IV.A. of the GLOBE Model proposed rule (90 FR 60310 through 60311) and this final rule, CMS presents studies that show that high drug costs limit access to care and treatment. Consequently, we expect that by lowering drug costs and out-of-pocket costs, patients' well-being, fiscal security, and overall health will improve.

In section IV.D. of the GLOBE Model proposed rule (90 FR 60312 through 60318) and this final rule, CMS acknowledges uncertainty associated in estimating the impacts of the GLOBE Model, including manufacturer and other stakeholder behavior and pricing dynamics. Regulatory analysis requires forecasts about the future, and what the future holds is not known for certain. CMS estimates reflect the full range of how the benefits and costs of the rule might vary based on the information available at this time.

*Comment:* A commenter urges CMS to re-examine its projections on potential GLOBE Model savings and model the potential sets of manufacturer behavioral responses rather than assume static pricing trajectories will yield Medicare program savings.

*Response:* We thank the commenter for their input. We disagree that the estimated savings are static. In section IV.D. of the GLOBE Model proposed rule (90 FR 60312 through 60313) and this final rule, CMS describes its analysis which incorporates adjustments to account for certain behavioral responses that vary across time, and which focuses on the areas that are most likely to be affected by the GLOBE Model. For this reason, we disagree with the commenter's suggestion to re-examine its projections on the estimated GLOBE Model savings.

*Comment:* A few commenters suggested that the initial RIA did not account for administrative costs, including costs to providers to verify beneficiary cost-sharing, or costs to manufacturers to acquire proprietary data.

*Response:* In the GLOBE Model proposed rule (90 FR 60319) and this final rule, CMS acknowledges that administrative costs such as those involved with reading and understanding the rule, are not included because they are expected to be marginal for several reasons. Table 17 shows the aggregate 5-year burden for manufacturers to comply with this rule. This burden includes the time manufacturers spend reading and understanding requirements across different countries. We estimate the total burden to be $3.3 million over 5 years, with a low and high estimate of $0.2 to $10.3 million over 5 years. This results in an annual dollar burden of $0.7 million ($3.3/5), with a low and high estimate of $0.0 and $2.1 million. This annual burden when compared against the $80 million annualized savings presented in Table 10, is 0.8 percent of savings, with a low and high estimate of 0.3 and 2.6 percent. Furthermore, as discussed in section II.G.8. of this final rule, providers and suppliers will continue to buy and bill for GLOBE Model drugs as usual and receive separate payment under Medicare Part B, as applicable. Although CMS does not anticipate that providers will require additional support beyond the claims reimbursement process to ensure the accurate collection of coinsurance from their beneficiaries, as discussed in other parts of the final rule, CMS will disseminate key material and information to minimize potential administrative costs such as the GLOBE Model drug list along with each drug's cost sharing reduction percentage associated with each applicable quarter, and the list of ZIP codes to enable providers to prospectively identify which beneficiaries will receive the cost sharing.

In section II.G.1.a. of this final rule, we note that commercial data sources are widely used by interested parties within the biopharmaceutical industry, domestic and foreign governments, and commercial organizations, as well as the health technology assessment and drug pricing research communities. As such, it may be likely that manufacturers of GLOBE Model drugs have access to and familiarity with these existing data sources, and that any financial burden associated with access to such data source related to participation in the GLOBE Model would be minimal.

*Comment:* A couple of commenters urged CMS to evaluate and publicly disclose how tying U.S. drug prices to international benchmarks could affect ASP over time and potentially reshape the drug market, including impacts on patient access. They also raised concerns that changes to ASP calculations could create operational challenges for suppliers and call for analysis of effects both within and outside the GLOBE Model's scope.

*Response:* We thank the commenters for sharing their feedback on how the GLOBE Model might impact ASP, and potential operational challenges for suppliers which we interpret to mean that this could create additional administrative burdens not included in the initial RIA. In section IV.D. of the GLOBE Model proposed rule (90 FR 60244 and 60244), we noted that ASP is used as an input, through the specified

amount, in determining the per unit GLOBE Model rebate amount and as such should not be directly impacted by the GLOBE Model. The model does not change the Medicare Part B payment limit, including the add-on payment. However, we acknowledge that manufacturers may change list prices or price concessions in the U.S. across all payers to counteract the lost revenue from the model which could in turn indirectly impact the ASP amount. In section IV.D. of the GLOBE Model proposed rule (90 FR 60314), we discussed several expected behavioral responses including potential price increases during the GLOBE Model performance period. Further, in addition to discussing in the RIA several possible approaches to the proposed regulation including raising prices, we also welcomed comments on the probability and magnitude of manufacturers responding by raising list prices across all payers to counteract the lost revenue from the model. We have not received comments with respect to the probability or magnitude of changes in domestic prices nor in our analysis of this option in the RIA, in response to this request. We respond to commenters' concerns related to administrative costs in the preceding comment.

*Comment:* Many commenters raised concerns about the impacts on manufacturers and how they would respond strategically to the GLOBE Model in ways that could undermine its intended benefits or create market distortions that would offset the expected savings. These strategic responses may include increasing drug prices internationally, shifting costs to other markets such as increasing the prices of the GLOBE Model drug for commercial plans or increasing the prices of drugs in the U.S. that are outside of the GLOBE Model, altering launch, distribution or contracting strategies, or withdrawing from certain markets, including Medicare. A commenter also stated that CMS has not proposed a policy to address white-bagging.

*Response:* We thank the commenters for their concern that the GLOBE Model has the potential to motivate behavioral responses or other potential changes that would offset the savings of the GLOBE Model. Section IV.D. of the GLOBE Model proposed rule (90 FR 60314) discussed several expected behavioral responses including price increases, white bagging, increased use of OM utilization of prescription drugs, and acknowledges that these behavioral responses would offset potential savings. We decline to propose a policy to address white-bagging as we have considered this behavioral response.

Where possible we have estimated the impact of these responses on anticipated Medicare Savings as a percentage of Medicare Part B spending. We acknowledged in the GLOBE Model proposed rule that manufacturers may raise list prices across all payers to counteract the lost revenue from the model. We welcomed comments on the probability and magnitude of this response but did not receive any. We also acknowledge commenters' concerns that manufacturers could alter launch, distribution or contracting strategies, or withdraw from certain markets. However, we believe the GLOBE Model effects are time-limited and impacts a narrow population; therefore, the estimated impacts that would alter launch, distribution or contracting strategies, or withdrawing from certain markets such as Medicare are expected to be minimal. Further, the GLOBE Model does not impose direct burden on foreign governments. We note that the commenters did not explicitly comment on the quantified estimates in section IV.D. of the GLOBE Model proposed rule nor did they offer alternative estimates. We believe the GLOBE Model proposed rule has focused on the major behavioral responses. As we annually monitor the progress of the GLOBE Model, we will carefully assess what other responses are being made and may be addressed through future rulemaking.

*Comment:* A commenter stated that because non-340B and 340B drugs have different payment calculations, there is a potential concern that any change in the Medicare Part B benchmark may have an impact on 340B pricing and asked CMS to consider this issue in their analysis.

*Response:* We appreciate the commenter's concern that changes in the Medicare Part B benchmark may have on the 340B and non-340B programs. In sections II.N. (90 FR 60306) and IV.D. (90 FR 60312) of the GLOBE Model proposed rule, CMS stated that the GLOBE Model may interact with other federal programs such as the 340B program, the Veterans Health Administration, the Department of Defense, the Public Health Service, the Coast Guard, and Medicare. CMS describes potential indirect impacts on the 340B ceiling price and states that while manufacturer participants may have the incentive to shift utilization toward 340B units (as a result of 340B units being excluded from rebate amount calculations for the Medicare Part B Drug Inflation Rebate Program and the proposed GLOBE Model alternative rebate amount calculation), the extent of this shift is likely to be small since most GLOBE Model drugs have a relatively low proportion of 340B units.

*Comment:* Many commenters raised concerns about unintended consequences of the GLOBE Model, particularly its potential impact on MA plans. A commenter also urges CMS to provide additional information about how the GLOBE Model will impact Medigap plans.

*Response:* We thank the commenter for their input. In section IV.D. of the GLOBE Model proposed rule (90 FR 60314) and this final rule, CMS discusses the impact it estimates the GLOBE Model will have on MA plans and supplemental benefits offered by MA plans and acknowledges that GLOBE will likely reduce supplemental benefits to MA beneficiaries.

*Comment:* A commenter requested that CMS disclose the range of coinsurance reduction estimates under different assumptions.

Response: CMS shared a regulatory impact analysis in the GLOBE Model proposed rule that presented the estimated costs and benefits associated with the proposed policies that would have resulted in an overall cost sharing savings for OM beneficiaries of $1.4 billion over the duration of the model. In this final rule, the overall cost sharing savings for OM beneficiaries, updated to reflect the final rule policy changes summarized in IV.B. of this final rule, is $$50 million as shown in Table 14. If we combine savings from cost sharing with the premium savings for OM beneficiaries of $61 million, the total out-of-pocket savings for OM beneficiaries is $111 million.

*Comment:* Many commenters believed that there would be minimal savings for beneficiaries, since most have supplemental insurance, and that savings may accrue mainly to the federal government, not patients. Commenters cited a study that suggests that only a very small percentage (~0.3 percent, or about 22,000 beneficiaries) would see out-of-pocket changes because it has been estimated that about 90 percent of beneficiaries enrolled in OM are also enrolled in supplemental insurance plans such as Medigap. Another commenter states that the GLOBE Model as proposed does not establish a clear and consistent pathway by which program-level savings translate into predictable, patient-centered affordability improvements.

*Response:* We thank the commenter for their input. CMS has designed the GLOBE Model to be limited in scope in order to test an alternative rebate approach for Medicare Part B drugs. In

section IV.D. of the GLOBE Model proposed rule (90 FR 60314) and this final rule, CMS also acknowledges that many of these OM beneficiaries are dual eligible status or have supplemental prescription drug coverage, resulting in a fraction of these GLOBE eligible beneficiaries realizing direct cost sharing reduction. While the share of beneficiaries may be small as a percentage of Medicare Part B beneficiaries, CMS believes that the cost sharing reduction for these beneficiaries is an important part of the GLOBE Model and has the potential to meaningfully increase access for these beneficiaries. Additionally, beneficiaries may see reduced Medicare Part B premiums regardless of whether they have supplemental insurance. As part of GLOBE Model implementation, CMS will post documents on the GLOBE Model website that provides information to beneficiaries and to providers on the cost sharing reduction amount for each GLOBE Model drug. Therefore, we believe the GLOBE Model has established a clear and consistent pathway to show how program-level savings translate into affordability improvements for patients.

*Comment:* A commenter recommended that CMS conduct and publish a formal Title VI disparate-impact analysis prior to implementation.

*Response:* On December 9, 2025, the Justice Department issued a final rule that ensures that the nation's federal civil rights laws are firmly grounded in the principle of equal treatment under the law by eliminating disparate-impact liability from its Title VI regulation.

*Comment:* Many commenters sought clarification from CMS regarding the interaction of the GLOBE Model with other CMS programs and agreements. They emphasized the need for CMS to clearly define whether participation in other models or MFN agreements would affect inclusion in GLOBE, noting that without this information, stakeholders cannot accurately assess impacts, and that if those products are not subject to the GLOBE Model it would affect savings for the Medicare Program and its beneficiaries. Commenters also warned that overlapping requirements across multiple programs could create uncertainty and unintended incentives affecting product development and market entry, particularly for smaller manufacturers. Additionally, commenters raised concerns that introducing new pricing models after prior agreements undermines business certainty and could disproportionately harm companies that relied on earlier negotiated terms.

*Response:* We thank the commenters for their input on the interaction of the GLOBE Model with existing CMS programs and agreements. In section II.M. of this final rule, we have provided responses to comments on how the GLOBE Model will overlap with other CMS Innovation Center models. In section IV. of this final rule, we provide an estimate of savings for the model that assumes that manufacturers with signed GENEROUS Model participation agreements will not participate in the GLOBE Model and reflects manufacturer participation estimates using the best available information at this time.

*Final Decision:* CMS has revised this section to incorporate relevant public comments and to align with the final policies set forth in this rule.

2. Estimated Impacts to Medicaid

While the GLOBE Model rebate does not apply to units from dual eligible beneficiaries as these units are excluded from the Medicare Part B Drug Inflation Rebate Program, dual eligible beneficiaries are included in the GLOBE Model beneficiary list and are eligible to receive the GLOBE Model beneficiary coinsurance adjustment. Dual eligible beneficiaries are people who are enrolled in both Medicare (Part A, Part B, or both) and Medicaid. Medicaid savings of the GLOBE Model would therefore be reflected via the reduced cost sharing and premiums that Medicaid pays on behalf of dual eligible beneficiaries in the model geographic areas. Based on historical experience we expect that 30 percent of the reduced cost sharing will come from dual eligible 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 Medicare Part B premiums are paid by Medicaid on behalf of dual eligible 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 ($millions) | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | Total |
|---|---|---|---|---|---|---|---|
| Federal Cost Sharing Savings | 3 | 2 | 1 | 0 | 0 | 0 | 6 |
| State Cost Sharing Savings | 2 | 1 | 1 | 0 | 0 | 0 | 5 |
| Federal Premium Savings | 2 | 6 | 6 | 2 | 1 | 0 | 17 |
| State Premium Savings | 1 | 4 | 3 | 1 | 1 | 0 | 10 |
| Total Medicaid Savings | 9 | 12 | 11 | 3 | 3 | 0 | 39 |

Note: Totals may not add up due to rounding.

The following is a summary of the comments received and our responses.

*Comment:* A couple of commenters stated that the GLOBE Model may have spillover effects on Medicaid and dual eligible beneficiaries that should be considered.

*Response:* We thank the commenters for sharing their concern on the potential spillover impacts on Medicaid. In sections IV.D. (90 FR 60312) and II.N. (90 FR 60306) of the GLOBE Model proposed rule, CMS discussed potential impacts of the GLOBE Model on Medicaid. Specifically, CMS noted that, although not required as part of manufacturer participation in the GLOBE Model, to the extent that manufacturers reduce prices available to purchases and those prices would be included in a manufacturer's determination of the Medicaid Best Price, a manufacturer's Medicaid Best Price could potentially be lower and possibly increase Medicaid rebates. However, we do not expect such potential manufacturer behavioral response would result in a material impact on a manufacturer's Medicaid Best Price. Therefore, our estimate only reflects Medicaid savings related to the GLOBE Model via the reduced cost sharing and premiums that Medicaid pays on behalf of dual eligible beneficiaries in the model geographic areas.

*Final Decision:* CMS has revised this section to incorporate relevant public comments and to align with the final policies set forth in this final rule.

3. Review of Paperwork (Information) Burden

As discussed in section III. of this final 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 final rule and show it is marginal. 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.

For Table 16, we take a conservative approach and estimate the paperwork burden for manufacturers of GLOBE Model drugs regardless of their participation status in the GENEROUS Model and therefore, do not account for waivers that may waive the requirements for mandatory participation of manufacturers of GLOBE Model drugs under § 513.100. For Table 17, our low estimate accounts for participation status in the GENEROUS Model and assume that manufacturers participating in the GENEROUS Model will not participate in the GLOBE Model.

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**TABLE 16: DISCUSSION OF QUANTIFIABLE BURDEN FOR SUBMISSION**

| Line ID | Description | 2027 | 2028 – 2031 |
|---|---|---|---|
| (1) | Number of manufacturers | 19 | 19 |
| (2) | Quarters per year | 4 | 4 |
| (3) | Hours/Preparation | 20 | 10 |
| (4) | Hours/Submission | 6 | 3 |
| (5)=(2)*((3)+(4)) | Total hours per period per manufacturer | 104 | 52 |
| (6)=(1)*(5) | Total unadjusted aggregate hours for full period | 1976 | 988 |
| (7) | Percent applied for period | 1 | 1 |
| (8)=(6)*(7) | Total aggregate hours for period | 1976 | 988 |
| (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)+(9b)+9(c)+(9e)) +3/13*(9a) | Average weighted hourly wage for five professions | $52.71 | $52.71 |
| (10) | Factor for fringe benefits/Overtime | 2 | 2 |
| (11)=(9f)*(10) | Adjusted mean wage | $105.43 | $105.43 |
| (12)=(11)*(8) | Total Estimated Cost | $208,325 | $104,163 |
| (13)=sum of row (12) with a weight of 4 for years for 2028-2031 | Total Cost 5 Years | $624,975 | $624,975 |

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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 final rule. As a conservative estimate meant to include more manufacturers than likely would participate in the GLOBE Model, the proposed rule (90 FR 60316) used 40 manufacturers. However, as a result of both stakeholder comments and internal deliberations, a decision was reached to update § 513.130(c) to exclude: (1) a Part B rebatable drug that is designated as a drug for one or more rare diseases or conditions under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) and for which the only approved indication (or indications) is for one or more such rare disease or conditions; (2) a Part B rebatable drug that is listed on the FDA Approved Cellular and Gene Therapy Products website; and (3) a Part B rebatable drug that is a plasma-derived product as set forth in 42 CFR 427.400. Therefore, based on the illustrative 2024 GLOBE Model drug list in Table 4 of this final rule, the number of manufacturers participating initially with GLOBE is estimated to be 19.[227] This number, which might fluctuate during the duration of the GLOBE Model, is used in this final rule for the 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 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

[227] Assuming manufacturers who are participating in the GENEROUS Model receive a waiver for the requirements of mandatory participation of manufacturers of GLOBE Model drugs under § 513.100 as further discussed in section II.M. of this final rule, the number of remaining manufacturers of GLOBE Model drugs would be four. The information burden for four manufacturers is presented in Table 17.

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:* Based on comments in II.A. of this final rule, the GLOBE Model will begin on January 1, 2027, with the collection of voluntary manufacturer-submitted international drug net pricing data. The model will include 5 performance years, will begin on April 1, 2027 and ending March 31, 2032, during which the GLOBE Model beneficiary coinsurance and adjusted payments to providers and suppliers could apply and monitoring activities will occur. The model will also include a seven-year payment period, will begin on April 1, 2027, and will end on March 31, 2034, during which CMS will calculate, invoice, collect, and reconcile the GLOBE Model rebates for a performance year. Since the paperwork burden is associated with reporting, we use a full year for 2027 and full years for 2028–2031. Hence, the full period for each of these 5 years is used. Although there are other dates associated with the GLOBE Model, such as the period for beneficiary coinsurance payment adjustments, the performance, or the payment period, these do not directly affect the voluntary reporting by manufacturers which is the major driver of burden, and hence, these are not considered.

*Lines 9a through 9f:* The $ 22.90 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 five staff occupations 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,[228] CMS uses a factor of 2 to account for overtime and fringe benefits.

*Lines 11–13:* These are computations as indicated in the row header. Minor errors are due to rounding once at the end rather than at each step.

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. For a high factor we assume that 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 broad range of possible costs.

For a low estimate, we assume that manufacturers who are participating in the GENEROUS Model receive a waiver for the requirements of mandatory participation of manufacturers of GLOBE Model drugs under § 513.100 as further discussed in section II.M. of this final rule. Using the 2024 illustrative GLOBE Model drug list in Table 4 of this is final rule and our assumption of GENEROUS Model participation, we estimated that 4 manufacturers would participate in the GLOBE Model. This creates a low estimate of 20 percent (4/19). This contingency of joining the GENEROUS Model was not considered in the regulatory impact analysis in the GLOBE Model proposed rule but is plausible and therefore included in this final rule.

*Reference 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 final 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, if we were to assume that the preparation time is the same 10 hours/country for 9 of the 19 reference countries, we would multiply the bottom line cost burden by a factor of 10 for those 9 reference countries. We would then incorporate the total preparation time and corresponding cost burden associated with the remaining 10 reference countries to arrive at the total cost burden. For example, 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 15 percent (2/13). Therefore, we take 1.15 and 11 as the low and high estimates (where we rounded 10.5 downwards to obtain a wider range and similarly chose 11 over 10 to get a wider range) and insert an additional estimate in between these 2. In the GLOBE Model proposed rule we used a factor of 9.5 reflecting half the manufacturers; we have updated this 9.5 to 11 for greater clarity and transparency since the number of manufacturers entering or departing will be a whole number.

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 maximum increasing factor of 11) 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 16, $624,975 by 16.5 (1.5 * 11) and obtain a high cost burden of $10.3 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 $0.1 million and $10.3 million.

[228] Assistant Secretary for Planning and Evaluation. 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) | Preparation for 19 reference countries | 1.15 | 6 | 11 |
| (2) | New and departing participants to GLOBE | 0.2 | 0.9 | 1.5 |
| (3)=(1)*(2) | Product of factors | 0.23 | 5.4 | 16.5 |
| (4) From Table 16 | | $624,975 | $624.975 | $624,975 |
| (5)=(4)*(3) | Range of possible adjusted cost burden over 5 years | $143, 744 | $3,374,867 | $10, 312,093 |

**Notes:** 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.

The following is a summary of the comments received and our responses.

*Comment:* Some commenters stated that the GLOBE Model reporting requirements would place significant burden on manufacturers.

*Response:* We thank the commenters for sharing their concern related to the burden of manufacturer net price reporting costs. CMS estimated the costs to manufacturers in the Globe Model proposed rule in section IV.D.3. of the GLOBE Model proposed rule (90 FR 60314) and this analysis is repeated in this final rule in Tables 16 and 17 to which further modifications and clarifications have been added. In addition, while new requirements are being added to manufacturers under the GLOBE Model, they are marginal and limited in scope as the GLOBE Model builds on the already existing framework created by the IRA. We therefore believe that manufacturers should be able to absorb these marginal costs of reporting when they choose to submit data to inform a Method II GLOBE Model benchmark calculation.

*Final Decision:* Based on the final inclusion criteria, CMS has determined that this final rule will not have a significant economic impact on paperwork burden for manufacturers. CMS has revised section IV.D. of this final rule to reflect the final policies established in this rule.

*E. Final 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 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 final 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 at least a 3 percent revenue effect on at least 5 percent of impacted small entities.[229] As discussed in section II. of this final 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 net pricing information (as described in section II.G. of this final rule) and would not be less than any rebate owed under the Medicare Part B Drug Inflation Rebate Program. Our analysis includes the final exclusion criteria in § 513.130(c) to exclude a Part B rebatable drug from the GLOBE Model (1) that is designated as a drug for one or more rare diseases or conditions under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) and for which the only approved indication (or indications) is for one or more such rare diseases or conditions, (2) that is a listed on the FDA Approved Cellular and Gene Therapy products website, and (3) that is a plasma-derived product as set forth 42 CFR 427.400. Our analysis shows that the final rule will impact one small firm, and the impact is estimated to represent 2.3 percent or less of that firm's annual revenue in the U.S. As such, the Secretary certifies that this final rule will not have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this final rule, serves as the Final Regulatory Flexibility Analysis, as required by the RFA.

1. Description and Number of Affected Small Entities

Based on the final drug exclusion criteria set forth in § 513.130(c) and not considering manufacturer participation status in GENEROUS, we identified 19 manufacturers that would be associated with the illustrative 2024 GLOBE Model drugs from Table 4 of this final rule.[230] Using the financial data, we determined that 1 of these manufacturers would be considered small based on the SBA definition.[231] Based on a March 31, 2026 news release, we determined that the one small manufacturer is expected to be acquired by a large company and that this transaction is expected to close in the second quarter of 2026. Given this announcement and to recognize that not all announced merger and acquisition activities get finalized, our analysis assumes that one small manufacturer would be affected by the GLOBE Model. As the estimated impact to this one small manufacturer (2.3 percent or less of the firm's annual revenue in the U.S.) is not considered economically significant under HHS standards, we conclude that 0 percent of impacted small entities are significantly impacted and the estimated impact on this one small manufacturer meets the 0–5

[229] 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.*

[230] Assuming manufacturers who are participating in the GENEROUS Model receive a waiver for the requirements of mandatory participation of manufacturers of GLOBE Model drugs under § 513.100 as further discussed in section II.M. of this final rule, the number of remaining manufacturers of GLOBE Model drugs would be 4.

[231] The SBA considers any ''Pharmaceutical Preparation Manufacturing'' firm (NAICS code 325412) with fewer than 1,300 employees as a small business.

percent threshold of the RFA for non-significance.

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.[232] 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.[233]

Assuming that the announced consolidation of the two companies is not finalized, and using 2024 data, the identified small company employs 501–999 employees in the U.S. and reported revenue of $781.37 million. The potential GLOBE Model drug associated with this small entity is classified as immunological agent 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 in Table 4. Further, based on CMS expertise, the potential GLOBE Model drug associated with this small entity has therapeutically equivalent substitutes.

**TABLE 18: NUMBER OF SMALL ENTITIES BY EMPLOYMENT SIZE AND REVENUE, 2024**

| Company Size | Total Number of Employees in the U.S. | Total Global Revenue ($million) | Total U.S. Revenue ($million) | Average U.S. Revenue per Company ($million) |
|---|---|---|---|---|
| Small | 1300 or fewer | $781.37 | $781.37 | $781.37 |
| Large | 1300+ | $643,200.95 | $370,728.16 | $20,596.01 |
| Total | | $643,982.32 | $371,509.53 | $19,553.13 |

*Final Decision:* We did not receive comments in this section. We have updated this section to reflect our final drug inclusion and exclusion criteria at § 513.130.

2. Description of the Potential Impacts on Small Entities

CMS anticipates that payments to CMS in the form of GLOBE Model rebate amounts, if any, as set forth in § 513.500 of this final rule, will represent the largest impact to small entities, if any, affected by the GLOBE Model. However, as noted in section IV.E.1. of this final rule, based on the final selection criteria and updated analysis, the Secretary concludes that the final rule will not have a significant impact on a substantial number of small entities.

We estimate a potential impact assuming the consolidation of the two companies does not get finalized. To estimate a lower bound, we estimate that 0.0 percent of the estimated incremental GLOBE Model rebate amount would be associated with the small entity. The estimate of 0.0 percent was derived by calculating the ratio of small company rebate reliability to large company rebate reliability.[234] As the lower estimate is 0.0 percent based on the available data for that small manufacturer and to be conservative, we also estimate an upper bound using an average GLOBE Model rebate per company ($18.25 million), including both large and small manufacturers from the illustrative 2024 GLOBE Model Drug HCPCS Level II Codes List (Table 4). Using this estimate as an upper bound, we estimate that GLOBE Model rebates could represent up to 2.3 percent of a small entity's average revenue in the U.S. ($18.25 million/$781.37 million). Using the lower and upper bound estimates, and OACT's estimate of the incurred calendar year GLOBE Model rebates, we estimate the incremental GLOBE Model rebate amounts would range from $0.0 to $3.1 million per small entity over the model performance period. Table 19 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 less than 0.4 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 final rule are not included in these estimates. However, as noted in the RIA, these costs are estimated to be marginal.

In the GLOBE Model proposed rule (90 FR 60319), CMS noted that these estimates were based on available data which could change in the future and as such, the estimated impacts could vary. The estimates in this Final Regulatory Flexibility Analysis 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 final rule. Based on our updated analysis, the Secretary concludes that the final rule will not have a significant impact on a substantial number of small entities.

**TABLE 19: ESTIMATED IMPACT ON SMALL ENTITIES[235]**

| Description | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | 2033 |
|---|---|---|---|---|---|---|---|
| Estimated Incremental GLOBE Model Rebate Amount for Small Entities ($millions) | 2.4 | 3.1 | 2.9 | 0.8 | 0.6 | 0.2 | 0.0 |
| Estimated Total GLOBE Model Rebate for Small Entities as Percent of Total U.S. Revenue of Small Entities | 0.3% | 0.4% | 0.4% | 0.1% | 0.1% | 0.0% | 0.0% |

[232] Most companies self-identified as ''global'' and provided information separately for their global consolidated business and for the U.S. For purposes of this analysis, we use revenue and employment size information based on data reported for the U.S.

[233] Internal Revenue Service. Yearly average currency exchange rates. Available at: *https://www.irs.gov/individuals/international-taxpayers/yearly-average-currency-exchange-rates.*

[234] Using available data from Table 4 (Illustrative 2024 GLOBE Model Drug HCPCS Level II Codes List), we estimate that the small company would not have owed an incremental GLOBE Model rebate. CMS was unable to identify a per unit GLOBE Model benchmark for the small company's illustrative GLOBE Model drug—a per unit GLOBE Model benchmark was unavailable.

3. Other Potential Options To Reduce Adverse Burden on Small Entities

As discussed in introduction of this section (section IV.E. of this final rule), the RFA requires discussion of any meaningful options that achieve the objectives of the final rule with less significant adverse economic impact on the small entities. Therefore, this section discusses several such considerations.

In particular, we considered including limited price reductions for drugs selected for the Negotiation Program, increasing utilization of 340B units, changing list pricing information, changing incentives to participate in the Negotiation Program, and studying impacts to MA plans and Medicaid. In each case we either determined the 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.

In the GLOBE Model proposed rule (90 FR 60319), we welcomed comments on our estimate of significantly affected small manufacturers and the magnitude of estimated effects. We also welcomed comments on adjustments to the GLOBE Model that could be considered while preserving the innovative approach to payment in the GLOBE Model.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters stated strong opposition to the GLOBE Model, indicating that it would disproportionately harm small and mid-sized biotechnology and pharmaceutical companies, weaken U.S. biotechnology leadership, disrupt R&D, and harm patient access directly. The commenters described that small and mid-sized companies lack scale, diversified portfolios, and negotiating leverage compared to large companies that may avoid impacts due to separate negotiations. The commenters described that small firms depend on external capital funding, downstream revenues, and on one or few products to finance their pipelines. The commenters added that the GLOBE Model would lead to revenue compression which would reduce their ability to fund early-stage research, as well as their ability to raise capital because lower expected reimbursement in the U.S. would translate into reduced investor confidence. The commenters stated that this could slow down development of gene therapies, biologics and rare disease treatments. The commenters also expressed other concerns including increased uncertainty, administrative burden, overlap with other existing programs, and limited evidence on improved affordability of access.

*Response:* We thank the commenters for their input on the potential impact to small business entities. Based on the updated drug exclusion criteria in § 513.130(c) and the updated analysis presented in section IV.E. of this final rule, CMS disagrees the GLOBE Model will disproportionately harm small and mid-sized biotechnology and pharmaceutical companies. The updated analysis indicates that only 1 potentially affected entity qualifies as small under the SBA definition, with GLOBE Model rebates representing no more than 2.3 percent of the small entity's average revenue–below the HHS significance threshold of 3 percent or more.[236] Because the estimated impact does not exceed 3 to 5 percent, the Secretary concludes that the GLOBE Model will not have a significant economic impact on a substantial number of entities.

Additionally, the GLOBE Model is a time-limited 5-year model that tests an innovative payment methodology on a subset of Part B rebatable drugs for a limited population—25 percent of OM Part B beneficiaries. The model's rebate obligation also reaches only drugs exceeding $100 million in OM Part B allowed charges over a 12-month period—a threshold reflecting substantial market penetration—and affects only the OM Part B market, leaving commercial, MA, and ex-U.S. revenues unaffected. Therefore, we disagree that the model will weaken U.S. biotechnology leadership, disrupt R&D, or slow down development of biologic treatments. We refer readers to the introduction of section II. and section II.B. of this final rule for our more comprehensive responses related to impacts on U.S. biotechnology leadership, R&D, and development of treatments. We also refer readers to sections II.E. and IV.D. of this final rule, for our responses related to mandatory participation of small and mid-sized companies and evidence on improved affordability for OM Part B beneficiaries.

*Comment:* A few commenters also expressed concern that the GLOBE Model would penalize small and mid-sized companies that rely on out-licensing or co-licensing agreements, and turn partnering or out-licensing into a ''poison pill'' for small and mid-sized companies. The commenters note that small firms do not have a physical presence outside of the U.S. and that they often license products internationally but do not control foreign pricing or net pricing data. Commenters cited survey results indicating that 75 percent of an organization's membership noted reliance on out-licensing agreements, and that companies do not have control over pricing.

*Response:* We thank the commenters for their input on the impact to small business entities and their reliance on out-licensing or co-licensing agreements. As finalized in this final rule, we are modifying the criteria for GLOBE Model drugs such that orphan-only[237] Part B rebatable drugs would be excluded from the model. As a result of this exclusion, the GLOBE Model's final rule identifies one small entity, down from two in the GLOBE Model proposed rule (90 FR 60318), and the estimated GLOBE Model rebates impact for small entities has decreased from up to 2.6 percent (90 FR 60318) down to 2.3 percent. We also believe that the exclusion of orphan-only drugs would significantly reduce the number of GLOBE Model drugs where the U.S. manufacturer or its affiliate does not sell international analogs of the GLOBE Model drug outside of the U.S. Based on our analysis of potential GLOBE Model drugs for performance year 1, we observed the U.S. manufacturer and manufacturer in a reference country are most often the same entity or affiliated entities. We recognize that there could be cases where the U.S. manufacturer of a GLOBE Model drug is not affiliated with the entity (or entities) that sell international analogs for a GLOBE Model drug in reference countries. To support manufacturers of GLOBE Model drugs, CMS is exploring options for technical support for manufacturers through the model helpdesk as discussed in section II.G. of this final rule. We refer readers to sections II.G.1.d. and II.G.6. of this final rule for our additional responses related to this out-licensing and co-licensing.

*Comment:* A commenter urged CMS to supplement its employee-count

[235] This estimated impact on small entities for Table 19 is based on the upper bound estimate that GLOBE Model rebates could represent up to 2.3 percent of a small entity's average revenue in the U.S.

[236] Department of Health and Human Services. Guidance on Proper Consideration of Small Entities in Rulemakings of the U.S. Department of Health and Human Services, May 2003. Available at: *https://aspe.hhs.gov/sites/default/files/documents/dd6288d1b8db19ee8a1f37b3ce775003/guidance-proper-consideration-hhs-2003-rulemaking.pdf.*

[237] Orphan-only drug means a drug that is designated as a drug for only one or more rare diseases or conditions under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) and for which the only approved indication (or indications) is for one or more such rare diseases or conditions. Refer to § 513.130(c) for the GLOBE Model drug exclusion criteria.

threshold analysis with an additional criterion that includes the length of time that has elapsed since a manufacturer's first product to market. The commenter further stated that the GLOBE Model applies an arbitrary definition of ''small'' manufacturer and that the threshold of more than 1300 employees fails to consider the role of mid-sized biotech companies.

*Response:* We thank the commenter for their feedback on the criterion used to define a small entity in the Initial Regulatory Flexibility Analysis (section IV.E. of the GLOBE Model proposed rule). The definition of size used in this rule is based on the regulatory definitions and methodology presented in 13 CFR 121.201 on which the NAICS standard sizes are based. Moreover, as just indicated, these definitions are based on the methodology also presented there. Definitions are based on several factors including employee size and revenue. As such, we disagree CMS used an arbitrary definition of ''small'' and are retaining our methodology presented by these regulations.

*Final Decision:* As discussed in section IV.E.1. of this final rule, based on the final inclusion criteria and the expected consolidation of two companies, CMS has determined that this final rule will not have a significant economic impact on a substantial number of small entities. CMS has revised section IV.E.2. of this final rule accordingly to reflect the final inclusion criteria and the updated results of its analysis.

3. Actions Taken To Reduce Burden on Small Entities

Although as pointed out previously, the number of small entities impacted is 1, nevertheless, CMS considered a variety of options to reduce effect on small entities. More specifically the provisions require the following, each of which has the effect of reducing possible burden on small entities: (1) setting the spending threshold for inclusion in the model as discussed in section II.B. of this final rule at $100 million over a 12-month period (further specified in § 513.130) and (2) the new drug exclusion criteria for orphan-only drugs,[238] plasma-derived products as set forth in 42 CFR 427.400, and drugs listed by FDA as Approved Cellular and Gene Therapy products finalized in § 513.130(c).

For the purpose of thoroughness, we point out that CMS also considered other options to minimize the impact on small entities: (1) establishing a different spending threshold; (2) establishing an exemption process; and (3) establishing different compliance dates. However, we decided against implementing these for the following reasons.

- *Spending threshold:* As discussed in section II.B. of this final rule, CMS proposed 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 final rule; (2) are single source drugs or sole source biological products; (3) have a HCPCS Level II code with OM Part B spending greater than $100 million over a 12-month period (as further specified in proposed § 513.130(d)); and (4) are not excluded from the GLOBE Model as proposed in § 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 over a 12-month period. 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 proposed 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 two manufacturers, both of which are considered large manufacturers (they employ more than 5,000 employees in the U.S.). 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 final 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 the proposed exclusion, we do not believe that additional processes for exemptions are needed. CMS sought 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 alternative Medicare Part B drug 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 welcomed comments on the alternatives considered as well as other factors that could be considered to mitigate the impact on small manufacturers.

The following is a summary of the comments received and our responses.

*Comment:* A couple of commenters recommend CMS exempt small manufacturers to mitigate the potential impact. Commenters recommended several potential exemptions, including exempting from the model drug manufactured by companies with fewer than 500 employees and no prior commercialized products from the $100 million Medicare Part B threshold; considering the length of time elapsed since a manufacturer's first FDA product approval as a criterion for defining a small manufacturer; excluding manufacturers whose Medicare Part B prescription drug spending constitutes less than 1.0 percent of total Medicare Part B prescription drug spending; and raising the $100 million Medicare Part B allowed charges threshold for drugs as an alternative means of limiting the model's applicability to small manufacturers.

*Response:* We thank the commenters for the suggestion that we adopt an alternative policy to exempt small manufacturers. We respond to these comments in section II.E.1. of the final rule. Further, based on the updated analysis and final inclusion criteria in

[238] Orphan-only drug means a drug that is designated as a drug for only one or more rare diseases or conditions under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) and for which the only approved indication (or indications) is for one or more such rare diseases or conditions. Refer to § 513.130(c) for the GLOBE Model drug exclusion criteria.

this rule, we conclude that we do not anticipate that the final rule will have a significant economic impact on a substantial number of small entities. For these reasons we decline to adopt the alternative approaches suggested by the commenters.

*Final Decision:* Based on the final inclusion criteria and the updated findings set forth in sections IV.E.1. and IV.E.2. of this final rule, CMS has determined that exemptions for small entities are not warranted.

*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 OM 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 Association [239] there are 6,093 hospitals in the U.S. Using data from 2021 and 2025, we estimate that there are 1,524 small rural hospitals in the U.S.[240] 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,[241] and that Medicare Part B spending in all hospitals represented about 41 percent of total Medicare Part B spending in 2022 ($19.3 billion/$46.9 billion).[242] 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.[243] 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.[244] We tentatively concluded that the GLOBE Model proposed rule, if finalized as proposed, would not have a significant impact on small rural hospitals. We sought comments on this conclusion, as well as data or other factors that had not been considered.

The following is a summary of the comments received and our responses.

*Comment:* A few commenters expressed concerns about the potential downstream effects and administrative burden of the GLOBE Model on small and rural providers operating on narrow margins. The commenters suggested that reduced reimbursement would risk discontinuing certain treatments for patients and that the additional compliance requirements would divert capacity away from patient care.

*Response:* We thank the commenters for sharing their concerns related to potential downstream effects and administrative burden on small and rural providers. The GLOBE Model does not change ASP or the add-on percentage (ASP + 6 percent). Additionally, if a GLOBE Model beneficiary receives a reduced coinsurance percentage, Medicare will make upward adjustments to the Medicare payment amount to providers and suppliers. Therefore, we do not expect impacts on margins of providers or suppliers or changes to reimbursement for GLOBE Model drugs.

Further, consistent with the Regulatory Flexibility Act in section IV.E. of this final rule, CMS concluded that it does not anticipate that the final rule will have a significant economic impact on a substantial number of small entities. CMS acknowledges that some administrative costs associated with reading and understanding the rule are not included in the Final Regulatory Impact Analysis but expects these costs to be marginal.

*Final Decision:* After consideration of the public comments received, the Secretary has determined that this final rule will not have a significant impact on small rural hospitals.

*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. In 2026, that threshold is approximately $193 million. This final rule will 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 $193 million in any one year. However, this final rule will result in additional impacts that we do not quantify associated with changes in behavior. We requested comments, including on the potential magnitude of this impact and the extent to which it is a funded or unfunded mandate.

The following is a summary of the comments received and our responses.

*Comment:* A commenter urges CMS not to impose additional administrative burdens and unfunded mandates on pharmacies, pharmacists, or pharmacy personnel related to payment, reconciliation, reimbursement, reporting, or distribution.

[239] 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.*

[240] 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.*

[241] 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.*

[242] MedPAC. July 2025 Data Book Section 10: Prescription Drugs, Data Book, July 17, 2025. Available at: *https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf.*

[243] 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.

[244] 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.*

*Response:* We thank the commenter for input on this topic. In section II.G. of the GLOBE Model proposed rule (90 FR 60265) and consistent with the UMRA, CMS estimated that the GLOBE Model would not impose a mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $193 million in any one year. In addition, CMS sought comment on the potential magnitude of additional impacts and the extent to which it is funded or unfunded. We did not receive any comments on these topics and are therefore finalizing this section with modification to update the threshold to 2026 dollars.

*Final Decision:* After consideration of the public comments received and its analysis, the Secretary has determined that this final rule will not impose a Federal mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, exceeding the $193 million UMRA threshold in any one year.

*H. Federalism*

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this final 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.

*Final Decision:* We did not receive comments related to Federalism implications and are finalizing this section without modification.

*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.'' This final rule is exempt from otherwise-applicable requirements under E.O. 14192, per footnote 1 of OMB's Accounting Methods.[245]

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on September 23, 2026.

[245] *https://www.reginfo.gov/public/pdf/eo14192/Accounting_Methods_under_EO_14192.pdf.*

**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 amends 42 CFR chapter IV by adding part 513 to read as follows:

## PART 513—GLOBAL BENCHMARK FOR EFFICIENT DRUG PRICING (GLOBE) MODEL

Sec.

**Subpart A—General Provisions**

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**Subpart C—Coinsurance Adjustment and Adjusted Medicare Payment for GLOBE Model Drugs**

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513.310 Included international data.

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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.

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513.500 Calculation of the total GLOBE Model rebate amount and the incremental 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 Drug Net Pricing Data**

513.600 Definitions.
513.610 Submission and verification of international drug 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 GLOBE Model rebate reports and reconciliation-incremental approach.
513.720 Suggestion of error.
513.730 Manufacturer access to GLOBE Model rebate reports.
513.740 Deadline and process for payment of incremental GLOBE Model rebate amount.

**Subpart I—Enforcement of Manufacturer Payment of Incremental GLOBE Model Rebate Amounts Due**

513.800 Civil money penalty notice and appeals procedures.

**Subpart J—Quality Strategy, Beneficiary Protections, and Compliance Activities**

513.900 Quality measures.
513.910 Beneficiary protections.

**Subpart K—Waivers**

513.1000 Waivers of Medicare program requirements for purposes of testing the GLOBE Model.

**Authority:** 42 U.S.C. 1302, 1315a, 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 Medical Insurance Trust Fund for each calendar quarter during the model performance period when a GLOBE Model rebate is owed in accordance with § 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 starts on January 1, 2027. Subject to paragraphs (c)(1), (2), and (3) of this section, the GLOBE Model has a test period consisting of a 5-year performance period and a 7-year payment period that are preceded by an initial reporting quarter.

(1) The first performance year begins on April 1, 2027, and the final performance year ends on March 31, 2032, unless sooner terminated in accordance with § 513.100(d)(4).

(2) The first payment year begins on April 1, 2027, and the final payment year ends on March 31, 2034, or upon the completion of all model payment activities, whichever is later, unless sooner terminated in accordance with § 513.100(d)(4).

(3) The initial reporting period for voluntary manufacturer-submitted international drug net pricing data begins on January 1, 2027, for the applicable ASP calendar quarter ending December 31, 2026.

(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 the volume-weighted average GDP (PPP) adjusted net prices in U.S dollars for all reference countries, where the weights are the sales volume in HCPCS billing units for each reference country. The across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit is obtained by the manufacturer by adding for all applicable international analogs in 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 sales volume in HCPCS billing units and then dividing by the sum of the sales volume in HCPCS billing units for all applicable international analogs in all reference countries.

*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 amount determined in accordance with section 1847A(b)(4) of the Act.

*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 § 513.400(d).

*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.

*CPI–U* has the same meaning set forth in 42 CFR 427.20.

*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 long descriptor as calculated in accordance with § 513.410.

*Currently in shortage* has the same meaning set forth in 42 CFR 427.400.

*Date of receipt* means the calendar day following the day on which a report of a GLOBE Model rebate amount (as set forth in § 513.500(a) through (f)) is made available to the manufacturer of a GLOBE Model drug by CMS.

*Drug shortage or shortage* has the same meaning set forth in 42 CFR 427.400.

*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 § 513.430.

*GLOBE Model benchmark amount* means the amount calculated in accordance with § 513.400.

*GLOBE Model beneficiary* means a Medicare beneficiary who has been identified by CMS as set forth in § 513.120 for inclusion in the model, added to the model cohort for all or a portion of the GLOBE Model performance period, and is furnished a GLOBE Model drug for which OM Part B makes separate payment under the model as determined by CMS.

*GLOBE Model beneficiary coinsurance percentage* means the applicable coinsurance percentage as determined under § 513.210.

*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 § 513.520(b).

*GLOBE Model drug* means a 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 § 513.130.

*GLOBE Model eligible beneficiary* means a Medicare beneficiary meeting the criteria in § 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 § 513.120(b)(1).

*GLOBE Model geographic areas* means the set of ZIP Codes in the U.S., excluding U.S. territories, identified in accordance with § 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 § 513.100.

*GLOBE Model payment period* means the 7-year period beginning on April 1, 2027, through March 31, 2034, or upon the completion of all model payment activities, whichever is later, as specified in § 513.1(c).

*GLOBE Model performance period* means the 5-year period beginning on April 1, 2027, through March 31, 2032, as specified in § 513.1(c).

*GLOBE Model test period* means the period beginning on January 1, 2027 (the model start date) and ending on March 31, 2034, or upon the completion of all model payment activities, whichever is later, unless sooner terminated in accordance with § 513.100(d)(4).

*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 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 Public Health Service (PHS) Act in the U.S.

*International generic drug* means 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 Federal Food, Drug, and Cosmetic Act (FD&C Act) in the U.S.

*International drug net pricing information* means the data specified in § 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 section 351(a) of the PHS Act or approved under a pathway similar to section 505(c) of the FD&C 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 in U.S. currency).

*Manufacturer* has the meaning 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 part 414, subpart J.

*Method I GLOBE Model benchmark* means the lowest per unit GDP (PPP) adjusted country-level price of the reference countries specified in § 513.310 for a GLOBE Model drug as determined in § 513.410.

*Method II GLOBE Model benchmark* means the volume-weighted average of the manufacturer's net pricing for sales within a set of reference countries specified in § 513.310 for a GLOBE Model drug as determined in § 513.420.

*National Drug Code (NDC)* has the same meaning set forth in 42 CFR 427.20.

*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).

*Not Otherwise Classified (NOC)* has the same meaning set forth in 42 CFR 427.20.

*OECD* means Organisation for Economic Co-operation and Development.

*OM* stands for Original Medicare.

*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 April 1 and ending on March 31 during the GLOBE Model test period.

*Per unit GLOBE Model benchmark amount* means the amount calculated in accordance with § 513.400.

*Plasma-derived product* has the same meaning set forth in 42 CFR 427.400.

*Performance year (PY)* means a 12-month period beginning on April 1 and ending on March 31 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 § 513.310(b).

*Reference product means* an FDA-licensed biological product approved under section 351(a) of the PHS Act against which a biosimilar biological product is evaluated in an application submitted to the FDA under section 351(k) of the PHS Act.

*Single source drug* 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 product* means a biological product licensed by the FDA 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 calendar quarter during the GLOBE Model performance period, 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 under a BLA under section 351(k) of the PHS Act. The biosimilar biological product must be recognized in the FDA's most recent publication of ''Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations'' (the ''Purple Book'') and be identified as sold or marketed as set forth in 42 CFR 427.20. At the time of evaluating inclusion in the GLOBE Model for each applicable calendar quarter during the GLOBE Model performance period, 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.

*Unit* has the same meaning set forth in 42 CFR 427.20.

*U.S. originator drug* means the original biologic and drug licensed or approved via section 351(a) of the PHS 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 drugs, 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 that are furnished to a GLOBE Model beneficiary during the GLOBE Model performance period.

(b) *GLOBE Model participant requirements during the GLOBE Model test period.* During the GLOBE Model

test period described in § 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 § 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 § 513.610 and the GLOBE Model data agreement (§ 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 October 1, 2026, a GLOBE Model participant must adhere to the requirements set forth in § 513.610 and the GLOBE Model data agreement (§ 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 Model participant must maintain and provide 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 § 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 Model 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 90 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 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 OM Part B beneficiaries have an address of record as set forth in § 513.120.

(c) No later than 75 calendar days prior to the start of the model performance period, 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 performance period using available Medicare program administrative information as determined by CMS, CMS—

(1) Identifies the Medicare beneficiaries who are enrolled in Medicare Part B, have Original 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 § 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 Original 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 monthly), using available Medicare program administrative information as determined by CMS, CMS identifies the Medicare beneficiaries who are—

(1) Enrolled in Medicare Part B, have Original 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

§ 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 OM Part B 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.

**§ 513.130 GLOBE Model drugs and excluded drugs.**

(a) Subject to paragraph (b) of this section, for each applicable calendar quarter during the model performance period, CMS identifies the Part B rebatable drugs that are included in the GLOBE Model for purposes of—

(1) Application of the GLOBE Model coinsurance adjustment and adjusted Medicare payment as set forth in 42 CFR part 513, subpart C; and

(2) Determining total GLOBE Model rebate amounts as set forth in 42 CFR part 513 subpart F.

(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) that meet all of 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) categories.

(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 USP DC 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 USP DC to identify their category.

(iii) CMS adds new USP DC categories that stem from the USP DC categories listed in paragraph (b)(1) of this section 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) Part B rebatable drugs with total OM Part B allowed charges greater than the applicable minimum spend threshold over a 12-month period ending 6 months prior to the start of the applicable calendar quarter, as determined by CMS under this paragraph and paragraph (d) of this section. If the Part B rebatable drug meets this criterion for an applicable calendar quarter, it continues to meet this criterion for all applicable calendar quarters thereafter during the model performance period, even if the OM Part B allowed charges falls below the applicable minimum spend threshold for any applicable calendar quarters thereafter during the model performance period.

(i) *Minimum spend threshold.* CMS calculates the applicable minimum spend threshold as follows—

(A) For the applicable calendar quarter beginning April 1, 2027, the applicable minimum spend threshold is equal to $100 million.

(B) Subject to paragraph (b)(3)(iii) of this section, for each subsequent applicable calendar quarter, the applicable minimum spend threshold is equal to the unrounded applicable minimum spend threshold for the preceding applicable calendar quarter increased by the percentage increase in the CPI–U for the specified 12-month period.

(ii) The specified 12-month period for an applicable calendar quarter is the consecutive 12-month period ending 6 months prior to the start of that applicable calendar quarter. If the percentage increase in the CPI–U for the specified 12-month period is not available, as determined by CMS, CMS uses the percentage increase in the CPI–U for the most recent consecutive 12-month period that is prior to the specified 12-month period for which data is available from the Bureau of Labor Statistics.

(iii) If the percentage increase in the CPI–U for the specified 12-month period for an applicable calendar quarter is negative, as determined by CMS, the percentage increase for such period is zero.

(iv) If the resulting amount under paragraphs (b)(3)(i)(B) of this section is not a multiple of $10, CMS rounds that amount to the nearest multiple of $10.

(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 (as defined in section 1191(c)(3) of the Act) 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.

(iv) A Part B rebatable drug that is designated as a drug for one or more rare diseases or conditions under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) and for which the only approved indication (or indications) is for one or more such rare diseases or conditions.

(v) A Part B rebatable drug that is a product listed on the FDA Approved Cellular and Gene Therapy Products website.

(vi) A Part B rebatable drug that is a plasma-derived product as set forth in 42 CFR 427.400.

(2) [Reserved]

(d) *Original Medicare (OM) Part B allowed charges.* For a Part B rebatable drug for an applicable calendar quarter, CMS calculates the total OM Part B 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 OM Part B 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 HCPCS code used to describe the Part B rebatable drug as follows:

TABLE 1 TO PARAGRAPH (d)(1)

| Applicable calendar quarter beginning on | OM Part B final action claims with date of service from | OM Part B final action claims with date of service through |
|---|---|---|
| April 1, 2027 | October 1, 2025 | September 30, 2026. |
| July 1, 2027 | January 1, 2026 | December 31, 2026. |
| October 1, 2027 | April 1, 2026 | March 31, 2027. |
| January 1, 2028 | July 1, 2026 | June 30, 2027. |
| April 1, 2028 | October 1, 2026 | September 30, 2027. |
| July 1, 2028 | January 1, 2027 | December 31, 2027. |
| October 1, 2028 | April 1, 2027 | March 31, 2028. |
| January 1, 2029 | July 1, 2027 | June 30, 2028. |
| April 1, 2029 | October 1, 2027 | September 30, 2028. |
| July 1, 2029 | January 1, 2028 | December 31, 2028. |
| October 1, 2029 | April 1, 2028 | March 31, 2029. |
| January 1, 2030 | July 1, 2028 | June 30, 2029. |
| April 1, 2030 | October 1, 2028 | September 30, 2029. |
| July 1, 2030 | January 1, 2029 | December 31, 2029. |
| October 1, 2030 | April 1, 2029 | March 31, 2030. |
| January 1, 2031 | July 1, 2029 | June 30, 2030. |
| April 1, 2031 | October 1, 2029 | September 30, 2030. |
| July 1, 2031 | January 1, 2030 | December 31, 2030. |
| October 1, 2031 | April 1, 2030 | March 31, 2031. |
| January 1, 2032 | July 1, 2030 | June 30, 2031. |

(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 (e)(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 are 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.

### § 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 a GLOBE Model drug furnished to a GLOBE Model beneficiary with respect to an applicable calendar quarter, when 42 CFR 410.152(m), 419.41(e), and 489.30(b)(6) as applicable apply, CMS uses the following steps:

(1) CMS identifies the lesser of the per unit GLOBE Model benchmark amount as set forth in § 513.400(c)(4) and the inflation-adjusted payment amount for the applicable calendar quarter determined under 42 CFR 427.302(g) as determined by CMS.

(2) If the payment amount as set forth in 42 CFR 427.201(b)(3) exceeds the amount identified in paragraph (b)(1) of this section, the GLOBE Model beneficiary coinsurance adjustment applies and the GLOBE Model beneficiary coinsurance is calculated by multiplying the amount identified in paragraph (b)(1) of this section 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.

(3) If the payment amount as set forth in 42 CFR 427.201(b)(3) does not exceed the amount identified in paragraph (b)(1) of this section, the adjustment to the beneficiary coinsurance set forth in paragraph (b)(2) 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 489.30(b)(1) as applicable.

(4) *Application of the GLOBE Model beneficiary coinsurance adjustment.* The applicable GLOBE Model beneficiary coinsurance adjustment is determined solely by CMS and administrative and judicial review is

precluded consistent with sections 1847A(i)(8) and 1115A(d)(2) of the Act.

(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:

*Annual real GDP,* for purposes of § 513.310(b), 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.

*Real GDP per capita,* for purposes of § 513.310(b), 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.

### § 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) Czech Republic.
(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, CMS identifies available international drug pricing information data sources for the GLOBE Model drug, by aligning the GLOBE Model drug's assigned billing and payment code long description (including dosage form) with the data source's 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 reference countries specified in paragraph (b) of this section and the U.S.

(ii) The data source must use a standardized method for identifying all of the following across countries within that data source, as determined by CMS:

(A) Drugs, such as using internationally recognized scientific and nonproprietary names.

(B) Dosage form and route of administration 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 expressed in internationally recognized measures such as milligrams or milliliters.

(D) Regulatory approval pathway that at a minimum distinguishes international originator drugs, international generic drugs, international biosimilar biological products, and U.S. originator drugs.

(iii) The data source must contain one of the following categories of international drug pricing information:

(A) Drug-specific sales data that represent actual or calculated prices paid to the manufacturer by wholesalers, distributors, and other purchasers (expressed in U.S. currency) and corresponding volume data, meaning quantity of units (for example, number of items or packages) sold.

(B) Drug-specific pricing data that represent actual or calculated list prices, ex-manufacturer prices, retail prices or other prices paid to the manufacturer by wholesalers, distributors, and other purchasers (expressed in U.S. currency) and corresponding volume data, meaning quantity of units (for example, number of items or packages) sold.

(C) Drug-specific pricing data that represent actual or calculated list prices, ex-manufacturer prices, retail prices or other prices paid to the manufacturer by

wholesalers, distributors, and other purchasers (expressed in U.S. currency).

(iv) The data source must have mechanisms in place to maintain, update, validate, and correct, if necessary, the international drug pricing information in the data source on at least a quarterly basis.

(v) The data source must 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 (3) of this section, 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 § 513.410.

(i) The data source contains drug-specific sales data and corresponding volume data for the applicable ASP calendar quarter from at least one country described in paragraph (b) of this section.

(ii) The data source does not have drug-specific sales data and corresponding volume data for the applicable ASP calendar quarter but contains drug-specific sales data and corresponding volume data for any prior calendar quarter beginning on or after April 1, 2025 from at least one country described in paragraph (b) of this section. If sales data and corresponding volume data from a prior calendar quarter are used, CMS uses sales data and corresponding volume data from the most recent calendar quarter for which both sales data and corresponding volume data are available.

(iii) The data source contains drug-specific pricing data and corresponding volume data for the applicable ASP calendar quarter from at least one country described in paragraph (b) of this section.

(iv) The data source does not contain drug-specific pricing data and corresponding volume data for the applicable ASP calendar quarter but contains drug-specific pricing data and corresponding volume data for any prior calendar quarter beginning on or after April 1, 2025 from at least one country described in paragraph (b) of this section. If pricing data and corresponding volume data from a prior calendar quarter are used, CMS uses pricing data and corresponding volume data from the most recent calendar quarter for which both sales data and corresponding volume data are available.

(v) The data source contains drug-specific pricing data 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 the drug-specific pricing information. CMS does not use more than one data source for a GLOBE drug across countries.

(d) *Identification of available manufacturer-submitted international drug net pricing data used to identify the per unit Method II GLOBE Model benchmark*—(1) *General.* Subject to § 513.610 and the GLOBE Model data agreement (§ 513.620), for each GLOBE Model drug for an applicable calendar quarter as set forth in § 513.20, CMS assesses manufacturer-submitted submitted international drug net pricing data for the applicable ASP calendar quarter that was determined by CMS to be an applicable submission as set forth in § 513.610(a)(4).

(2) *Determining availability of international drug net pricing data.* For purposes of identifying available manufacturer-submitted international drug net pricing data 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 manufacturer-submitted international drug net pricing data for the applicable ASP calendar quarter (as set forth in § 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 an applicable submission from each manufacturer of the GLOBE Model drug, CMS identifies international drug net pricing data 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) Net pricing data elements for at least one of the countries specified in paragraph (b) of this section with across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit and sales volume in HCPCS billing units greater than zero; and

(C) The presentation level information is not for an international generic or international biosimilar biological product (as applicable for data for a country).

(3) *Limitation.* If CMS determines that manufacturer-submitted international drug net pricing data is not complete and valid per § 513.610, then such manufacturer-submitted international drug net pricing data is not available for purposes of § 513.420.

## 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 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) of this section, 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 § 513.410).

(2) The per unit Method II GLOBE Model benchmark (as determined in § 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) of this section, 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 paragraph (d) of this section.

(2) CMS calculates the 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)(1)(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 (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 § 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 § 513.310(b), as available, using the following steps:

(1) *Identify available international drug pricing information.* Subject to paragraph (c) of this section, by country, using the data source selected in accordance with § 513.310(c)(2), CMS identifies available international drug pricing information for the 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 international drug pricing information for the countries specified in § 513.310(b) and the U.S. from the selected international drug pricing information data source 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 long 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 information as follows:

(A) When international drug pricing information with drug-specific sales data or pricing data and corresponding volume data are available, CMS excludes international drug sales and pricing data without both sales data or pricing data and corresponding volume data that are greater than zero.

(B) 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 that product.

(ii) [Reserved]

(3) *Convert volume data to unit of measurement delineated in the HCPCS Level II code long descriptor.* CMS converts the volume data to the unit of measurement delineated in the GLOBE Model drug's HCPCS Level II code long 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 long 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, 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 therapeutic dose, per dose, or per treatment.

(4) *Calculate the per unit country-level price for the GLOBE Model drug by country.* Using the international drug pricing information extracted, adjusted, and converted in accordance with paragraphs (a)(1) through (3) of this section, CMS calculates the per unit country-level price, using the calculation that is applicable.

(i) If an international drug pricing information data source with drug-specific sales data or pricing data and corresponding 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 U.S. price as set forth in paragraph (d) of this section.

(B) Using remaining data, CMS sums the converted volume data (as specified in paragraph (a)(3) of this section) for the presentation levels of the applicable international analogs (as defined in § 513.600).

(C) Using remaining data, if drug-specific sales data is available, CMS sums the total sales for all the presentation levels for the applicable international analogs (as defined in § 513.600), and divides that sum by the sum determined in paragraph (a)(4)(i)(B) of this section, resulting in an average country-level price per unit, where the unit is the same unit delineated in the HCPCS Level II code long descriptor.

(D) Using remaining data, if drug-specific pricing data are available, for each extracted price for a presentation level of the applicable international analogs (as defined in § 513.600), CMS—

(*1*) Divides the price by the number of HCPCS billing units for the presentation level of the applicable international analogs (as defined in § 513.600) 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 long descriptor. CMS limits the number of HCPCS billing units as described in paragraph (a)(3)(ii) of this section as applicable.

(*2*) Calculates the sum the products of the price per unit (as calculated in paragraph (a)(4)(i)(D)(*1*) of this section) and the corresponding converted volume amount (as set forth in paragraph (a)(3) of this section), and divides that total by the sum determined in paragraph (a)(4)(i)(B) of this section, resulting in an average country-level price per unit, where the unit is the same unit delineated in the HCPCS Level II code long descriptor.

(ii) If an international drug pricing information data source with drug-specific pricing data is used, and the data source does not contain available volume data, the applicable calculation is as follows:

(A) For each extracted price, CMS calculates the number of HCPCS billing units for the presentation levels of the applicable international analogs (as defined in § 513.600) by dividing the quantity of drug in a presentation level by the quantity of drug represented in the HCPCS dosage from the HCPCS

Level II code long descriptor. CMS limits the number of HCPCS billing units as described in paragraph (a)(3)(ii) of this section as applicable.

(B) CMS divides the price 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 long descriptor.

(C) CMS removes pricing information at the dosage form and strength level for a country that falls below 5 percent of the average U.S. price as set forth in paragraph (d) of this section.

(D) Using remaining data, CMS calculates the sum of the price per unit (as calculated in paragraph (a)(4)(ii)(B) of this section) for each 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 prices 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 long descriptor.

(iii) CMS performs the applicable calculation for each country specified in § 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 in § 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 earlier of—

(i) The first applicable calendar quarter for which the Part B rebatable drug is a GLOBE Model drug; or

(ii) The first applicable calendar quarter during the model performance period for which CMS identifies a per unit Method I GLOBE Model benchmark for the GLOBE Model drug.

(3) Subject to paragraphs (c)(4) and (5) of this section as applicable, the per unit Method I GLOBE Model benchmark for the GLOBE Model drug remains in place for each applicable calendar quarter thereafter until the end of the model performance period.

(4) When the per unit Method I GLOBE Model benchmark for a GLOBE Model drug is identified under paragraph (c)(2)(ii) of this section, for each subsequent applicable calendar quarter, CMS determines a per unit Method I GLOBE Model benchmark for that GLOBE Model drug for the first applicable calendar quarter during the model performance period for which such benchmark is available and applies such benchmark for that subsequent applicable calendar quarter and the remaining applicable calendar quarters until the end of the model performance period.

(5) When the data source selected in accordance with § 513.310(c)(2) makes updates to the international drug pricing information for international analogs for a GLOBE Model drug available to users within 90 days from the end of the calendar quarter for which drug pricing information is compiled, CMS uses the updated international drug pricing information as available, as determined by CMS, to identify the per unit Method I GLOBE Model benchmark amount for purposes of determining the per unit GLOBE Model rebate amount for such GLOBE Model drug, and for purposes of calculating the GLOBE Model beneficiary coinsurance adjustment as set forth in § 513.210(b).

(d) *Average U.S. price.* (1) Subject to paragraph (d)(2) of this section, using the U.S. drug pricing information extracted, adjusted, and converted in accordance with paragraphs (a)(1) through (3) of this section from the selected data source, CMS identifies the volume-weighted average U.S. price per unit using the calculation that is applicable, resulting in a volume-weighted U.S. price per unit, where the unit is the same unit delineated in the HCPCS Level II code long descriptor.

(i) If drug-specific sales data or pricing data and corresponding volume data are available, CMS uses the calculation steps in paragraph (a)(4)(i) of this section as applicable, except paragraph (a)(4)(i)(A) of this section is not applied.

(ii) If drug-specific pricing data are available and the data source does not contain available volume data, CMS uses the calculation steps in paragraph (a)(4)(ii) of this section as applicable, except paragraph (a)(4)(ii)(C) of this section is not applied.

(2) If the selected data source 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 percentage 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 § 513.610(a)(4) 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 § 513.310(d), and the methodology described in this section.

(a) *Identify available across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit.* For the GLOBE Model drug, using available manufacturer-submitted international drug net pricing data for the applicable ASP calendar quarter (as identified by CMS in accordance with § 513.310(d)) 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 HCPCS billing units. The sum of the volume of HCPCS billing units is calculated by summing the volume in HCPCS billing units in the applicable submission.

(ii) CMS sums the amounts calculated in paragraph (b)(2)(i) of this section.

(iii) CMS calculates the total volume by summing the volume in HCPCS billing units across all applicable submissions.

(iv) CMS divides the sum calculated in paragraph (b)(2)(ii) of this section 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 CMS determines that manufacturer-submitted international drug net pricing data for an applicable calendar quarter (as set forth in § 513.20) is not available for purposes of § 513.420 as set forth in § 513.310(d)(3) or CMS is unable to identify an available across country volume-weighted average GDP (PPP) adjusted net price per HCPCS billing unit as set forth in paragraph (a) of this section, 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. real GDP (PPP) per capita by the country's real GDP (PPP) per capita and rounds the result at the third decimal place. For a country, subject to paragraph (b) of this section, CMS calculates the real GDP per capita by dividing the total gross domestic product based on purchasing power parity (PPP) by the total population.

(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 real GDP per capita at the start of the applicable ASP calendar quarter, as determined by CMS, using the total gross domestic product based on purchasing power parity (PPP) and the total population for the same year as estimated and available in the World Bank World Development Indicators GDP per capita PPP (current international) (NY.GDP.PCAP.PP.CD), if available, otherwise as available in the International Monetary Fund GDP per capita, current prices, purchasing power parity series.

(c) *Limitations.* (1) The country's real GDP (PPP) per capita and U.S. real 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 per unit country-level price set forth in § 513.410(a)(4), if available, or the most recent earlier year available.

(d) *Minimum 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 § 513.510(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), as applicable, 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 (d)(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) [Reserved]

(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 (d) 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 § 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 § 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.* 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 OM Part B made separate payment under the model.

(c) *Identify the total number of GLOBE Model billing units.* The sum of the billing units identified as set forth in paragraph (b) of this section equals the total number of GLOBE Model billing units for the GLOBE Model drug for the applicable calendar 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-U.S. analog whose scientific or nonproprietary name, dosage form, and route of administration (if applicable) aligns with a GLOBE Model drug and that is sold in one or more reference countries specified in § 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.

*Average net-to-gross ratio* means, for a reference country, the sum of net sales for the set of applicable international analogs in the reference country divided by the sum of gross sales for the same set of applicable international analogs in the same reference country.

*Gross sales amount* means for each sale of an applicable international analog 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 analog'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 of an applicable international analog 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:* 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:* 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 average net price in U.S. dollars for a reference country where the weights are sales volume in HCPCS billing units. The volume-weighted net price for a reference

country is obtained by the manufacturer by adding the products of the net sales amounts in U.S. dollars multiplied by the corresponding sales volume in HCPCS billing units for the set of applicable international analogs in the reference country and then dividing by the sum of the sales volume in HCPCS billing units for the same set of applicable international analogs in the same reference country.

**§ 513.610 Submission and verification of international drug net pricing data.**

(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 applicable international analogs with sales in the reference countries specified in § 513.310(b) 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 accepted 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 completeness and validity.

(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 (d)(2) 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 basic data elements described in paragraph (b) of this section and net pricing data elements described in paragraph (c) of this section contained within 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*) Manufacturer submission of additional supporting information or data or both must be submitted to CMS within 5 business days after the date of CMS's request for additional supporting information or data or both.

(*2*) Failure to respond within 5 business days will result in CMS being unable to confirm the validity of the submission.

(4) *Applicable submission.* CMS determines that a submission is an applicable submission for purposes of § 513.420 if the submission—

(i) Is complete (as described in paragraph (a)(3)(i) of this section);

(ii) Includes the basic data elements as specified in paragraph (b) of this section, includes the net pricing data elements for one of the two options specified in paragraph (c) of this section; and

(iii) Is valid as determined by CMS as set forth in paragraph (a)(3)(ii) of this section.

(b) *Basic data elements required.* (1) Subject to paragraph (b)(3) of this section, a submission must include all the following basic data elements, including presentation level information:

(i) GLOBE Model drug brand name, scientific or nonproprietary name, and HCPCS Level II codes.

(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 variations in 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 or concentration;

(*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*) The number of HCPCS billing units is 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.

(3) If a manufacturer is unable to include certain basic data elements in its submission, the manufacturer must submit supporting documentation, including any reasonable assumptions that were applied, to fully explain why such data element is not included.

(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 (only have sales data for international originator drugs).

(ii) International drug net pricing data without both sales and volume data greater than zero.

(2) Subject to paragraph (c)(3) of this section, a submission must include net pricing data elements in complete fulfillment of one of the following net pricing data submission options. A manufacturer must select one of the net pricing data submission options for the duration of the model performance period:

(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*) The exchange rate 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 data source was used and continues to use this exchange rate data source for subsequent submissions.

(*4*) Volume-weighted net price in U.S. dollars rounded to 5 decimal places for each reference country; and

(*5*) GDP (PPP) adjuster 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, and for every sale involving an applicable international analog aggregated at the reference country level—

(*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 rounded to 5 decimal places 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*) The exchange rate 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 data source was used and continues to use this exchange rate data source for subsequent submissions.

(*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) adjuster 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.

(3) If a manufacturer is unable to include certain net pricing data elements in its submission, the manufacturer must submit supporting documentation, including any reasonable assumptions that were applied, to fully explain why such data element is not included.

(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.

(2) *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 drug net pricing data in a form which discloses the identity of a specific manufacturer and their international drug 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 in paragraph (b) of this section.

(2) *Use of the applicable submission.* CMS uses applicable submissions, determined in accordance with paragraph (b) of this section, § 513.610(b) and (c), and as specified in the applicable executed data agreement, to identify the per unit Method II

GLOBE Model benchmark, subject to § 513.310(d) and § 513.420 for the applicable ASP calendar quarter corresponding to the submission.

(3) *Requirements for a voluntary submission option of net pricing data elements.*

(i) If a manufacturer elects to voluntarily submit manufacturer's international drug net pricing data, the manufacturer—

(A) Selects one submission option for net pricing data elements for all applicable international analogs to a GLOBE Model drug; and

(B) Except where paragraph (a)(3)(ii) 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 any of the reference countries specified in § 513.310(b) for the applicable ASP calendar quarter.

(ii) After the data agreement specified in paragraph (b) of this section is effective, if a manufacturer chooses to no longer submit voluntary international drug net pricing data for GLOBE Model drug(s) for which the manufacturer has submitted voluntary international drug net pricing data and CMS has determined sales of applicable international analogs to such GLOBE Model drug(s) have occurred in the reference countries specified in § 513.310(b) for the applicable ASP calendar quarter, CMS may terminate the data agreement for all GLOBE Model drugs of the manufacturer. In accordance with paragraph (b) of this section, the manufacturer may also elect to terminate the data agreement.

(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

### § 513.710 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 § 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 § 513.410.

(v) The per unit Method II GLOBE Model benchmark, if available, as identified under § 513.420.

(vi) The per unit GLOBE Model benchmark amount as set forth in § 513.400.

(vii) The per unit GLOBE Model rebate amount as set forth in § 513.510(a).

(viii) The incremental per unit GLOBE Model rebate amount as set forth in § 513.510(b).

(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 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 amount, if any, by which the specified amount as determined under 42 CFR 427.302(b) exceeds the per unit GLOBE Model rebate amount under § 513.510(a) for the GLOBE Model drug for the applicable calendar quarter as set forth in § 513.510(a)(1)(i).

(xii) The total GLOBE Model rebate amount as set forth in § 513.500(a).

(xiii) The incremental GLOBE Model rebate amount as determined in § 513.500(b).

(xiv) Any applied reductions as determined under 42 CFR part 513, subpart F.

(xv) The proportion of manufacturer-reported ASP units, if applicable.

(xvi) The reduced incremental GLOBE Model rebate amount, if applicable.

(xvii) The incremental or reduced incremental GLOBE Model rebate amount due, if any.

(xviii) Other data elements as determined by CMS.

(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's review of a Suggestion of Error as set forth in § 513.720, if applicable, and any CMS-determined recalculations in accordance with paragraph (d)(2) of this section.

(2) The GLOBE Model Rebate Report is the invoice of a manufacturer's incremental GLOBE Model rebate amount due or reduced incremental GLOBE Model rebate amount as determined under § 513.510, if any, for a GLOBE Model drug for an applicable calendar quarter.

(3) The manufacturer's incremental or reduced incremental GLOBE Model 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 paragraphs (b)(1)(i) through (xviii) of this section and provides the information via a Preliminary GLOBE Model Reconciliation Rebate Report set forth in paragraphs (b)(1) and (d)(1)(i)(A) through (J) 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 § 513.520.

(B) Updated per unit Method I GLOBE Model benchmark amount as determined under § 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 § 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 § 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 § 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 § 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's review of a Suggestion of Error as set forth in § 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 § 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 § 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.

(2) [Reserved]

(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 an incremental 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 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 § 513.710(b) as well as any report of a reconciled GLOBE Model rebate amount as set forth in § 513.710(c)(1).

(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 § 513.710, including any report of reconciled rebate amount.

(2) Submit a suggestion of error as set forth in § 513.720.

(3) Pay an incremental GLOBE Model rebate amount due.

(b) [Reserved]

### § 513.740 Deadline and process for payment of an incremental GLOBE Model 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 either of the following:

(1) A GLOBE Model Rebate Report as set forth in § 513.710.

(2) A report of a reconciled incremental GLOBE Model rebate amount as set forth in § 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 42 CFR part 513, subpart I.

(c) *Refund to the manufacturer.* If a reconciled incremental GLOBE Model rebate amount for an applicable calendar quarter as set forth in § 513.710(d) is less than what the manufacturer paid for that applicable calendar quarter, CMS initiates 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 § 513.500 by the payment deadline as set forth in § 513.740(a) for such GLOBE Model drug for such applicable calendar quarter. The provisions of 42 CFR 427.600 regarding the imposition of civil money penalties and their respective appeals also apply with respect to this subchapter to the same extent as they are applicable with respect to 42 part 427, except that, in applying such provisions with respect to this subpart, any reference to 42 CFR 427.301(a) must be considered a reference to the incremental GLOBE Model rebate amount calculated in accordance with § 513.500.

(b) *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, including claims-based measures, 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.

CMS establishes 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 42 CFR 427.302 and 427.301 as related to calculation of rebate amounts as necessary to permit testing of an alternative rebate amount 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 42 CFR 410.152(m), 419.41(e), 489.30(b)(1), and 489.30(b)(6) 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.*

[FR Doc. 2026–20281 Filed 9–30–26; 4:15 pm]

**BILLING CODE 4169–69–P**

# FEDERAL REGISTER

Vol. 91 Friday,

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Part V

## The President


Presidential Determination No. 2026–24 of September 25, 2026—Presidential Determination on Refugee Admissions for Fiscal Year 2027

Executive Order 14432—Streamlining Access to Government Services Through America.gov

Executive Order 14433—Eliminating Disease-Carrying Pests and Restoring Enjoyment of the Great Outdoors

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Friday, October 2, 2026

# Presidential Documents

Title 3—

The President

**Presidential Determination No. 2026–24 of September 25, 2026**

## Presidential Determination on Refugee Admissions for Fiscal Year 2027

**Memorandum for the Secretary of State[,] the Secretary of Homeland Security[, and] the Secretary of Health and Human Services**

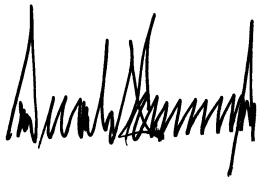
By the authority vested in me as President by the Constitution and the laws of the United States, in accordance with section 207 of the Immigration and Nationality Act (the ''Act'') (8 U.S.C. 1157), and after appropriate consultations with the Congress, I hereby make the following determinations and authorize the following actions:

The admission of up to 17,500 refugees to the United States during Fiscal Year 2027 is justified by humanitarian concerns or is otherwise in the national interest.

The admissions shall primarily be allocated among Afrikaners from South Africa pursuant to Executive Order 14204. Refugee admissions under this determination, which may reach but not exceed the numerical limit described herein, are in all respects subject to the requirements of other Presidential policies and actions, whether issued prior or subsequent to this determination. Those Presidential policies and actions include, but are not limited to: Executive Order 14161, which mandates that refugees receive the most stringent identification verification of any class of alien seeking admission or entry to the United States; Executive Order 14163, which suspends the entry into the United States of refugees other than when the Secretaries of State and Homeland Security jointly determine that an admission is in the national interest and does not threaten the security or welfare of the United States; Executive Order 14204, which provides for refugee resettlement of Afrikaners from South Africa who are victims of unjust racial discrimination; and Proclamation 10998, which restricts the entry of certain foreign nationals whose admission would be detrimental to the national interest.

In accordance with section l0l(a)(42)(B) of the Act (8 U.S.C. 1101(a)(42)(B)), and after appropriate consultation with the Congress, I specify that, for Fiscal Year 2027, those processed under Executive Order 14204 may, if otherwise qualified, be considered refugees for the purpose of admission to the United States within their countries of nationality or habitual residence.

The Secretary of State is authorized and directed to publish this determination in the *Federal Register*.



THE WHITE HOUSE,
*Washington, September 25, 2026*

[FR Doc. 2026–20318
Filed 10–1–26; 11:15 am]
Billing code 4710–10–P

# Presidential Documents

**Executive Order 14432 of September 29, 2026**

## Streamlining Access to Government Services Through America.gov

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.* For generations, Americans seeking essential services from the Federal Government have been required to navigate a system organized around the structure of Government rather than the needs of the people. Americans must search across numerous executive departments and agency (agency) websites, interpret complicated Government terminology, frequently provide the same information, and repeatedly prove their identities to a Government that may already possess the information necessary to serve them. The American people deserve better.

Advances in technology now make possible a fundamentally different relationship between the people and the Federal Government, defined by simplicity, speed, accuracy, security, and respect for the individual. The same spirit of American innovation that can accelerate scientific discovery can also help Americans complete essential interactions with the Federal Government.

This order therefore directs the establishment of America.gov as the unified digital front door to the Federal Government for every individual in the United States seeking Federal information or services. America.gov will not be merely another website, search engine, or directory of Government links. It will be a secure, intelligent, and service-oriented point of entry through which an individual may sign in, communicate in plain language, receive accurate answers, and, where authorized and technically available, complete Government transactions without being required to navigate the websites of multiple agencies. America.gov will enable the Federal Government to do its own paperwork so that the American people may get on with their lives.

**Sec. 2**. *Policy.* It is the policy of the United States to:

(a) provide every individual in the United States seeking Federal information or services with a single, secure, conversational point of entry through which the citizen may discover, access, and, where authorized, complete covered Federal transactions;

(b) establish common standards of quality, simplicity, accessibility, interoperability, security, reliability, and design across participating Federal digital services and public-facing websites;

(c) preserve each agency's custody and control of its records, systems, statutory responsibilities, and adjudicatory authority and ensure that unifying access to Federal services does not create a centralized Federal system of records concerning the American people;

(d) protect personal information through data minimization, secure authentication, auditable authorization, and disclosure practices consistent with applicable law;

(e) ensure that super intelligence used in connection with America.gov is accurate, reliable, and transparent; and

(f) preserve existing lawful methods by which Americans may obtain Federal services, including in-person, telephone, mail, and agency-specific

digital services, so that America.gov provides a better option but does not become the only option.

**Sec. 3**. *Definition.* The term ''covered services'' means public-facing Federal services that serve more than 100,000 users in a 12-month period and can be accessed or applied for online. The term excludes tax filing services provided by the Internal Revenue Service and services provided by the Department of War and elements of the Intelligence Community. The Director of the Office of Management and Budget (OMB) may, by memorandum, add or exclude ''covered services.''

**Sec. 4**. *Establishing America.gov.* The Administrator of General Services, in coordination with the Administrator of the National Design Studio and the Director of OMB, shall:

(a) establish and operate America.gov as the single point of entry for Americans to access covered services online; and

(b) take such steps as are necessary to integrate Login.gov with America.gov, including using Login.gov as the authentication service for America.gov.

**Sec. 5**. *Implementing America.gov.* (a) Within 90 days of the date of this order, the Director of OMB shall issue a memorandum to the heads of agencies on implementation of this order.

(b) Heads of agencies shall:

(i) identify covered services in their respective agencies;

(ii) integrate the provisions of such services with America.gov in a secure and privacy-preserving manner, including by making the public Application Programming Interfaces, dashboards, and digital forms that already support services accessible through the America.gov platform;

(iii) complete integration with Login.gov consistent with the requirements of section 1523(b)(1)(D) of title 6, United States Code, and OMB Memorandum M–26–18; and

(iv) provide, on an ongoing basis, the Administrator of General Services and the Director of OMB with historical and current usage and performance data for covered services.

**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

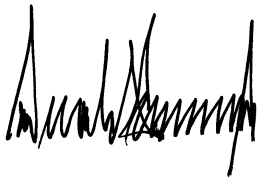
(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(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) Nothing in this order shall be construed to require the disclosure of information that is prohibited by law, or to authorize any person other than the originating agency to access records maintained by that agency about an individual, except as provided by the Privacy Act of 1974 (5 U.S.C. 552a) or other applicable law.

(e) The costs for publication of this order shall be borne by the General Services Administration.



THE WHITE HOUSE,
*September 29, 2026.*

[FR Doc. 2026–20319
Filed 10–1–26; 11:15 am]
Billing code 6820–61–P

# Presidential Documents

**Executive Order 14433 of September 29, 2026**

## Eliminating Disease-Carrying Pests and Restoring Enjoyment of the Great Outdoors

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**. *Background and Purpose.* Ticks and mosquitoes are among the deadliest animals worldwide, transmitting major diseases that impose growing health and economic burdens on the American public. Foreign, invasive mosquitoes, especially the Asian tiger and Egyptian mosquitoes, are multiplying across the United States and have become the dominant species in some areas, including the District of Columbia (DC), spreading disease and diminishing quality of life. Furthermore, the expanding tick populations in the United States expose Americans, our pets, and our livestock to debilitating and expensive health risks. Historical approaches have relied primarily on the use of conventional pesticides; however, the use of commonsense, non-chemical, technology-enabled measures can significantly reduce the negative effects of these pests, enhancing enjoyment of the great outdoors for all Americans.

**Sec. 2**. *Policy.* It is the policy of the United States to develop and deploy commonsense approaches and technological capabilities to suppress tick and mosquito populations and address the harms these insects cause, using improved detection, screening, prevention, and health care interventions. These goals will be achieved through the following policy priorities:

(a) Leading the world in safe and effective tick and mosquito population control to prevent disease through smart land management techniques and procedures, natural predator populations, non-chemical pest control measures, and advanced technologies, including sterile insect techniques and insect control tools developed with safe and effective biotechnologies.

(b) Diagnosing, preventing, and treating the syndromes and diseases spread by ticks and mosquitoes in the United States, including alpha-gal syndrome, Theileriosis, Rocky Mountain spotted fever, Lyme disease, and Babesiosis (spread by ticks), and viral infections such as West Nile, Zika, Chikungunya, and Dengue fever (spread by mosquitoes).

(c) Advancing the objectives of the DC. Safe and Beautiful Task Force set forth in Executive Order 14252 of March 27, 2025 (Making the District of Columbia Safe and Beautiful), by reducing the invasive tick and mosquito populations across DC both safely and effectively, without negative effects on beneficial insects, native plants and animals, or the natural beauty of our parks, waterways, and recreational areas.

(d) Expanding the successful techniques and approaches developed in section 3 of this order as a model for nationwide control of tick and invasive mosquito populations.

**Sec. 3**. *Implementation.* (a) Within 60 days of the date of this order, the Secretary of the Interior, the Secretary of Agriculture, the Administrator of the Environmental Protection Agency, and the Administrator of General Services, in consultation with the Secretary of Health and Human Services, shall develop and implement a campaign across DC to, by 2028, reduce the Asian tiger mosquito, Egyptian mosquito, and other invasive mosquito populations, as appropriate, by 90 percent and reduce the tick population by 50 percent, with further reductions as practicable. The campaign shall:

(i) remediate tick and mosquito breeding grounds on lands subject to Federal jurisdiction throughout DC, including by reducing tick and mosquito habitats through landscaping and drainage improvements, *e.g.,* mowing and rain gardens, and strategic deployment of natural, targeted controls;

(ii) control pest transport and key host reservoir or amplification populations, including rodents and deer, that facilitate ticks and tickborne diseases;

(iii) prioritize the use of commercial capabilities or cooperative agreements, including the deployment of advanced technological solutions such as sterile insect techniques for mosquitoes or other safe and effective biotechnologies; and

(iv) include a plan, developed in consultation with the Government of DC, as appropriate, for implementing tick and mosquito controls on lands across DC communities.

(b) Within 60 days of the date of this order, to expedite the campaign ordered in subsection 3(a) of this order, the Administrator of the Environmental Protection Agency, in consultation with the Secretary of Agriculture and the Secretary of Health and Human Services, shall:

(i) submit to the President, through the Assistant to the President and Homeland Security Advisor, a regulatory framework, informed by relevant academic centers and industry, for the planned development and release into the environment of advanced, safe, and effective tick and mosquito control technologies. This framework shall consider sterilization techniques, safe genetic modification, and use of safe, beneficial bacteria, in alignment with Executive Order 14292 of May 5, 2025 (Improving the Safety and Security of Biological Research); and

(ii) prioritize and expeditiously advance or register novel tick and mosquito control methods or products that the Administrator of the Environmental Protection Agency finds to be both safe and effective.

(c) Within 90 days of the date of this order, the Secretary of Health and Human Services, building on the Lyme Disease Moonshot initiative already underway, as appropriate, shall:

(i) issue prize competition announcements under 15 U.S.C. 3719 or other applicable laws, or direct research and development programs for rapid diagnostics to identify, prophylactics to prevent—and therapeutics to treat—tick- and mosquito-borne diseases of consequence as determined by the head of the agency, including those listed in subsection 2(b) of this order; and

(ii) review available and candidate immunotherapy treatments for alpha-gal syndrome and develop a research agenda to accelerate the clinical review of viable candidates.

(d) Within 90 days of the date of this order, the Secretary of Agriculture, in coordination with the Secretary of the Interior, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency, shall issue prize competition announcements under 15 U.S.C. 3719 or other applicable laws, or direct research programs, for the development of non-chemical means to reduce tick- and mosquito-borne diseases of consequence, including through reducing tick and mosquito populations.

(e) Within 60 days of the date of this order, the Secretary of Agriculture and the Secretary of Health and Human Services, as appropriate, shall explore options for labeling food and drug products that include significant amounts of alpha-galactose, in a manner similar to other allergy warnings.

(f) The Secretary of the Interior, the Secretary of Agriculture, the Secretary of Health and Human Services, and the heads of other relevant agencies, in coordination with the Director of the Office of Management and Budget, shall review available resources to support the implementation of this order.

**Sec. 4**. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

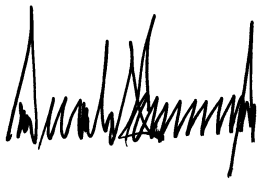
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(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 the Interior.



THE WHITE HOUSE,
*September 29, 2026.*

[FR Doc. 2026–20320
Filed 10–1–26; 11:15 am]
Billing code 4310–10–P

# Presidential Documents

**Executive Order 14434 of September 29, 2026**

## Inaugurating the Era of Super Intelligence

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.* America stands at the forefront of a new technological revolution in intelligence. The modern field of artificial intelligence was born in the United States, where American scientists first gave the field its name and laid the foundations for its development. Seventy years later, powered by our Nation's unmatched culture of innovation, world-leading companies and research institutions, and entrepreneurial spirit, America is once again pushing the technological frontier forward.

The extraordinary technologies being pioneered by American innovators far exceed what was envisioned when the term ''Artificial Intelligence'' first came into use. The capabilities of today's frontier systems do much more than imitate or automate discrete aspects of human intelligence. They increasingly amplify human ingenuity and unlock new forms of creativity, empowering Americans to achieve what was previously impossible across science, medicine, and nearly every other domain of human endeavor. As these capabilities continue to improve, they increasingly represent not merely artificial intelligence, but a new era of Super Intelligence.

The terminology used by the Federal Government should reflect the transformative capabilities of these technologies and the limitless opportunities they create for the American people. Accordingly, the term ''Super Intelligence'' more appropriately captures the promise, potential, and rapidly advancing capabilities of these technologies. It is therefore the policy of my Administration that, to the maximum extent permitted by law, the executive branch shall use the terms ''Super Intelligence'' and ''SI'' in place of ''Artificial Intelligence'' and ''AI'' and will not acknowledge the usage of ''Artificial Intelligence'' and ''AI'' in any applicable setting.

**Sec. 2**. *Implementation.* (a) To the maximum extent permitted by law, executive departments and agencies (agencies) shall use ''Super Intelligence'' and ''SI'' in place of ''Artificial Intelligence'' and ''AI'' in official correspondence, public communications, websites, reports, policy documents, and other non-statutory documents within the executive branch.

(b) Nothing in this section requires the alteration of previously issued regulations, Presidential actions, contracts, grants, or other historical documents.

**Sec. 3**. *Definition.* (a) For purposes of this order, and except where otherwise provided by law, the terms ''Super Intelligence'' and ''SI'' mean the technologies and systems encompassed by the term ''artificial intelligence'' as defined in section 9401(3) of title 15, United States Code. This definition shall govern the implementation of this order unless and until superseded by subsequent Presidential action consistent with applicable law or by an Act of Congress.

(b) Within 60 days of the date of this order, the Assistant to the President for Science and Technology (APST), in consultation with the heads of other agencies as the APST deems appropriate, shall submit to the President proposed legislative language to establish a Federal definition of ''Super Intelligence'' and ''SI'' that reflects the capabilities described in section 1 of this order. The proposal shall include:

(i) an assessment of whether, and to what extent, the definition of ''Super Intelligence'' and ''SI'' should modify, expand upon, or otherwise supersede the existing statutory definition of ''artificial intelligence'';

(ii) any proposed conforming amendments, as appropriate, to existing statutory references to ''artificial intelligence'' and ''AI''; and

(iii) recommendations for any additional Presidential or executive action necessary to implement the proposed definition throughout the executive branch.

**Sec. 4**. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

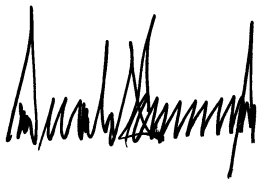
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(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 Science and Technology Policy.



THE WHITE HOUSE,
*September 29, 2026.*

[FR Doc. 2026–20321
Filed 10–1–26; 11:15 am]
Billing code 3270–F9–P

# Presidential Documents

**Notice of September 30, 2026**

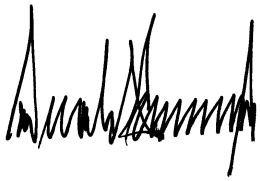
## Continuation of the National Emergency With Respect to the Situation in and in Relation to Syria

On October 14, 2019, by Executive Order 13894, the President declared a national emergency pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) to deal with the threat to the national security and foreign policy of the United States constituted by the legacy situation in and in relation to Syria. On January 15, 2025, the President issued Executive Order 14142 in view of changing circumstances on the ground in Syria and in order to take additional steps with respect to the national emergency declared in Executive Order 13894.

On June 30, 2025, I issued Executive Order 14312 to expand the scope of the national emergency declared in Executive Order 13894 and to take additional steps to ensure meaningful accountability for perpetrators of war crimes, human rights violations and abuses, and the proliferation of narcotics trafficking networks in and in relation to Syria during the former regime of Bashar al-Assad and by those associated with it, as perpetrators of such actions threaten to undermine the peace, security, and stability in the region.

This situation continues to pose an unusual and extraordinary threat to the national security and foreign policy of the United States. For this reason, the national emergency declared in Executive Order 13894 of October 14, 2019, with respect to which additional steps were taken in Executive Order 14142 of January 15, 2025, and which was expanded in scope in Executive Order 14312 of June 30, 2025, must continue in effect beyond October 14, 2026. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 13894 with respect to the situation in and in relation to Syria.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
*September 30, 2026.*

[FR Doc. 2026–20322
Filed 10–1–26; 11:15 am]
Billing code 3395–F4–P

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